Interim Report
Pancreas Transplantation Committee

July 24, 2009
Chicago, Illinois

The following is a summary of the Pancreas Transplantation Committee meeting on July 24, 2009 held in Chicago, Illinois.

1. 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.

2009-2010 Pancreas Transplantation Committee Goals

1. Evaluate pancreatic utilization/wastage data and consider operational or system improvements aimed at reducing pancreas discards
2. 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
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)
4. 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

2. Pancreas DRI Subcommittee Update

David A. Axelrod, MD, MBA, presented the work of the Pancreas DRI Subcommittee. **(Exhibit A)**

Background

Careful pancreas selection is viewed 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.

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 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 donor 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 B.**

3. OMB Data Collection Forms

The Committee reviewed the Pancreas Outcomes Review Model Subcommittee's recommendations for changes to the OMB data collection forms.

Cardiac Function

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:

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

The Committee considered whether c-peptide should be fasting. 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:

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

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:

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 -Transplant Recipient Follow-Up
Add HbA1c	%	4-15 -Not available as an option	-Deceased Donor Registration

Pancreas Outcomes Review Model Subcommittee minutes are attached as **Exhibit C.**

4. Update from the Kidney Transplantation Committee

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 waitlist 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 transplant 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.

5. Development of a National System for Pancreas Allocation

Dixon B. Kaufman, MD, PhD, provided a comprehensive review of the work to date on the development of a new pancreas allocation system. 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 0 mismatch, highly sensitized (PRA $\geq$ 80%) potential recipients (locally, regionally, nationally) before any other pancreas potential recipients because of kidney sharing requirements. SPKs usually follow other multi-organs and kidney paybacks.

Problems with the Current Pancreas Allocation System

There are several problems 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, changes to the kidney allocation system, specifically the plan 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 both the pancreas transplantation community, the kidney transplantation community (adult and pediatric), and the other major stakeholders. As part of their investigation of a new kidney allocation system, the Kidney Committee requested that the Pancreas 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 PA and SPK candidates
- To reduce waiting time for both PA and SPK candidates

- To decrease geographic disparities in pancreas waiting time

The proposed concept for a national pancreas allocation system to be 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

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 kidney follows the pancreas system.

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 this data was to investigate changes to pancreas allocation that would be necessary in light of the Kidney Committee's decision to have 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 PTA and 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

Jennifer L. Wainright, PhD, presented the data the Committee had gathered regarding pancreas allocation over the previous two years. **(Exhibit D)** The Committee discussed the need for SPK listing criteria to allow only candidates who really need both a kidney and a pancreas to be listed for SPK. 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 transplant performed that year), indicating that transplant

centers are not listing candidates for a 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 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 waitlist death rates and net benefit for SPK and kidney-alone recipients. Both diabetic SPK and diabetic KI candidates had shorter waitlist 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 waitlist and transplant rates by age group. There is a higher percentage of 18-49 year old candidates on the SPK waitlist than on the KI waitlist and a higher percentage of 18-49 year old SPK recipients than KI recipients.

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 (88.11%), followed by kidney-pancreas (7.85%) and kidney-liver (3.47%). Whereas the trend in the number of kidney-pancreas has decreased from 8.28% in 2005 to 7.41% in 2007, the trend in the number of kidney-liver transplants has increased from 3.12% in 2005 to 3.87% 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 Pancreas Allocation System
In 2007, the Pancreas 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 see 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:

1. Choose the allocation system that is most like your OPO's policy for SPK allocation as it relates to kidney alone allocation:
    a. Kidney follows pancreas (e.g., SPKs are allocated first, then kidney alone.)
    b. 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).
    c. Mixed (e.g., No formal policy. We allocate from all three lists on an ad hoc basis).
2. Choose the allocation system that is most like your OPO's policy for pancreas allocation:
    a. We prioritize SPK and allocate from the SPK list first.
    b. We prioritize solitary pancreas and allocate from the PA list first.

c. We combine the SPK and PA lists into a single list and allocate from that.
d. 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).

3. 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.)

Results 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 kidney follows pancreas, 8 as pancreas follows kidney, 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 kidney follows pancreas, 4 as pancreas follows kidney, 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 the KI follows the PA, a higher percentage of pancreas transplants are SPK transplants, compared to DSAs where the PA follows the 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 the KI follows the 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 the PA follows the 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 II diabetes in DSAs where the KI follows the 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 II diabetes in 2007, they were performed at 28 centers with each center performing 5 or less 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 the KI follows the PA in 2006, and 87.5% were in DSAs where the KI follows the PA in 2007. Note that 85.6% of SPK transplants are done in DSAs where the KI follows the PA. Of the 16 candidate who were listed for SPK, but received a KI in 2006, half were in DSAs where the KI follows the PA, 12.5% were in DSAs where the PA follows the 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 the kidney follows the pancreas, whereas 6-10 year old KI candidates have the shortest waiting time in DSAs where the pancreas follows the kidney. 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 the kidney follows the pancreas, whereas adult kidney-alone waiting time is lower in DSAs where the pancreas follows the kidney and in mixed systems.

