OPTN/UNOS Pancreas Transplantation Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, FL

Summary

I. Action Items For Board Consideration

- None

II. Other Significant Issues

- The Kidney Transplantation Committee is examining potential changes to policy regarding kidney allocation. One of the possible components is for the kidney to follow the pancreas locally in allocation to diabetic, uremic candidates for simultaneous pancreas-kidney (SPK) transplantation. As a result of this decision, the Pancreas Transplantation Committee is considering different options for modifying the national pancreas allocation system. Considerations include:
    - how the waiting list for pancreas recipients should be managed
    - whether more specific listing criteria should be developed for SPK candidates
    - the specific algorithm for kidney allocation for the SPK recipients in relation to kidney paybacks and pediatric and adult kidney recipients
    - what impact these changes might have on the operational effectiveness of the allocation system
- The Pancreas Transplantation Committee is requesting feedback on the following proposed concepts for pancreas allocation:
    - That candidates on the waiting list for a kidney-pancreas or pancreas-alone be combined on a solitary list;
    - That more specific listing criteria be developed for SPK waiting list candidates (e.g., on dialysis or having a GFR or CrCl<20mL/min and a minimum c-peptide threshold in consideration with the HgbA1c level); and
    - That kidney allocation for SPK candidates meeting appropriate listing criteria follow the pancreas and precede kidney paybacks and pediatric and adult kidney-alone recipients. (Item 1, Page 3)
- The Committee worked with the SRTR to develop a pancreas donor risk index (DRI) model. This DRI can be used to inform clinical decisions, to assess pancreas utilization, and in allocation. (Item 2, Page 14)
- The Committee made recommendations for revisions to the pancreas and kidney-pancreas data collection forms. (Item 3, Page 15)

- The Committee worked with the SRTR to develop a combined SPK/PAK/PTA model for use by the MPSC in evaluating pancreas programs. The Committee recommended that the MPSC evaluate pancreas programs using the 1-year patient survival model. The Committee requested more time to improve the index of concordance of the 1 year graft failure model before it is used by the MPSC to evaluate pancreas programs. (Item 4, Page 21)

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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 at its meetings held on November 21, 2008; January 23, 2009; March 27, 2009; July 24, 2009; and October 1, 2009.

1. Concept for a New National Pancreas Allocation System

In November 2008 and July 2009, Dixon B. Kaufman, MD, PhD, and Jennifer L. Wainright, PhD, presented a review of the data evaluated by the Pancreas Allocation Subcommittee. **(Exhibit A)**

Currently, pancreas allocation policy (Policy 3.8) allows OPOs to choose to allocate from the simultaneous pancreas-kidney (SPK) list, pancreas alone (PA) list, or the kidney alone (KI) list in any order they wish. The OPO must follow the order of potential recipients on the list but may switch to another list at any time. OPOs must offer SPKs to zero mismatch, highly sensitized (CPRA $\geq$ 80%) potential recipients (locally, regionally, nationally) before any other pancreas potential recipients because of kidney sharing requirements. SPKs usually follow other multi-organ transplants and kidney paybacks.

Concerns with the Current Pancreas Allocation System

There are several concerns with the current pancreas allocation system. It is not a national allocation system, unlike other organs. Also, access to SPK transplant varies widely across the country because of local or regional allocation decisions. The current policy does not seek to maximize the utilization of the pancreas.

Why Now?

The current environment in pancreas transplantation provides an appropriate context for a change to the national pancreas allocation system. The pancreas is the only organ that does not have a truly consistent national system for allocation in the context of simultaneous pancreas/kidney transplantation. Additionally, potential changes to the kidney allocation system, specifically the possibility for the kidney to follow the pancreas in allocation (i.e. allocating from the PA or SPK list before allocating from the KI list), are not feasible without changes to pancreas allocation. The challenge is to develop a national pancreas allocation system that will be acceptable to the pancreas transplantation community, the kidney transplantation community (adult and pediatric), and the other major stakeholders. As part of its investigation of a new kidney allocation system, the Kidney Transplantation Committee requested that the Pancreas Transplantation Committee investigate the development of a pancreas allocation policy where the kidney follows the pancreas locally to accompany the new kidney allocation system and the development of SPK listing criteria.

Goals of a New National Pancreas Allocation System

The goals of a new national pancreas allocation system are:

- To increase utilization of the pancreas
- To increase access for both SPK and PA candidates
- To reduce waiting time for both SPK and PA candidates
- To decrease geographic disparities in pancreas waiting time

The proposed concept for a national pancreas allocation system discussed by the Committee is to have a combined SPK and PA list ordered based on waiting time. SPK listing criteria would be:

- Kidney: the candidate is on chronic maintenance dialysis or GFR or CrCl ≤ 20 mL/min (per Kidney Committee)
- Pancreas: the candidate must have a minimum c-peptide value

In July 2009, the Committee discussed the value of transplanting SPKs in candidates who have a GFR greater than 20 mL/min. The Committee noted that it would need to have evidence that transplanting SPK candidates with a higher GFR results in better outcomes, especially when kidney alone candidates cannot receive a kidney unless they meet these criteria. The Committee also wanted to define what an appropriate minimum c-peptide value would be so that appropriate patients are accorded priority under a system where the kidney follows the pancreas in allocation.

Since 2007, the Committee has been conducting extensive data analysis regarding current allocation and utilization practices around the country and simulations of potential allocation options. The purpose of collecting these data was to investigate changes to pancreas allocation that would be necessary if the kidney follow the pancreas in the new kidney allocation system; to consider the effects of combining the PA and SPK lists; to develop listing criteria for kidney-pancreas transplants; to investigate the use of net benefit in pancreas allocation; and to determine the effect any changes to pancreas allocation might have on pediatric kidney transplantation.

Combining the SPK and PA Lists

Outcomes for pancreas transplant alone (PTA) and pancreas after kidney (PAK) transplants have been improving so that they are closer to the outcomes of SPK transplants. Therefore, the Committee has considered combining the SPK and PA waiting list. The Committee noted several advantages to combining the SPK and PA waiting lists:

- A single list for all pancreas candidates is easy to use
- Candidates for all types of pancreas transplants have an equal opportunity to receive offers for high quality pancreata
- Increased national consistency in pancreas allocation
- Encourages the use of living kidney donors for appropriate candidates with PAK to follow
- Returns some high quality kidneys to the kidney allocation system in cases in which the pancreas is used for solitary transplant
- Is consistent with the allocation of kidney allografts with other extra-renal organs

However, combining the SPK and PA lists may result in fewer SPK transplants (approximately 80 fewer SPK transplants than could be achieved with an absolute SPK priority). Committee members noted their concern that SPK candidates have greater mortality and that they should perhaps receive additional priority.

SPK Listing Criteria

Previous survey data showed that the vast majority of DSAs already allocate pancreata for SPK candidates according to a kidney follows pancreas system (see below). The Committee verified that the pancreas transplant community is appropriately listing candidates for SPK in the current system. Very few PA candidates later decide they also want or need a kidney after initially being listed just for PA (51 candidates in 2006 and 40 in 2007). In 2006, only 16 kidney-pancreas candidates who were on the SPK list in 2006 received a kidney-only transplant (among 924 SPK transplants performed that year), indicating that transplant centers are not listing candidates for an SPK when they only want the kidney. Additionally, few Type 2 diabetic candidates over the age of 45 receive SPK transplants. Out of 318 SPK

recipients in 2006 who were older than 45 years old, 38 had Type 2 diabetes (as opposed to 221 who had Type 1 diabetes, 56 who had diabetes type unknown, and 3 who did not have diabetes). Approximately 2% of SPK candidates have never had a creatinine clearance less than 20 **and** are not yet on dialysis, whereas approximately 1% of adult KI candidates have never had a creatinine clearance less than 20 **and** are not yet on dialysis. The Committee commented that instituting listing criteria for when the kidney follows the pancreas based on these data likely would have little impact on what types of pancreas candidates are transplanted. The Committee noted that these data show that the pancreas transplant community is being a responsible steward of scarce resources.

Pancreas Transplantation Demographics and Net Benefit
Kathryn Meyer, MS, reviewed waiting list death rates and net benefit for SPK and kidney-alone recipients. Both diabetic SPK and diabetic KI candidates had shorter waiting list lifespan than non-diabetic KI candidates for all age groups. However, diabetic SPK recipients have a longer lifespan post-transplant and greater LYFT than diabetic KI recipients.

The Committee assessed whether there were any differences in donor and recipient characteristics by transplant type (SPK, PAK, PTA). The Committee did not note any significant differences. The Committee also compared SPK and kidney-alone waiting list and transplant rates by age group. There is a higher percentage of 18-49 year old candidates on the SPK waiting list than on the KI waiting list and a higher percentage of 18-49 year old SPK recipients than KI recipients. SPK patient survival, pancreas graft survival, and kidney graft survival are similar for the 18-49 age group and the 50-60 age group, but outcomes are worse for the greater than 60 age group.

The Committee also compared waiting list, transplant, and donor data for DSAs that gave absolute priority to SPK candidates over PA and KI candidates versus DSAs that did not give absolute priority for SPKs. The median donor age was 24 years old in DSAs with absolute SPK priority versus 22 years old in other DSAs. In DSAs with absolute SPK priority, there is a higher percentage of candidates in the 50-60 age group (26.2% vs. 21.7% in other DSAs). However, there is a smaller percentage of SPK transplants for recipients in the 50-60 age group in DSAs with absolute SPK priority (17.2% vs. 19.7% in other DSAs).

SPK, Pediatric KI, and Multi-Organ Transplants
The Committee analyzed how many kidneys are transplanted into multi-organ recipients. In 2005, 2006, and 2007, kidney-alone recipients account for the majority of all kidney transplants (88.1%), followed by kidney-pancreas (7.9%) and kidney-liver (3.5%). Whereas the trend in the number of kidney-pancreas has decreased from 8.3% in 2005 to 7.4% in 2007, the trend in the number of kidney-liver transplants has increased from 3.1% in 2005 to 3.9% in 2007. For donors under the age of 35, both kidneys from a donor were transplanted into adult multi-organ recipients in only 2.3% of donors in the post-Share 35 period.