The Committee explored the relationship between allocation system, age, and patient and graft survival. For patient survival, in DSAs where the KI follows the 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 the PA follows the 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 as 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 the kidney follows the pancreas. 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.

The Committee examined data showing how a uniform national system of kidney follows the pancreas would affect the number of kidney-alone transplants in the adult and pediatric patient populations.

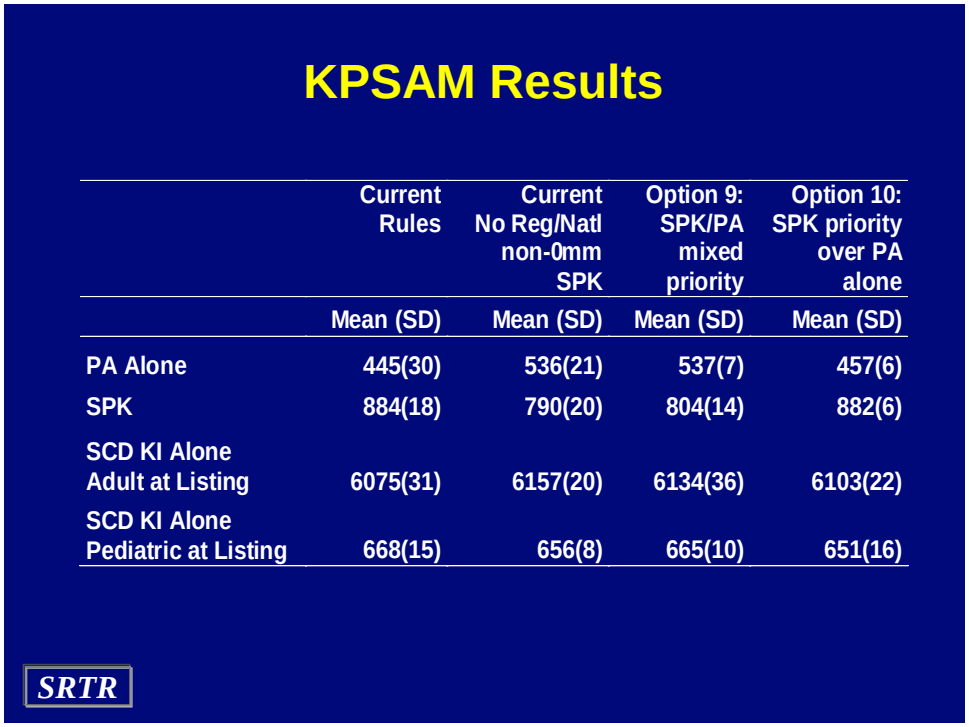
Simulated Allocation Modeling

Kathryn Meyer presented the SRTR simulation results from the KPSAM modeling **(Exhibit E)**. 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 1.

Figure 1: KPSAM Modeling Results



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 recipients. The concern with this path forward is that it could discourage living kidney donation in SPK candidates that are considering a living 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 Allocation Subcommittee minutes are attached as **Exhibit F.**

PANCREAS COMMITTEE		JULY 1, 2009 - DECEMBER 31, 2009
	MONTH	JULY
	DAY	24
	FORMAT	In Person
NAME	COMMITTEE POSITION	
Dixon Kaufman MD, PhD	Chair	X
David Axelrod MD, MBA	Vice Chair	X
James Markmann MD, PhD	Regional Rep.	by phone
Stuart Geffner MD	Regional Rep.	X
Rubin Zhang MD, PhD	Regional Rep.	X
Edmund Sanchez MD	Regional Rep.	X
Horatio Rilo MD	Regional Rep.	X
David Scott MD	Regional Rep.	X
Brian Flanagan PhD	Regional Rep.	X
Ahmad Abdulkarim MD, PhD	Regional Rep.	X
Mark Laftavi MD, FACS	Regional Rep.	X
Jonathan Fridell MD	Regional Rep.	by phone
Chris Chiarello	At Large	X
Mary Beth Drangstveit RN	At Large	X
Albert Hwa PhD	At Large	X
Christian Kuhr MD	At Large	by phone
Patricia Niles RN, BS, CPTC	At Large	X
Meg Rogers	At Large	X
Paul Volek MPH	At Large	X
Rainer W. Gruessner MD	Ex. Officio	by phone
James Bowman III, MD	HRSA	X
Elizabeth Ortiz-Rios MD, MPH	HRSA	by phone
Charlotte Arrington MPH	SRTR Liaison	X
Doug Fuller	SRTR Liaison	X
Kathryn Meyer MS	SRTR Liaison	X
Randall Sung MD	SRTR Liaison	X
Elizabeth Sleeman MHA	Committee Liaison	X
Jennifer Wainright PhD	Support Staff	X