Data by Allocation System
In March and July 2009, Jennifer Wainright, PhD, UNOS Research liaison to the Committee, presented the data collected by the Pancreas Review Subcommittee. In 2007, the Pancreas Transplantation Committee conducted a survey on pancreas allocation. Several questions on the survey related to local pancreas allocation practices. The Committee planned to use these responses to classify DSAs and to analyze data to determine if results differ based on local allocation practice. In order to accurately classify DSAs, the Committee sent three follow-up questions to all OPO Executive Directors regarding their local pancreas allocation practices. The Committee decided to classify the OPO responses into three categories:

- Kidney follows the pancreas (KI follows PA)
- Pancreas follows the kidney (PA follows KI)
- Mixed

DSAs were classified into the above three categories based on their answers to the following questions:

- Choose the allocation system that is most like your OPO's policy for SPK allocation as it relates to kidney alone allocation:
  - Kidney follows pancreas (e.g., SPKs are allocated first, then kidney alone.)
  - Pancreas follows kidney (e.g., Kidney is allocated first. SPK candidates might receive a kidney if they reach a certain threshold on the kidney alone list, such as within the top 20% of kidney candidates or in the top 12 candidates on the kidney alone list).
  - Mixed (e.g., No formal policy. We allocate from all three lists on an ad hoc basis).
- Choose the allocation system that is most like your OPO's policy for pancreas allocation:
  - We prioritize SPK and allocate from the SPK list first.
  - We prioritize solitary pancreas and allocate from the PA list first.
  - We combine the SPK and PA lists into a single list and allocate from that.
  - When both types of pancreas transplants are possible, we manually allocate to one from separate SPK and PA waiting lists based on certain criteria (e.g., waiting time).
- Describe your OPO's pancreas allocation policy in your own words. In particular, we are interested in the order that your OPO allocates from your pancreas alone, SPK, and kidney alone lists. (e.g., In the absence of 0 mismatch pancreata and/or multiple 0 mismatch kidneys, paybacks, etc., we have a kidney follows pancreas system where we allocate first from the SPK list. If we do not place an SPK, we try to allocate the pancreas from the pancreas alone list and the kidneys from the kidney alone list.)

The subcommittee polled all 58 OPOs by e-mail. The first e-mail was sent to OPO Executive Directors on December 17, 2008. A second e-mail was sent on January 6, 2009. DSAs were classified according to their responses to these three questions with responses received as of January 23, 2009.

If the OPO did not respond to these three questions, responses from the OPO to the 2007 Pancreas Committee Survey on barriers to pancreas placement were used to classify the DSA. If the OPO did not respond to the original survey or the follow up questions, UNOS staff called these OPOs to request a response to the three follow-up questions.

48 (82.8%) of the OPOs submitted a response to the follow-up questions. All of these responses were used to classify these 48 DSAs. 10 (17.2%) of the OPOs did not respond the follow-up questions. However, 9 of these OPOs had responded to the 2007 Pancreas Survey. These 9 DSAs were classified according to the responses to the 2007 Pancreas Survey. The one remaining DSA was classified based on the allocation scheme defined in its approved pancreas and kidney-pancreas alternative allocation system.

Additional Information on the 2007 Pancreas Survey

This subcommittee sent out a survey on barriers to pancreas placement to OPOs and transplant centers in November 2007. The survey was closed in January 2008. The response rates are below:

- OPO Survey:
  - 56% overall response rate
  - 36.2% of Executive Directors responded
  - 50.0% of Directors of Procurement responded
  - 84.5% of the OPOs responded (at least one employee from the OPO completed the survey)

- 79.2% of 2006 pancreas transplant (PA and KP) activity is represented by the OPOs that responded

Results **(Exhibit B)** include deceased donor pancreas transplants that occurred during 2008 unless otherwise noted. These data include only pancreata allocated locally unless otherwise noted.

The Committee investigated what types of allocation schemes were most common across the country. Out of all 58 DSAs, 44 DSAs were classified as KI follows PA, 8 as PA follows KI, and 6 as mixed. Of the DSAs where the kidney follows the pancreas, 28 give SPK absolute priority, 4 give PA absolute priority, and 6 have a combined SPK/PA list based on waiting time. Out of the 53 DSAs that allocate the pancreas locally, 43 DSAs were classified as KI follows PA, 4 as PA follows KI, and 6 as mixed. Of the DSAs where the kidney follows the pancreas, 27 give SPK absolute priority, 4 give PA absolute priority, and 6 have a combined SPK/PA list based on waiting time.

The Committee also examined whether the number of pancreas transplants, particularly SPK, differs by allocation system. KI follows PA systems represented the largest percent (83.2%) of locally allocated pancreata transplanted in the US in 2007 (SPKs and PAs) and represented 85.6% of SPK transplants. In DSAs where KI follows PA, a higher percentage of pancreas transplants are SPK transplants, compared to DSAs where PA follows KI.

The Committee considered whether donor and recipient characteristics differ by allocation system. The median age of donors for SPK transplants was similar across allocation systems. DSAs where KI follows PA had a slightly higher proportion of deceased donors over the age of 40 (for SPKs). The median age of SPK recipients was similar, with slightly older recipients in DSAs where PA follows KI. There was a similar distribution of SPK recipients by age among the allocation systems, with slightly more 56-60 and older than 60 year old recipients in KI follows PA group. The proportion of SPK recipients over the age of 50 with a donor under the age of 35 is similar across allocation systems. There are more SPK recipients with Type 2 diabetes in DSAs where KI follows PA and in mixed systems, but numbers are small for all groups. The Committee reviewed the distribution of Type 2 diabetic SPK recipients by center. For the 56 SPK transplants in candidates with Type 2 diabetes in 2007, they were performed at 28 centers with each center performing 5 or fewer transplants. Of the small number of SPK transplants for candidates with a CrCl >20 and not yet on dialysis, 86.7% were in DSAs where KI follows PA in 2006, and 87.5% were in DSAs where KI follows PA in 2007. Note that 85.6% of SPK transplants are done in DSAs where KI follows PA. Of the 16 candidate who were listed for SPK, but received a KI in 2006, half were in DSAs where KI follows PA, 12.5% were in DSAs where PA follows KI, and 37.5% were in DSAs with mixed systems.

The Committee investigated the correlation between waiting time and allocation system. Adult SPK waiting time is slightly higher in DSAs with mixed systems. Pediatric KI waiting times decreased from the pre-Share 35 period to the post- Share 35 period for all types of pancreas allocation systems. 0-5 year old KI candidates have the shortest waiting time in DSAs where KI follows PA, whereas 6-10 year old KI candidates have the shortest waiting time in DSAs where PA follows KI. 11-17 year old KI candidates have similar waiting times for all three types of pancreas allocation systems. The Committee also discussed the difference in pediatric kidney-alone, adult SPK, and adult kidney-alone waiting times by type of allocation system. The pediatric waiting time is lowest for all three systems. Adult SPK waiting time is lower in DSAs where KI follows PA, whereas adult kidney-alone waiting time is lower in DSAs where PA follows KI and in mixed systems.

The Committee explored the relationship between allocation system, age, and patient and graft survival. For patient survival, in DSAs where KI follows PA, those aged 56-60 have a somewhat lower rate of survival but the difference was very small. Those over age of 60 have a notably lower survival rate. For

DSAs where PA follows KI, there is not much difference between the age groups 18-49 and 50-55. (There were not enough recipients in other age groups to calculate outcomes.) For DSAs with mixed allocation systems, there is not much difference, although survival for 50-55 year olds is somewhat lower than for younger adults. There are similar results for kidney graft and pancreas graft survival.

The Committee assessed competing risks for SPK candidates added to the waiting list from 2000 to 2005. Candidates in DSAs where KI follows PA were more likely to have been transplanted and less likely to be still waiting. Also, there was a smaller cumulative rate of patients removed from the waiting list because of death or a change in health status.

The Committee concluded that significant variation exists between DSAs on the priority given to SPK candidates. However, the majority of DSAs already employ an allocation system where KI follows PA. The donor and recipient demographics were not notably different for SPK transplantation according to the type of the allocation system. Having a system where the kidney follows the pancreas did not increase SPK transplantation in patients with Type 2 diabetes, those not on dialysis, or in the number of young donor kidneys transplanted into older recipients. In DSAs where the kidney follows the pancreas, SPK patient waiting time to deceased donor transplant was significantly reduced. Both overall rate of pancreas transplantation and proportion of SPK transplants increased in systems where the kidney follows the pancreas. These data provide insights about how to develop and model a new and consistent national allocation system for pancreas transplant recipients that increases access and decreases waiting time for transplantation.

Simulated Allocation Modeling

On November 21, 2008, Kathryn Meyer presented the results from simulated allocation modeling requested by the Pancreas Review Subcommittee. **(Exhibit C)** At its April 2008 meeting, the subcommittee has made several modeling requests of the SRTR, comparing combinations of:

- SPK priority over PA vs. a combined SPK/PA list based on waiting time
- Local SPK priority over local Peds KI vs. local Peds KI priority over local SPK

The subcommittee requested that the SRTR model four allocation options:

- Option 1: Local SPK priority over local Pediatric KI; SPK priority over PA
- Option 2: Local SPK priority over local Pediatric KI; SPK and PA combined into one list
- Option 3: Local Pediatric KI priority over local SPK; SPK priority over PA
- Option 4: Local Pediatric KI priority over local SPK; SPK and PA combined into one list

The simulations assumed that there is no zero mismatch sharing for adult kidney candidates with a PRA of 0 to 20% and that there are no paybacks. Figure 1 shows the number of pancreas-alone, kidney-pancreas, pediatric kidney, and adult kidney transplants that would occur under each option.

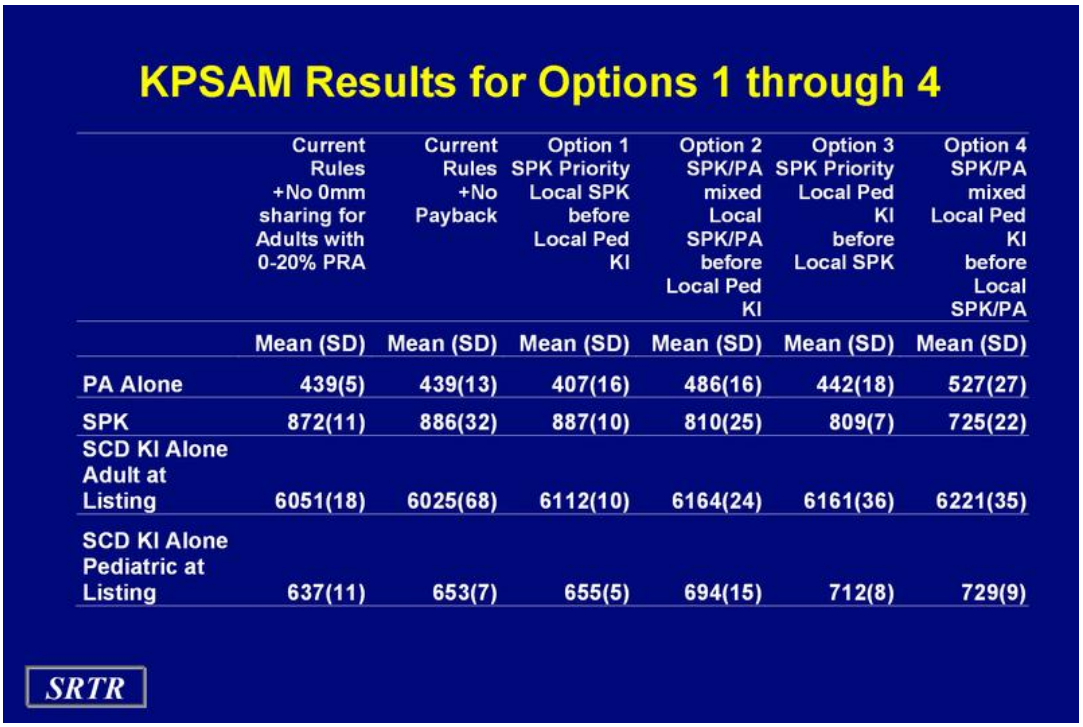

Figure 1: KPSAM Results for Options 1 through 4

The results show that combining the SPK and PA lists increases PA transplants and decreases SPK transplants. All options result in more pediatric KI transplants and more adult KI transplants than the current system. The Committee suggested that it would be helpful to assess outcomes other than number of transplants, such as mean waiting time. The Committee requested that the Pancreas Review Subcommittee meet to define the goals of the allocation change and to request further simulations.

In July 2009, Kathryn Meyer, SRTR liaison to the Committee, presented further SRTR simulation results from the KPSAM modeling. **(Exhibit D)** The modeling used a cohort of candidates and donors from 2003 and assumed no variances. There are four modeling runs:

- Current allocation scheme
- Current allocation scheme with no regional or national sharing of SPKs and no mandatory sharing of zero mismatch kidneys with a PRA under 20%
- Allocation Option #9: All kidneys are offered to a multi-organ (through local KP) first, then to KI; KP and PA combined into one list
- Allocation Option #10: All kidneys are offered to a multi-organ (through local KP) first, then to KI; KP priority over PA

To mitigate the effect of other allocation changes, the Committee compared options 9 and 10 to the current allocation scheme with no regional or national sharing of SPKs and no mandatory sharing of zero mismatch kidneys with a PRA under 20%. This run will be referred to as the control run. Results can be found in Figure 2.

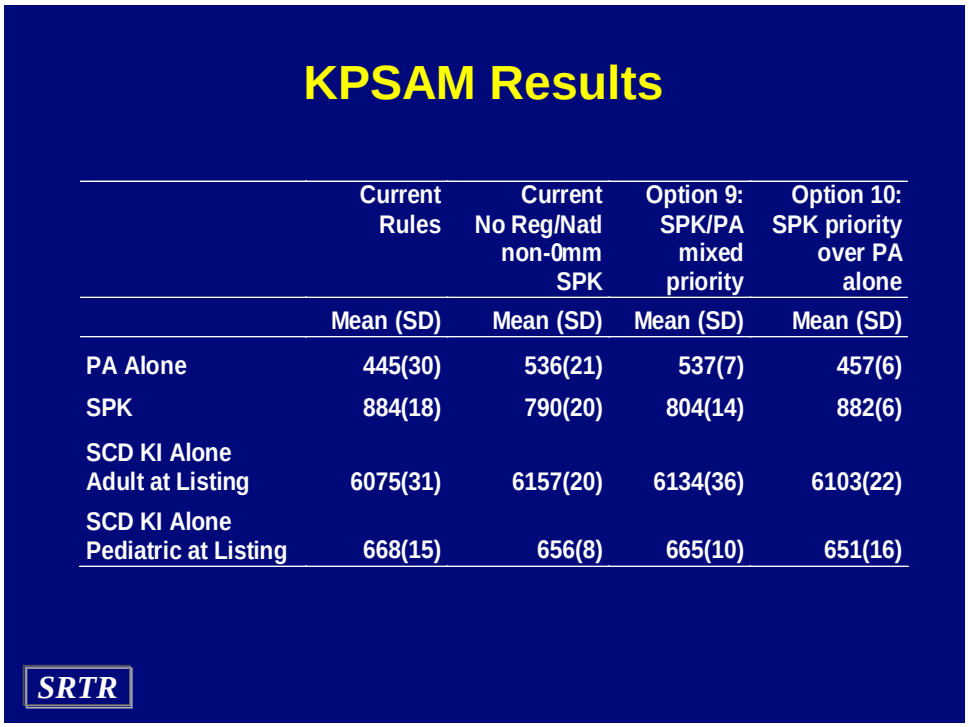

Figure 2: KPSAM Results for Options 9 and 10

The Committee noted that the difference in the number of kidneys going to pediatric KI candidates between the runs is small. None of the differences are greater than the between-run standard deviation. Between option 9 and the control run, there are no differences that are greater than the between run standard deviation. Between option 10 and the control run, there are more SPK transplants and fewer PA and adult KI transplants.

- 12% increase in SPK (92 transplants)
- 15% decrease in PA (79 transplants)
- 0.9% decrease in SCD adult KI alone (54 transplants)
- No difference in SCD pediatric KI alone

There is not a difference in the number of pediatric and adult KI candidates receiving a kidney from a donor under the age of 35 in any of the runs.

Based on these simulations, the Committee considered the pancreas allocation classifications shown in Table 1.

Table 1: Proposed Pancreas Allocation Classifications

Donor less than or equal to 50 years old and BMI less than or equal to 30 kg/m^2	Donor greater than 50 years old or BMI greater than 30 kg/m^2
0 ABDR Mismatch High CPRA OPO SPK & PA	0 ABDR Mismatch High CPRA OPO SPK & PA
0 ABDR Mismatch High CPRA Regional SPK & PA	0 ABDR Mismatch High CPRA Regional SPK & PA
0 ABDR Mismatch High CPRA National SPK & PA	0 ABDR Mismatch High CPRA National SPK & PA
OPO SPK & PA	OPO SPK & PA
Regional PA and SPK (if kidney available and at discretion of OPO)	OPO PA Islets
National PA and SPK (if kidney available and at discretion of OPO)	Regional PA Islets
OPO PA Islets	National PA Islets
Regional PA Islets	Regional PA and SPK (if kidney available and at discretion of OPO)
National PA Islets	National PA and SPK (if kidney available and at discretion of OPO)

The Committee again considered whether SPK candidates should receive absolute priority over pancreas-alone candidates. The concern with this path forward is that it could discourage living kidney donation in SPK candidates that are considering a living donor kidney transplant followed by a pancreas-alone transplant. Committee members suggested using a scoring system to give SPK candidates some degree of priority over pancreas-alone candidates since it would be consistent with the tenet of organ allocation to maximize organ use in candidates that show the greatest benefit. The Committee thought that a combined list was the appropriate path forward and that incorporation of a scoring system that adds an appropriate element of SPK priority could be considered as a future revision. The Committee also discussed having a review board for when a center wanted a candidate to be listed for SPK, but that candidate does not meet the SPK listing revision. This concept could also be considered as a future enhancement. The Committee voted to endorse the following concept:

- To have a combined SPK and PA list ordered based on waiting time.
- SPK listing criteria would be:
    - Kidney: the candidate is on chronic maintenance dialysis or GFR or CrCl $\leq$ 20 mL/min (per Kidney Committee)
    - Pancreas: the candidate must have a minimum c-peptide value (to be based on evidence)

(13-Support, 0-Oppose, 0-Abstain) The Committee will present this concept to other Committees and regions in order to build consensus in the fall and winter of 2009. The Committee will also reach out to groups like the AST, ASTS, AOPO, and ADA.

Pancreas Transplantation Committee Feedback on Kidney Allocation Score Request for Information
On January 23, 2009, the Committee discussed the KAS Forum on January 26, 2009 in St. Louis, MO. The Committee was concerned that some groups oppose the possibility of the kidney following the pancreas in a new kidney allocation system, which is being considered by the Kidney Transplantation Committee. The Committee voted to endorse the kidney following the pancreas in allocation and decided to draft a statement outlining the Committee's opinion. (12-Support, 0-Oppose, 0-Abstain) The final statement is below:

The OPTN/UNOS Pancreas Transplantation Committee disagrees with the ASTS statement regarding the proposed policy change for simultaneous pancreas and kidney transplants (SPKs) and strongly supports the kidney follows the pancreas proposal.

SPK transplants make up only a small portion (approximately 7%) of kidney transplants, yet result in the highest LYFT score of any adult kidney transplant group. SPKs are primarily performed in young recipients (50% are between 18-40 years old vs. 27% for kidney transplant recipients). In addition, SPK transplants provide significant life changing QOL benefits.

Currently, there is no mandate that kidneys must follow pancreas allocation. However, a recent UNOS analysis has shown that the majority of DSA already utilize the allocation scheme of the kidney follows the pancreas. In the only 20% of DSAs that employ the alternative allocation method (the pancreas follows the kidney), we find that the DSAs account for only 6% of SPK transplants and 22% of solitary pancreas transplant. This suggests reduced access to SPK transplants in those DSAs.

If there is to be a mandate that kidneys must follow pancreas allocation, the Pancreas Transplantation Committee agrees that it will be critical to have accurate, reproducible, and transparent listing criteria for SPK candidates that will prevent gaming of the system.

In this regard, there are two crucial questions: (1) Is there evidence of gaming the current system in which a substantial number of DSAs use a kidney follows pancreas allocation system? (2)Are the donors younger, are the recipients older, are there more pre-emptive transplants, are SPKs being used as bait for a kidney alone transplant? The Pancreas Transplantation Committee is looking into this, and we are not aware of known instances, but certainly we agree further analysis and assurance must be in place.

Furthermore, a recent UNOS analysis has examined the comparative effects of the two allocation methods - kidney following pancreas vs. pancreas following kidney to answer these questions. The analysis showed:

- No difference in median age of donors or recipients in SPKs.
- No difference in age demographics in SPK recipients.
- No difference in the percentage of SPK candidates receiving a pre-emptive SPK in recipients with a CrCl>20 and NYOD (<2% in each group).
- No difference in percentage of SPK recipients receiving a kidney alone when both organs are available to the transplant program (<1% in each group).
- However, there were 57 cases of recipients listed as having Type 2 diabetes (7%) receiving an SPK in DSAs using the kidney follows pancreas allocation system. This issue can easily be addressed by the Pancreas Transplantation Committee by developing appropriate listing criteria for SPK.

The Pancreas Transplantation Committee points out that data already exist regarding the impact this policy would have on pediatric candidates waiting for kidney only transplants. This data shows no impact on mean waiting time for pediatric kidney alone transplant recipients. Analyses for adult transplants will be performed.

We look forward to working with the Kidney Transplantation Committee and others to more fully evaluate how a consistent policy of kidney follows pancreas may be designed to improve efficiency and fairness of the system for both kidney and pancreas transplant recipients.

Plan for Consensus Building
On October 1, 2009, the Committee discussed the plan for building consensus on the concept for a new pancreas allocation system and reviewed the presentation to be used during the consensus building effort. The Committee discussed the consensus building document created by the Pancreas Allocation Subcommittee for use when discussing the concept for a new pancreas allocation system with other committees, regions, and external groups. **(Exhibit E)** This concept summary document can be shared with anyone interested on the Committee's concept for a new pancreas allocation system.

The Committee is engaging in a consensus building effort in the fall of 2009 to include regions, other committees, pancreas transplantation programs, external constituent organizations, and the general public. The regional representatives will present the concept and gather feedback during the fall 2009 regional meetings. Committee members will also present to the following committees:

- Kidney Transplantation
- Minority Affairs
- Operations and Safety
- Organ Availability
- Organ Procurement Organization
- Patient Affairs
- Pediatric Transplantation
- Policy Oversight
- Transplant Administrators
- Transplant Coordinators

The Committee sent a memo to all pancreas programs seeking feedback on the concept. The concept summary document was included with the memo. Pancreas programs can provide feedback by contacting their regional representative to the Committee, by attending their regional meeting, or by e-mailing the Committee liaison. All feedback will be reviewed at Committee meeting on November 20, 2009.

The Committee will request feedback from the following organizations as well:

- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- Juvenile Diabetes Research Foundation (JDRF)
- American Diabetes Association (ADA)
- Association for Organ Procurement Organizations (AOPO)
- NATCO, The Organization for Transplant Professionals

Committee members volunteered to investigate the best way to contact these organizations.

Finally, the Committee is considering having a LiveMeeting about the concept. This LiveMeeting would be open to patients, pancreas programs, external organizations, and the general public to give everyone an opportunity to provide feedback on the concept.

The purpose of the education and consensus building period is to identify concerns so that they can be addressed or incorporated in any final proposal. The Committee discussed some of the concerns received to date. Some from pediatric and adult kidney transplant programs are concerned that if the new allocation system increases access to pancreata for SPK transplantation, it will result in significantly fewer pediatric and adult kidney-alone transplants. The Committee is working with SRTR using the KPSAM methodology to model various allocation options to obtain data that will provide some indication as to how pediatric and adult kidney transplant activity might be impacted. These simulation results will be relevant data to address the concerns.

The Committee reviewed the consensus building presentation, which will be presented at the fall 2009 regional meetings. This consensus building presentation is a summary of the concept for the new pancreas allocation system, the rationale for the change, and the supporting evidence.

The Committee discussed whether SPK candidates should have any priority over PA candidates because of increased waiting list mortality. Committee members noted that having a combined list does not discourage living donation and could result in more kidneys going to the kidney-alone pool of candidates.

The Committee also discussed listing criteria for SPK candidates. The Committee noted that although most pancreas transplants currently are for candidates with Type 1 diabetes, there is concern that the number of transplants for candidates with Type 2 diabetes would increase. The Committee is concerned that only using c-peptide as a listing criterion would exclude some candidates with Type 1 diabetes. The Committee discussed having additional inclusion criteria for candidates who do not meet the c-peptide criterion, such as HbA1c level, insulin requirements, Clarke score, or presence of antibodies. Committee members will provide articles to support the use of these criteria and to demonstrate what values should be required.

Pancreas Allocation Subcommittee minutes are attached as **(Exhibit F).**

2. Pancreas Donor Risk Index

On November 21, 2008, and July 24, 2009, David A. Axelrod, MD, MBA, Vice Chair of the Committee, presented the work of the Pancreas Donor Risk Index (DRI) Subcommittee. **(Exhibit G)**

Background

Careful pancreas selection is considered as key to successful pancreas transplantation. The rate of pancreas graft thrombosis is considered high at 5% to 8%. Pancreas transplant alone (PTA) and pancreas after kidney (PAK) transplants have higher rates of graft failure than simultaneous pancreas-kidney (SPK) transplants. Overall, donor quality is decreasing. There are nearly 4,000 candidates waiting for PTA, PAK, or SPK. Waiting times to transplant 25% of the candidates exceed 645 days in some regions for SPK. The total number of pancreas transplants has been decreasing since 2006.

DRI is a measure of organ quality that is computed using a weighted function of several relevant donor and transplant characteristics. Donor Percentile Index (DPI) is developed by using the DRI to rank organs from highest to lowest quality and then assigning each organ a percentile based on where they rank according to other organs in the sample. This is how the kidney DRI is incorporated into the kidney allocation score (KAS). The DRI can be used to inform clinical decisions, to assess pancreas utilization, and in allocation.

The purpose of the pancreas donor risk index (DRI) is to develop a scoring system to assess the donor-related risk of pancreas graft failure. This index includes factors available at the time of transplantation. The pancreas DRI provides improved information for transplant professionals that will allow them to assess the differential impact of donor quality in isolated and combined pancreas transplant procedures and to consider variation in organ acceptance and utilization among regions, DSAs, and transplant centers.

Findings

The SRTR has created a 1-year pancreas graft failure model with an index of concordance of 66%. The pancreas DRI includes the following factors:

- Donor age

- Donor gender
- Donor race
- Donor serum creatinine >2.5
- DCD status
- Donor height (cm)
- Donor BMI ≤25
- Donor cause of death = CVA
- Donor cause of death = CVA and PAK recipient
- Pancreas Preservation Time (hrs)

The donors in the cohort were grouped into quintiles based on DRI. The majority of the transplants came from donors in the first three quintiles (lower DRIs). For the lowest DRI organs, there is very little difference in outcomes by pancreas transplant types whereas SPK outcomes are better than PAK and PTA outcomes for higher DRI organs. Centers that perform more transplants (greater than 40 transplants in a 2.5 year period) are more likely to use higher DRI organs. There is also variation in the use of higher DRI organs by region.

There are several limitations to this analysis. Some relevant data, such as HbA1c and pressor use, are not collected and cannot be included in the model. The model reflects actual practice, so it cannot predict outcomes for organs that are rarely used, such as for DCD donors or donors with high creatinine. Finally, the model does not account for gland appearance.

Conclusions
Pancreas DRI predicts allograft survival based upon donor factors identifiable prior to the time of the operative procurement process. Organ quality differentially affects isolated and combined pancreas transplants. Pancreas survival in SPK transplants is better for all DRI levels. Utilization of high DRI pancreata varies by region and by transplant center practice. Expedited placement of high DRI pancreata to experienced centers may increase utilization.

Pancreas DRI Subcommittee minutes are attached as **(Exhibit H).**

3. Recommendations for Changes to Data Collection Forms

In November 2008, the Committee discussed the process for making modifications to the data collection forms. All OPTN forms are reviewed and approved by the Office of Management and Budget (OMB). The current forms expire in October 2010. The time for Committee review is through spring 2009. Then the Ad Hoc Data Management Group will review all recommendations, and the Policy Oversight Committee will send all new data elements out as a single public comment proposal. This proposal will be sent to the Board for approval in March 2010. All recommendations for new data elements should adhere to the Principles of Data Collection and Operational Guidelines. The Committees should identify any important data elements that may be missing and try to clarify anything that may be difficult to understand. The Committees should consider whether forms are the appropriate place for this data. For example, data needed for allocation may fit better into Waitlist^{SM} or DonorNet®.

The Pancreas Outcomes Review Model Subcommittee has already identified several potential additional data elements. The subcommittee has developed a unified definition of pancreas graft function and failure (Table 2).

Table 2: Uniform Definition of Graft Function/Failure for Whole Pancreas and Islet Transplant

Description	Grade	Insulin Use (U/kg/day) baseline established prior to transplant	C-peptide	Euglycemia defined as:			Comments
				HbA1c	Fasting plasma glucose[1]	"Casual " plasma glucose[2]	
Full graft function	**A**	none	normal range[3]	less than 6.0%	<100 mg/dl	< 160 mg/dl	Full graft function definition requires HbA1c ≤6.0%, and (with rare exception), fasting & casual plasma glucose values within the specific limit
Substantial graft function	**B**	less than 0.2 U/kg/day	normal range[3]	within normal range for lab	<100 mg/dl	< 160 mg/dl	Substantial graft function definition requires HbA1c within the normal range, fasting & casual plasma glucose values within the specific limit
Partial graft function	**C**	less than 50% pre-transplant dose	>0.5 ng/ml	less than 7.0%	<126 mg/dl	< 200 mg/dl	
	D	more than 50% pre-transplant dose	>0.5 ng/ml	less than 7.0%	<126 mg/dl	< 200 mg/dl	
Graft failure	**E**	C-peptide < 0.5 ng/ml or suboptimal glycemia control defined as any HbA1c greater than or equal to 7.0%, or any fasting plasma glucose > than 126, or casual plasma glucose values > than 200 mg/dl					

Definitions:

- No caloric intake for at least 8 hours
- Plasma glucose any time of day without regard to time since last meal
- Can be considered "normal" if it is above the laboratory's reference range (often the case in pancreas allograft recipients)

In order to be able to use this definition, several new data elements (c-peptide, HbA1c, fasting plasma glucose, and casual plasma glucose) would need to be added. Additionally, the subcommittee has recommended that coronary artery disease be uncoupled from angina on the pancreas forms. Because this subcommittee is already familiar with the data, the Committee charged the Pancreas Outcomes Review Model Subcommittee with reviewing the pancreas data collection forms and bringing recommendations to the full Committee in the spring.

Cardiac Function
On March 27, 2009, the Committee reviewed the Pancreas Outcomes Review Model Subcommittee's (subcommittee) recommendations for changes to the data collection forms.

Table 3: Cardiac Dysfunction Recommendations from Subcommittee

Change	Units	Values	Forms
Add Cardiac Dysfunction		Yes/No	-Transplant Candidate Registration -Transplant Recipient Registration
Add Ejection Fraction (if yes for Cardiac Dysfunction)	%	10-80	-Transplant Candidate Registration -Transplant Recipient Registration
Add Documented Coronary Artery Disease Interventions (number of vessels)		-By CABG: 0, 1, 2, 3, 4+ -By stent: 0, 1, 2, 3, 4+	-Transplant Candidate Registration -Transplant Recipient Registration
Remove Angina			-Transplant Candidate Registration

In March 2009, the Committee thought that the field should be labeled "Cardiac Function" and that every kidney-pancreas candidate should have an ejection fraction value. For the transplant recipient registration form (TRR), the ejection fraction entered should be the one on the date closest to transplant. The Committee stated that the method of determining cardiac function could be a question as well. The Committee also considered asking whether a cardiac catheterization was done, then asking for the maximum narrowing percentage with the number of vessels with that percentage. The Kidney Transplantation Committee is also looking into these cardiac fields. The Kidney Transplantation Committee favors collecting ejection fraction and is working on developing more objective criteria for when ejection fraction should be collected. The Kidney Transplantation Committee was also concerned that there was no evidence supporting that the number of vessels bypassed predicts patient or graft survival. The Committee charged the subcommittee with finalizing these recommendations.

In July 2009, the Committee reviewed the additional comments from the subcommittee on the cardiac function fields. The Committee considered whether knowing the number of vessels that were bypassed or stented would be useful. The Committee noted that the data may be hard for those entering the data at the center to find in the chart. The Committee voted to only ask about documented coronary artery disease interventions and not include the number of vessels. (18-Support, 1-Oppose, 0- Abstain)

The Committee makes the following recommendations regarding cardiac function:

Table 4: Final Cardiac Function Recommendations

Change	Units	Values	Forms
Add Cardiac Function Enter Ejection Fraction	%	10-80; Not available	-Transplant Candidate Registration -Transplant Recipient Registration
Add Documented Coronary Artery Disease Interventions (number of vessels)		-CABG -Stent -Both -Neither	-Transplant Candidate Registration -Transplant Recipient Registration
Remove Angina			-Transplant Candidate Registration

Pancreas Graft Function
In March 2009, the Committee reviewed pancreas graft function recommendations from the subcommittee regarding the data collection forms.

Table 5: Pancreas Graft Function Recommendations from Subcommittee

Change	Units	Values	Forms
Add Average Daily Units of Insulin	Units/day	0-200	-Transplant Candidate Registration -Transplant Recipient Registration (as average daily insulin units at discharge) -Transplant Recipient Follow-Up
Add C-Peptide	ng/ml or nmol/L	0-15	-Transplant Candidate Registration -Transplant Recipient Follow-Up
Add HbA1c	%	4-15	-Transplant Candidate Registration -Transplant Recipient Follow-Up
Add Fasting Plasma Glucose	mg/dl	0-999	-Transplant Candidate Registration -Transplant Recipient Registration (as fasting plasma glucose at discharge) -Transplant Recipient Follow-Up
Add Casual Plasma Glucose	mg/dl	0-999	-Transplant Candidate Registration -Transplant Recipient Registration (as casual plasma glucose at discharge) -Transplant Recipient Follow-Up

In March 2009, the Committee decided that c-peptide should be fasting c-peptide and that it should only be required for recipients on insulin.

In July 2009, the Committee considered whether c-peptide should be fasting again. The Committee preferred to have the c-peptide data regardless of whether it is fasting or post-prandial. The Committee voted to not require that c-peptide be a fasting c-peptide and to have the center indicate whether the c-peptide is fasting, non-fasting, or unknown. (19-Support, 1-Oppose, 0- Abstain)

The Committee debated whether HbA1c and plasma glucose are reliable measures when comparing values across institutions. The Committee determined that HbA1c is a useful measure even without a reference range. The Committee voted to exclude both casual plasma glucose and fasting plasma glucose from the data collections forms. (11-Support, 8-Oppose, 0-Abstain)

The Committee makes the following recommendations regarding pancreas graft function:

Table 6: Final Pancreas Graft Function Recommendations

Change	Units	Values	Forms
Add Is the Candidate (Recipient) on insulin or oral glycemic agents?		-Yes -No	-Transplant Candidate Registration -Transplant Recipient Registration -Transplant Recipient Follow-Up
If yes to on insulin or oral glycemic agents, add Average Daily Units of Insulin	Units/day	0-200	-Transplant Candidate Registration -Transplant Recipient Registration (as average daily insulin units at discharge) -Transplant Recipient Follow-Up
If yes to on insulin or oral glycemic agents, add C-Peptide	ng/ml or nmol/L	0-15	-Transplant Candidate Registration -Transplant Recipient Follow-Up
Following C-Peptide, Add C-Peptide Method		-Fasting -Non-fasting -Unknown	
Add HbA1c	%	4-15	-Transplant Candidate Registration -Transplant Recipient Follow-Up

Other Recommendations
In March 2009, the Committee reviewed other recommendations from the subcommittee regarding the data collection forms.

Table 7: Other Recommendations from Subcommittee

Change	Units	Values	Forms
If yes to Symptomatic Peripheral Vascular Disease, add Interventions		-Claudication in the leg -Claudication in the pelvis -Surgically treated in the leg -Surgically treated in the pelvis -Stented in the leg -Stented in the pelvis	-Transplant Candidate Registration
Remove Symptomatic Cerebrovascular Disease			-Transplant Candidate Registration
Add History of Stroke		-Yes -No -Unknown	-Transplant Candidate Registration
Remove Peptic Ulcer			-Transplant Candidate Registration
Remove Medical Condition at Time of Listing			-Transplant Candidate Registration (as medical condition at time of listing) -Transplant Recipient Registration (as medical condition at time of transplant)

Remove Physical Capacity (Adult Forms Only)	-Transplant Candidate Registration -Transplant Recipient Registration -Transplant Recipient Follow-Up
Remove Academic Progress (Adult Forms Only)	-Transplant Candidate Registration -Transplant Recipient Registration -Transplant Recipient Follow-Up
Remove Academic Activity Level (Adult Forms Only)	-Transplant Candidate Registration -Transplant Recipient Registration -Transplant Recipient Follow-Up

In March 2009, the Committee noted that the Kidney Transplantation Committee is considering adding other indicators of peripheral vascular disease, such as amputation, to the forms. The Pancreas Committee would like to limit the amputation to only major limb amputation (Values: No, Yes-BKA, Yes-AKA, Yes-Other). The Committee endorsed the proposed changes to the OMB forms and charged the Pancreas Outcomes Review Model Subcommittee with finalizing the recommendations. (12-Support, 0-Oppose, 0- Abstain)

In July 2009, the Committee discussed the value of differentiating pancreas transplants which are part of multi-visceral transplants from SPK or pancreas alone transplants. The Committee debated the best way to express that they wanted to know whether a pancreas is part of a multi-visceral transplant, which usually means that the pancreas is transplanted along with the intestines and other organs. The voted to add the question "Is the candidate listed for (Did the recipient receive) a pancreas as part of a multi-visceral transplant?" (18-Support, 0-Oppose, 0-Abstain)

The Committee considered adding HbA1c to the deceased donor registration form. The Committee previously requested that HbA1c be added to DonorNet®, which is currently being programmed. Adding this field in the deceased donor registration would allow it to be used in analyses of donor factors. The Committee suggested that "not available" be an option so that additional data collection is not required. The Committee asked whether this field could be automatically populated from the field in DonorNet®. UNOS staff will investigate this request. The Committee voted to add HbA1c to the deceased donor registration form. (20-Support, 0-Oppose, 0-Abstain)

The Committee makes the following other data collection recommendations:

Table 8: Final Other Recommendations

Change	Units	Values	Forms
If yes to Symptomatic Peripheral Vascular Disease, add Interventions		-Claudication in the leg -Claudication in the pelvis -Surgically treated in the leg -Surgically treated in the pelvis -Stented in the leg -Stented in the pelvis -Major limb amputation: BKA -Major limb amputation: AKA	-Transplant Candidate Registration

Remove Symptomatic Cerebrovascular Disease			-Transplant Candidate Registration
Add History of Stroke		-Yes -No -Unknown	-Transplant Candidate Registration
Remove Peptic Ulcer			-Transplant Candidate Registration
Remove Medical Condition at Time of Listing			-Transplant Candidate Registration (as medical condition at time of listing) -Transplant Recipient Registration (as medical condition at time of transplant)
Remove Physical Capacity (Adult Forms Only)			-Transplant Candidate Registration -Transplant Recipient Registration -Transplant Recipient Follow-Up
Remove Academic Progress (Adult Forms Only)			-Transplant Candidate Registration -Transplant Recipient Registration -Transplant Recipient Follow-Up
Remove Academic Activity Level (Adult Forms Only)			-Transplant Candidate Registration -Transplant Recipient Registration -Transplant Recipient Follow-Up
Add "Is the candidate listed for (Did the recipient receive) a pancreas as part of a multi-visceral transplant?"		-Yes -No	-Transplant Candidate Registration -Transplant Recipient Registration
Add HbA1c	%	4-15 -Not available as an option	-Deceased Donor Registration

Pancreas Outcomes Review Model Subcommittee minutes regarding the OMB Forms are attached as **(Exhibit I).**

4. Pancreas Program Specific Report Models

The Pancreas Outcomes Review Model Subcommittee has been working with the SRTR to develop an outcomes review model for use by the Membership and Professional Standards Committee (MPSC). On November 21, 2008, Randall S. Sung, MD, presented the 1-year and 3-year graft failure and patient survival models developed by the SRTR and the Pancreas Outcomes Review Model Subcommittee. **(Exhibit J, Exhibit K, and Exhibit L)** Before this review of the pancreas models, the MPSC used an outcomes review model that included only simultaneous pancreas-kidney (SPK) transplants. The subcommittee has recommended that a combined SPK/PAK/PTA model be used so that more pancreas programs can be evaluated by the model. All of the combined models are stratified by transplant type, which allows SPK, PAK, and PTA recipients to have a differing hazard over time. The MPSC only uses the model to evaluate centers that perform ten or more transplants over a 2.5 year period. For each type of model, the combined model is compared to the existing SPK model in the tables below (Tables 9-12).

Table 9: 1-Year Graft Failure Model

	Combined SPK/PAK/PTA Model	SPK-only Model
Index of Concordance	63%	58.0%
Covariates	Deceased donor cause of death, donor age, recipient gender, **recipient age, recipient BMI, recipient PVD, previous pancreas transplant, donor gender, donor height**	Deceased donor cause of death, donor age, recipient gender, *duct management, HLA mismatch*
Interactions	• Recipient gender and PTA • Donor COD:CVA with PAK	
% of centers that perform less than 10 transplants in a 2.5 year period	34.8%	49.3%

Table 10: 3-Year Graft Failure Model

	Combined SPK/PAK/PTA Model	SPK-only Model
Index of Concordance	61%	57.8%
Covariates	Donor age, donor gender, recipient age, **recipient PVD, ESRD years (for SPK), previous pancreas transplant, albumin, donor height**	Donor age, donor gender, recipient age, *deceased donor cause of death, HLA mismatch*
Interactions	• Recipient age and SPK	
% of centers that perform less than 10 transplants in a 2.5 year period	34.8%	49.3%

Table 11: 1-Year Patient Survival Model

	Combined SPK/PAK/PTA Model	SPK-only Model
Index of Concordance	73%	60.4%
Covariates	Recipient age, years of ESRD treatment, **recipient BMI, duct management, donor age, donor race, pancreas preservation time**	Recipient age, years of ESRD treatment
Interactions	• Donor age and PAK	
% of centers that perform less than 10 transplants in a 2.5 year period	34.8%	49.3%

Table 12: 3-Year Patient Survival Model

	Combined SPK/PAK/PTA Model	SPK-only Model
Index of Concordance	64%	60.0%
Covariates	Recipient age, ESRD years, **recipient BMI, recipient albumin, recipient PVD, recipient primary insurance, donor age, donor gender, CMV mismatch**	Recipient age, ESRD years, *recipient gender*
Interactions	• Primary insurance and PTA	
% of centers that perform less than 10 transplants in a 2.5 year period	34.8%	49.3%

The Committee debated whether to recommend that the MPSC use the 1-year combined graft failure and patient survival models in its review of pancreas programs. The Committee was concerned that larger, more aggressive programs would be penalized by these models because they do not take into account all of the potential risk factors. This situation would encourage transplant centers to only transplant low risk candidates with pancreata from low risk donors, which could reduce access to transplantation. The Committee also commented that other groups, such as payers, are using these models, but they may not be aware of the limitations of the models. Additionally, the data that is available for input into these models is limited by what is collected. However, the models developed by the SRTR and the subcommittee are better than the models that were available previously. The Committee concluded that it could not recommend a model with an index of concordance below 66%, which is the index of concordance for the lung and liver 1-year graft failure models. The Committee wanted more time to try to reach a higher index of concordance for the models. The Committee voted to recommend that the MPSC:

- Recognize only the 1-year pancreas combined patient survival model for the assessment of pancreas programs
- Defer the use of the 1-year pancreas combined graft failure model at least one year until the index of concordance can reach at least 66%, which is the index of concordance of the liver and lung models, and allow the Committee to re-assess pancreas data collection and quality
- Post the combined graft failure model instead of the SPK model in the interim. (13-Support, 0-Oppose, 0- Abstain)

This recommendation would give the Committee time to assess pancreas data collection and to attempt the raise the index of concordance.

Pancreas Outcomes Review Model Subcommittee Minutes can be found in **(Exhibit M)**.

5. Updates on Board of Directors Meetings

On November 21, 2008, Rainer W. G. Gruessner, MD, Chair of the Committee, updated the Committee on the November 2008 Board of Directors meeting. Dr. Gruessner presented the major activities of the Committee to the Board. Dr. Gruessner also shared the trends in pancreas transplant by year. Figure 3 shows that the percentage of pancreata that are not recovered is increasing and the percentage of pancreata transplanted is decreasing.

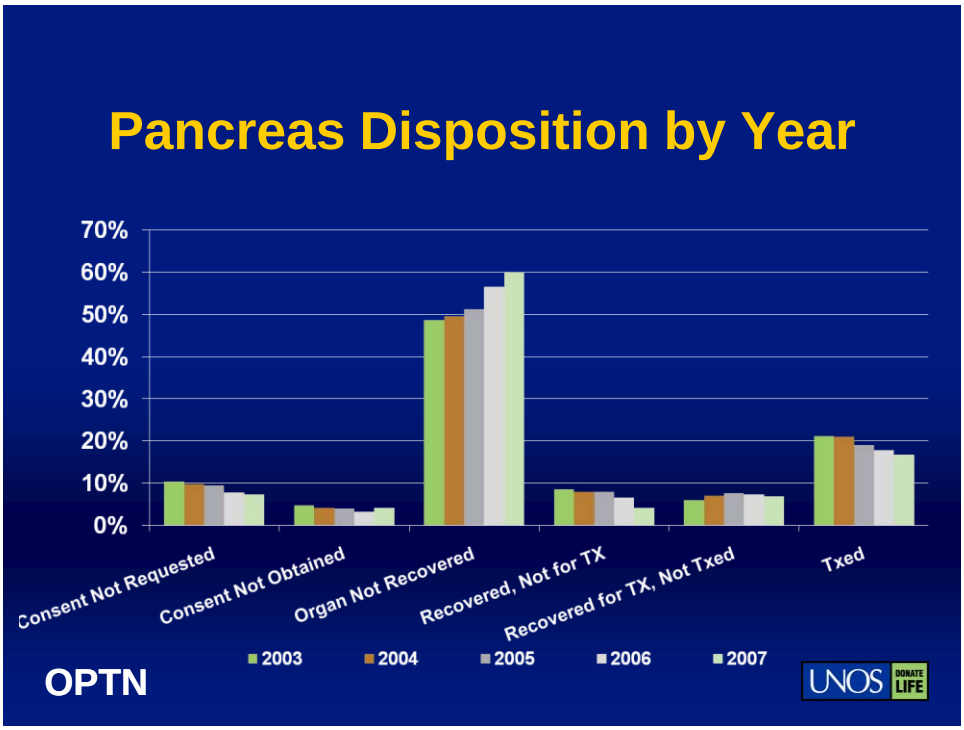

Figure 3: Pancreas Disposition by Year

Figure 4 shows that the pancreas discard rate is higher than every other organ and that the pancreas discard rate has increased from 2003 to 2007.

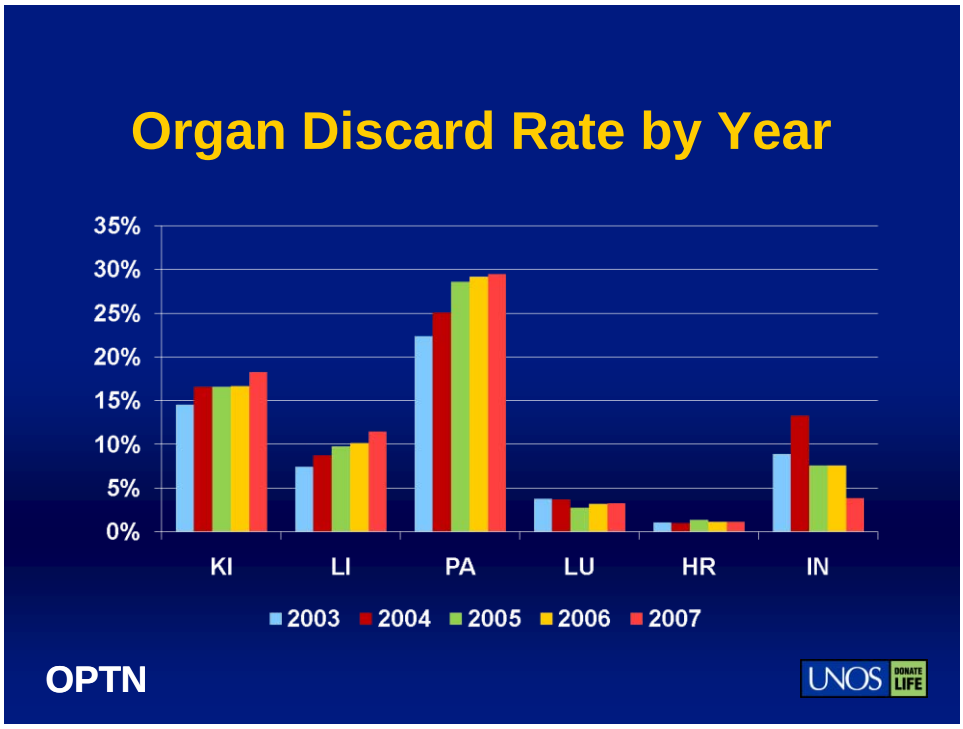

Figure 4: Organ Discard Rate by Year

The Committee noted that changes to payback rules and having the kidney follow the pancreas may improve these trends.

On March 27, 2009, Dr. Gruessner updated the Committee on the March 2009 Board of Directors meeting. The Committee sent two proposals to the Board for approval. The Board approved the proposal to allow candidates who need the pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list on the consent agenda (26-Support, 0-Oppose, 0-Abstain). The Board approved the proposal to clarify islet allocation protocol (26-Support, 0-Oppose, 0-Abstain). The implementation date for both proposals is scheduled for May 4, 2009.

6. Updates from the Kidney Transplantation Committee

On November 21, 2008, Peter G. Stock, MD, PhD, Chair of the Kidney Transplantation Committee, reviewed the major concepts in the kidney allocation score (KAS) request for information (RFI) with the Committee. The purpose of the RFI is to request input on concepts for possible incorporation into the allocation system for deceased donor kidneys. The proposed new kidney allocation system is based on three major concepts: ranking candidates based upon objective medical criteria (LYFT), replacing SCD/ECD with DPI, and changing from time since listing to time on dialysis (DT). These components are combined into a kidney allocation score. The proposed system will also maintain priority for pediatric candidates and prior living donors, include a sliding scale priority for sensitized candidates, eliminate absolute priority for 0-ABDR mismatch to unsensitized candidates, eliminate the kidney payback system, change SPK allocation, and incorporate the A_2/A_2B Committee-sponsored alternative allocation system nationally. The objectives of the proposed system are to improve outcomes of recipients of deceased donor kidneys through improved matching of graft/recipient projected survival and to improve access for biologically disadvantaged kidney transplant candidates (highly sensitized, blood group B, minority candidates). The KAS calculation is based on candidate life years from transplant (LYFT), candidate dialysis years (DT), donor profile index (DPI), and candidate sensitization level. LYFT is defined as the difference between a candidate's median projected lifespan post-transplant minus his projected median waiting list survival without a transplant. The time without a transplant is adjusted for quality of life. The DPI is a continuous measure which provides more clinical information than the current ECD/SCD categories about a donor's kidneys. More information should improve clinical decision making.

Projected Results

African-Americans will receive approximately 5% more kidneys under the proposed system. Distribution by blood type is similar between the current and proposed system, with a slight increase for B candidates in the proposed system. Candidates with glomular nephritis and hypertension will receive more kidneys under the proposed system, whereas candidates with diabetes over the age of 50 will receive fewer kidneys. Moderately sensitized candidates (PRA 20-79%) and younger candidates will receive a larger percentage of kidneys under the proposed system. In the proposed system, the average post-transplant lifetime increases from 11.8 years in the current system to 13.1 years. Average graft lifetime increases from 8 years in the current system to 8.2 years in the proposed system. Average extra years of life increases from 5.3 years in the current system to 5.7 years in the proposed system.

Committee members expressed concern that the proposed system disadvantages older candidates with diabetes. The Committee supported the proposed changes to SPK allocation because the changes are advantageous for pancreas candidates.

On July 24, 2009, John J. Friedewald, MD, Vice Chair of the Kidney Transplantation Committee (Kidney Committee), updated the Committee on the Kidney Committee's progress in developing a new kidney allocation system. In January 2009, the Kidney Committee hosted a public forum on concepts for kidney allocation (LYFT, DT, DPI). Feedback from forum participants was validated through an independent

assessment. This assessment was conducted by a professional in consensus building. The findings indicated that:

- ESRD Time and DPI are well accepted.
- LYFT is not well accepted, primarily due to complexity and data limitations.
- There is support for matching of kidney graft longevity and recipient longevity.

The Kidney Committee can confidently identify candidates with the longest survival from candidates with the shortest survival. However, the Kidney Committee is not as confident in differentiating survival for candidates with median survival. Therefore, a system with a continuous measure for ranking for all candidates is not accepted.

The Kidney Committee is considering several options as a path forward. The first option is to focus on allocating the longest lived kidneys to the longest lived recipients. Another option is to focus on not allocating the longest lived kidneys to the shortest lived recipients. The Kidney Committee is planning to test allocating the longest lived kidneys to the longest lived recipients as a start. The Kidney Committee aims to focus on building a system that is expandable over time, both as data improve and as experience is gained. One benefit to this approach is it is expandable. If it works, the definitions of "longest lived" could be expanded from 20% to 30%, for example. Similarly, the approach is contractable. If it does not work, the outcome metric could be set to "0", and there would be a system based on ESRD time. A possible risk to this approach is that, unlike a continuous measure, a cut-off draws a "hard line" in the allocation system meaning that similar candidates may fall on either side of the line. This approach may decrease predictability for candidates on the threshold.

LYFT prioritized those with short waiting list survival and long post-transplant survival, (e.g., candidates with Type 1 diabetes). Because LYFT was not accepted, the Kidney Committee is investigating options that achieve similar goals. The Kidney Committee will investigate using post-transplant survival (with four variables) instead of LYFT and having a separate priority for candidates with Type 1 diabetes.

The Kidney Committee is also considering several other features for a new kidney allocation system. Waiting time will be based on the date the candidate started dialysis or the date the candidate's glomerular filtration rate (GFR) is less than or equal to 20 mL/min. The Kidney Committee is also investigating utilizing post-transplant survival instead of LYFT. The Kidney Committee plans to make survival projections available for patient education to help address predictability concerns. Finally, the Kidney Committee is considering treating SPK transplants in the same way as simultaneous liver-kidney transplants, meaning that the organs would be allocated by the allocation system of the extra-renal organ.

The Committee inquired whether the Kidney Committee has considered the relative cost of transplanting younger versus older candidates.

7. Update on the Implementation of the Kidney Committee's Proposal to Limit Mandatory Sharing of Zero Mismatch Kidneys

On November 21, 2008, Aaron Powell, PMP, UNOS Project Office Manager, updated the Committee on the implementation of the Kidney Transplantation Committee's proposal to limit mandatory sharing of zero mismatch kidneys. In September 2008, the Executive Committee voted to give the implementation of this proposal greater priority. The expected implementation date for this proposal is January 21, 2009.

8. Islet Consensus Conference

On November 21, 2008, the Committee discussed having an islet consensus conference in spring 2009 to include the islet transplantation community, representatives from HRSA, CMS, FDA, NIH, JDRF, URN,

AOPO, and others. The preferred location would be Washington, DC so that government officials might be able to attend. The agenda would include a review of the current allocation policies and an update from CITR on outcomes. The Committee must find outside funding in order to be able to hold this consensus conference. The first step in the process is for the Committee to write up the purpose of the conference and explain how it is within the purview of the OPTN. Rainer Gruessner, MD, Dixon Kaufman, MD, PhD, Marlon Levy, MD, and Horatio Rilo, MD, volunteered to work on this justification. Islet Consensus Conference Subcommittee minutes are attached as **(Exhibit N)**.

9. Memo from the OPO Committee Regarding Establishing Priorities for Multi-Organ Allocation

On November 21, 2008, the Committee reviewed a memo from the OPO Committee. The OPO Committee has been receiving questions regarding priority for multi-organ transplants. The OPO Committee voted to recommend that each organ specific committee and the Pediatric Committee prioritize multi-organ versus individual organ allocation and establish very specific guidance as to the priority for allocation of organs in a multi-organ transplant situation. The OPO Committee would like updates on the other committees' progress in this area. The Pancreas Transplantation Committee decided to send the OPO Committee the multi-organ priority that the Committee has considered for the modeling changes to pancreas allocation. In this scheme, kidney-pancreas transplants would follow other types of multi-organ transplants.

10. Memo from the OPO Committee Regarding the Definition of Multi-System Organ Failure

On November 21, 2008, the Committee discussed a memo from the OPO Committee about the definition of multi-system organ failure. The OPO Committee is grappling with inconsistent data collection from OPOs regarding imminent and eligible (I & E) deaths. One of the concerns they have identified is the inconsistent manner in which multi-system organ failure (MSOF) is being interpreted and its effect on I & E data collection. The OPO Committee asked if there are specific criteria that the Pancreas Transplantation Committee would propose, if met, classify a pancreas as having failed or if the Committee has a definition for "organ failure" with respect to the pancreas. The Committee decided to send the OPO Committee the definition of pancreas graft failure and function developed by the Pancreas Outcomes Review Model Subcommittee.

11. Memo from the OPO Committee regarding HbA1c

In September 2008, the Committee sent a memo to the OPO Committee requesting feedback on adding HbA1c as a required field in DonorNet®. The Committee reviewed the OPO Committee's response at its May 2009 meeting. The OPO Committee has been revising Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization). On March 27, 2009, the Committee considered a memo from the OPO Committee on this issue. Members of the OPO Committee recognized the importance of including the HbA1c in the list of laboratory tests required for all pancreas donors. As such, the Committee requests that the Pancreas Committee provide input regarding the inclusion of the HbA1c in Policy 2.0 under mandatory tests for pancreas donors. The OPO Committee recommends that "<u>HbA1c (if available)</u>" be inserted into Policy 2.2.8 (For potential pancreas donors). This section describes the tests that are required for potential pancreas donors. The Committee supported the OPO Committee's recommendation to add "HbA1c if available" into policy language. (11-Support, 0-Oppose, 0- Abstain) This verbiage would encourage OPOs to provide HbA1c on all donors, but it would not prevent a match from being run if the test was not available. The Committee expects that the availability of HbA1c for donors will increase pancreas utilization.

12. Review of language regarding living donor pancreas transplantation on the Transplant Living website

On March 27, 2009, the Committee reviewed the language regarding living donor pancreas transplantation on the Transplant Living website. The Transplant Living website provides information on the types of organs that can be donated by living donors. Some Living Donor Committee members, especially the living donors serving on the Committee, have questioned the accuracy and/or tone of some information found on the Transplant Living website. The Living Donor Committee requested that the Pancreas Transplantation Committee review the language regarding living donor pancreas transplantation on Transplant Living and make recommendations for changes to the language. The current language is:

pancreas
Individuals can also donate a portion of the pancreas. Like the lung, the pancreas does not regenerate, but donors usually have no problems with reduced function.

The Committee recommended removing the sentence regarding donors not having problems with reduced function. Because this procedure is uncommon, there is not enough data to support the statement. Additionally, the Committee thought that the statement that the pancreas does not regenerate was unnecessary because most organs do not regenerate. The Committee chose not to add that very few transplant centers performed living donor pancreas transplants because they did not want to imply that living donors should try to find these centers. The Committee recommended using only the first sentence (12-Support, 0-Oppose, 0- Abstain):

pancreas
Individuals can also donate a portion of the pancreas.

13. Pancreas Waiting Time Subcommittee Update

On October 1, 2009, Elizabeth F. Sleeman, MHA, liaison to the Pancreas Transplantation Committee, provided an update on the Pancreas Waiting Time Subcommittee. **(Exhibit O)** The subcommittee reviewed a waiting time modification request by e-mail on June 17, 2009 through June 19, 2009. In this case, a transplant center requested that a candidate have waiting time begin on 09/28/2007. The candidate was added to the kidney waiting list on that date and inadvertently not added to the kidney/pancreas waiting list. The candidate was later removed from the kidney list for a living donor transplant. The center intended for the candidate to remain listed for a pancreas alone transplant. The subcommittee reviewed the following materials:

- An explanation of the waiting time reinstatement request from the center
- The letter the center originally sent to the candidate stating that the candidate had been listed on the kidney/pancreas list
- Signatures from all the active pancreas programs in the DSA agreeing that the candidate's waiting time should be modified, as required in Policy 3.2.1.8 (Waiting Time Modification)

The subcommittee voted to modify the candidate's waiting time on the pancreas list to begin on 09/28/2007. (4-Support, 0-Oppose, 0-Abstain)

14. Introduction to Pancreas Committee Activities

On July 24, 2009, Elizabeth Sleeman 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 for 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.

2009-2010 Pancreas Transplantation Committee Goals

- Evaluate pancreatic utilization/wastage data and consider operational or system improvements aimed at reducing pancreas discards
- Monitor progress of ongoing kidney allocation policy development and provide input on the potential impact of new kidney allocation policy on kidney/pancreas candidates and outcomes
- 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)
- Consider future modifications to pancreas allocation policy, incorporating concepts of net benefit, broader sharing, and donor risk as appropriate

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

- Committee Support Staff Overview by Elizabeth Sleeman
- Policy Development Process by Elizabeth Sleeman
- Policy Development Schedule by Elizabeth Sleeman
- Is Your Proposal Ready for Prime Time? by Elizabeth Sleeman
- POC scorecard 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 Charlotte Arrington, MPH
- Pancreas Policy Changes 2007-2009 by Dixon B. Kaufman MD, PhD
- Current Activities and Subcommittees by Dixon Kaufman

15. Public Comment Proposals

a. Proposal to increase the safety of allocations to candidates who do not appear on the match run
Membership and Professional Standards Committee

The Committee considered this proposal on November 21, 2008. The revision to Policy 3.1 will incorporate the definition of a directed donation into OPTN policy. The revision to Policy 3.2.4 will require the transplant center to:

- determine why the candidate does not appear on the organ match run for the donor, and
- verify that the donor organ is safe and appropriate for the candidate by comparing donor information and candidate information available in UNet^{SM} before the transplant.

The revision to Policy 3.9.3 will clarify that when multiple organs are allocated to a single recipient, the term "on **a** match run" means that the recipient must appear on the heart, lung, or liver match run. This clarification does not alter the organ allocation sequence defined by organ allocation policy.

The Committee was concerned about the impact this proposal could have on islet allocation. The Committee supported this proposal for whole organs, but it had concerns about the proposal being applied to islets. The Committee believes that this policy would open a loophole that would allow centers to transplant islet candidates who are not on the match run and cite the reason that it prevented islet wastage. The Committee thought that the proposal could open the door for islet transplants not being reported to UNOS because there are currently no islet follow-up forms. The Committee believes that recipients of islet transplants should always appear on the match run. The Committee voted to support the MPSC's proposal for whole organs but not for islets. (11-Support, 0-Oppose, 0- Abstain)

b. Proposal to clarify, reorganize and update OPO policies to align with current practices
OPO Committee

The Committee considered this proposal on November 21, 2008. The proposed modifications clarify the policy requirements, eliminate redundancy, and align policy with current OPO practices. The changes reorganize the content, eliminate repeated laboratory tests, and update terminology. The proposed policy modifications should clarify policy and reduce OPO confusion in order to reduce the OPO's risk of non-compliance and enhance patient safety.

The Committee voted to support the OPO Committee's proposal. (10- Support, 0- Oppose, 0- Abstain)

c. Proposed listing requirements for simultaneous liver-kidney transplant candidates
Proposed Policy 3.5.10 (Simultaneous Liver-Kidney Transplantation)
Kidney Transplantation Committee and Liver Intestinal Organ Transplantation Committee

The Committee considered this proposal on March 27, 2009. This proposal would set minimum criteria for candidates listed for simultaneous liver-kidney (SLK) transplantation. The intent of this proposal is first to identify candidates who are unlikely to regain renal function following liver transplantation. Once identified, these proposed policy changes would provide priority for these candidates to receive a SLK transplant. The goal of this proposal is to improve patient and renal graft survival following SLK transplant.

The Committee supports having listing criteria for simultaneous liver-kidney transplants. However, the Committee was concerned that the liver recipients who were listed for a kidney as part of the safety net

provision have such high priority for all types of kidneys. The Committee would like to know the mortality of the liver recipients who meet the safety net provision and whether this mortality warrants these patients having priority over payback kidneys and kidney-pancreas candidates. The Committee thought that all highly sensitized candidates should have priority over these liver recipients. The Committee thought that these recipients should have some priority for a subset of kidneys, such as ECD, DCD, or Hepatitis C positive kidneys. Another concern was that the safety net provision would discourage living kidney donation for these liver recipients. The Committee stated that they could not support this proposal until these concerns have been addressed. (0-Support, 13-Oppose, 0- Abstain)

d. Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors
Policy 4.1.1 (Communication of Donor History)
Living Donor Committee

The Committee considered this proposal on March 27, 2009. In its current form, Policy 4.1.1 (Communication of Donor History) requires that potential organ recipients be informed if their donor has a high risk status. The proposed policy changes would provide the potential living donor with the ability to discontinue the donation process rather than have their high risk status disclosed to a potential recipient or transplant center. This proposed change is designed to protect the health information of potential living donors.

The Committee agreed that the confidential health information of living donors should be protected and supported the proposal. (13-Support, 0-Oppose, 0- Abstain)

e. Proposal to change the OPTN/UNOS Bylaws, to clarify the process for reporting changes in key personnel
Appendix B, Section II, E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel)
Membership and Professional Standards Committee (MPSC)

The Committee considered this proposal on March 27, 2009. This proposal to change the bylaws will clarify when transplant centers must notify UNOS of changes in key personnel and further clarifies the expectation that member institutions that cannot notify UNOS within the expected time frame should voluntarily inactivate or withdraw the affected programs. This proposed language places greater emphasis on submitting complete applications. Additionally, it informs the member of the steps that will be taken if the member fails to inform the OPTN Contractor of changes in key personnel.

The Committee commented that it would be helpful to have a database where centers could access old applications. The Committee supported the proposal to clarify the process for reporting changes in key personnel. (11-Support, 0-Oppose, 0- Abstain)

f. Proposal to clarify, reorganize and update OPTN policies on OPO and transplant center packaging, labeling and shipping practices
Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials)
Organ Procurement Organization (OPO) Committee

The Committee considered this proposal on March 27, 2009. The proposed modifications to Policy 5.0 will clarify the policy requirements, eliminate redundant language, and give OPOs and transplant centers guidance on how to package, label, and ship organs, vessels, and tissue typing materials. The Committee has reorganized the entire content to promote clarity. The Committee defined types of organ packaging

and clearly described labeling and documentation requirements for solid organs, tissue typing materials, and vessels. Vessel recovery and storage requirements are listed, as are transportation responsibilities for renal, non-renal, and tissue typing materials.

The Committee supported the proposal to clarify, reorganize, and update policies on OPO and transplant center packaging, labeling, and shipping practices. (10-Support, 0-Oppose, 0- Abstain)

16. Recognition of Committee Members with Terms Ending June 30, 2009

On March 27, 2009, Dr. Gruessner thanked all the Committee members with terms ending on June 30, 2009 for their service on the Committee:

Rainer Gruessner, MD	Chair
Dixon Kaufman, MD, PhD	Vice-Chair
David Axelrod, MD, MBA	Region 1 Representative
Peter Abt, MD	Region 2 Representative
George Burke, MD, FACS	Region 3 Representative
Marlon Levy, MD	Region 4 Representative
Ron Taubman	Region 5 Representative
Chris Kuhr, MD	Region 6 Representative
Joseph Leventhal, MD, PhD	Region 7 Representative
Sandip Kapur, MD	Region 9 Representative
Venkatesh Krishnamurthi, MD	Region 10 Representative
David Harlan, MD	At Large Representative
Albert Hwa, PhD	At Large Representative
Khalid Khwaja, MD	At Large Representative
Christopher Marsh, MD	At Large Representative
Peter Stock, MD, PhD	Ex Officio

Committee members received certificates of appreciation in the mail.

Table 13: Pancreas Transplantation Committee Attendance, July 2008- June 2009

PANCREAS COMMITTEE		JULY 1, 2008 – JUNE 30, 2008		
	MONTH	NOVEMBER	JANUARY	MARCH
	DAY	21	23	27
	FORMAT	In Person	Live Meeting/ Teleconference	Live Meeting/ Teleconference
NAME	COMMITTEE POSITION			
Rainer W. Gruessner MD	Chair	X	X	X
Dixon Kaufman MD, PhD	Vice Chair	X	X	
David Axelrod MD, MBA	Regional Rep.	X	X	X
Peter Abt MD	Regional Rep.	X		
George Burke III, MD, FACS	Regional Rep.			
Marlon Levy MD	Regional Rep.	X		X
Ron Taubman	Regional Rep.		X	X
Christian Kuhr MD	Regional Rep.	X		X
Joseph Leventhal MD,PhD	Regional Rep.			
Ahmad Abdulkarim MD, PhD	Regional Rep.	X		
Sandip Kapur MD	Regional Rep.	X (by phone)		X
Venkatesh Krishnamurthi MD	Regional Rep.	X (by phone)	X	
Dinesh Ranjan MD	Regional Rep.	X	X	
Mary Beth Drangstveit RN	At Large	X	X	X
David Harlan MD	At Large			
Albert Hwa PhD	At Large			X
Khalid Khwaja MD	At Large	X		X
Christopher Marsh MD	At Large		X	X
Patricia Niles RN, BS, CPTC	At Large	X	X	
Horatio Rilo MD	At Large	X	X	X
Meg Rogers	At Large	X	X	X
Paul Volek MPH	At Large	X	X	X
Peter Stock MD, PhD	Ex Officio	X	X	X
Elizabeth Ortiz-Rios MD, MPH	Ex Officio (HRSA)	X		
James Bowman, MD	Ex Officio (HRSA)			X
Kathryn Meyer MS	SRTR Liaison	X	X	X
Randall Sung MD	SRTR Liaison	X		X
Elizabeth Sleeman MHA	Committee Liaison	X	X	X
Jason Chicirda	Support Staff	X (by phone)		
Jennifer Wainright PhD	Support Staff	X	X	X
Aaron Powell PMP	Support Staff	X		
Ciara Samana MSPH	Support Staff	X		X
Sally Aungier	Support Staff			X
David Kappus	Support Staff			X

Table 14: Pancreas Transplantation Committee Attendance, July 2009- June 2010

PANCREAS COMMITTEE		JULY 1, 2009 – JUNE 30, 2010	
	MONTH	JULY	OCTOBER
	DAY	24	1
	FORMAT	In Person	Live Meeting/ Teleconference
NAME	COMMITTEE POSITION		
Dixon Kaufman MD, PhD	Chair	X	X
David Axelrod MD, MBA	Vice Chair	X	X
James Markmann MD, PhD	Regional Rep.	by phone	
Stuart Geffner MD	Regional Rep.	X	
Rubin Zhang MD, PhD	Regional Rep.	X	X
Edmund Sanchez MD	Regional Rep.	X	
Jacqueline Lappin MD	Regional Rep.		X
Horatio Rilo MD	Regional Rep.	X	X
David Scott MD	Regional Rep.	X	X
Brian Flanagan PhD	Regional Rep.	X	X
Ahmad Abdulkarim MD, PhD	Regional Rep.	X	
Mark Laftavi MD, FACS	Regional Rep.	X	X
Jonathan Fridell MD	Regional Rep.	by phone	X
Chris Chiarello	At Large	X	
Mary Beth Drangstveit RN	At Large	X	X
Albert Hwa PhD	At Large	X	X
Christian Kuhr MD	At Large	by phone	
Patricia Niles RN, BS, CPTC	At Large	X	X
Meg Rogers	At Large	X	X
Paul Volek MPH	At Large	X	
Rainer W. Gruessner MD	Ex Officio	by phone	
James Bowman III, MD	Ex Officio (HRSA)	X	X
Elizabeth Ortiz-Rios MD, MPH	Ex Officio (HRSA)	by phone	X
Charlotte Arrington MPH	SRTR Liaison	X	
Doug Fuller MS	SRTR Liaison	X	X
Kathryn Meyer MS	SRTR Liaison	X	
Randall Sung MD	SRTR Liaison	X	
Elizabeth Sleeman MHA	Committee Liaison	X	X
Jennifer Wainright PhD	Support Staff	X	X