

**Interim Report
Pancreas Transplantation Committee**

**March 27, 2009
Microsoft Live Meeting/ Teleconference**

The following is a summary of the Pancreas Transplantation Committee meeting on March 27, 2009 held via Microsoft Live Meeting and teleconference.

1. Update from the March 2009 Board of Directors Meeting

Rainer Gruessner, MD, 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.

2. Review of the Office of Management and Budget (OMB) Pancreas and Kidney-Pancreas Data Collection Forms

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

Cardiac Dysfunction

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

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 Committee favors collecting ejection fraction and is working on developing more objective criteria for when ejection fraction should be collected. The Kidney Committee was also concerned that there was no evidence supporting that the number of vessels bypassed predict patient or graft survival. The Committee charged the subcommittee with finalizing these recommendations.

Pancreas Graft Function

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

The Committee decided that c-peptide should be fasting c-peptide and that it should only be required for recipients on insulin.

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	-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			-Transplant Candidate Registration

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

The Kidney 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)

3. Pancreas Review Subcommittee Update

Jennifer Wainright, PhD, presented the data collected by the Pancreas Review Subcommittee. The subcommittee polled OPOs to determine how pancreata are allocated in each DSA. 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.)

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 UNOS 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 A**) are based on OPTN data as of January 9, 2009 and include deceased donor pancreas transplants that were reported to have occurred during 2007 unless otherwise noted. These data include only pancreata allocated locally unless otherwise noted.

The subcommittee 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 subcommittee 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 requested data on the whether it is more likely to perform an SPK transplant in DSAs where the KI follows the PA.

The subcommittee 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 subcommittee 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 subcommittee 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 subcommittee 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 subcommittee considered that the DSAs may use a system where the kidney follows the pancreas because the adult kidney-alone waiting times are long rather than the kidney follows pancreas allocation system being the major reason for long kidney-alone waiting time.

The subcommittee 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 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 subcommittee stated that this data gave them insight into pancreas allocation and noted that there were no outlier allocation issues.

The subcommittee discussed sending a survey to pancreas programs to gauge their opinions on having a national system where the kidney follows the pancreas and whether they would favor a combined SPK and PA. The survey would ask pancreas transplant programs the following:

1. Would you prefer a national allocation system where organs are allocated from a pancreas match run before a kidney match run?
2. If organs are allocated from a pancreas match run first, would you prefer:
 - a. SPK has absolute priority over PA
 - b. PA has absolute priority over SPK
 - c. A combined SPK and PA list based on waiting time
3. If the only way for the pancreas to have priority is to have a combined list, would you prefer:
 - a. A combined PA and SPK list
 - b. The kidney match run having priority over the pancreas match run

UNOS staff is still working on the final language for the survey.

The Committee reviewed the following data requests made by the subcommittee:

- Waiting time (25th percentile) for KI and SPK candidates (combined) by pancreas allocation system
- Waiting time (25th percentile) for KI and SPK candidates (separately and combined) by pancreas allocation system, excluding DSAs that do not include an active pancreas transplant program
- Number and ratio of donors and transplants (KI and SPK, separately) by pancreas allocation system
- Update of pancreas allocation system analyses to include 2008 data where appropriate
- Association between number of SPK transplants and adult KI candidate waiting time (over past several years)
- Number of PAK, PTA, and SPK transplants 2000-2008
- Update survey questions to reflect subcommittee's comments

- Ratio of transplants to death/too sick removals from the waiting list (for KI and SPK, separately)
- Simulation Modeling
 - Allocation Option #9: All kidneys are offered to a multi-organ (through local KP) first, then to Peds 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 Peds KI; KP priority over PA

The Committee asked that the median be used instead of the 25th percentile if it is available. This information will be presented to the Committee at its July 2009 meeting.

4. Public Comment Proposals

a. 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

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)

b. 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

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)

c. 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)

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)

d. 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 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)

5. Review of 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.

6. 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). 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 “HbA1c (if available)” 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.

7. Recognition of Committee Members with Terms Ending June 30, 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 will receive certificates of appreciation in the mail.

Rainer W. G. Gruessner, MD, Committee Chair
University of Arizona
520-626-4409

Elizabeth F. Sleeman, MHA
UNOS Staff/Policy Analyst
804-782-4616

PANCREAS COMMITTEE	JANUARY 1, 2009 - JUNE 30, 2009	
	MONTH	MARCH
	DAY	27
	FORMAT (select)	Live Meeting/ Teleconference
NAME	COMMITTEE POSITION	
Rainer W. Gruessner MD	Chair	X
Dixon Kaufman MD, PhD	Vice Chair	
David Axelrod MD, MBA	Regional Rep.	X
Peter Abt MD	Regional Rep.	
George Burke III, MD, FACS	Regional Rep.	
Marlon Levy MD	Regional Rep.	X
Ron Taubman	Regional Rep.	X
Christian Kuhr MD	Regional Rep.	X
Joseph Leventhal MD, PhD	Regional Rep.	
Ahmad Abdulkarim MD, PhD	Regional Rep.	
Sandip Kapur MD	Regional Rep.	X
Venkatesh Krishnamurthi MD	Regional Rep.	
Dinesh Ranjan MD	Regional Rep.	
Mary Beth Drangstveit RN	At Large	X
David Harlan MD	At Large	
Albert Hwa PhD	At Large	X
Khalid Khwaja MD	At Large	X
Christopher Marsh MD	At Large	X
Patricia Niles RN, BS, CPTC	At Large	
Horatio Riolo MD	At Large	X
Meg Rogers	At Large	X
Paul Volek MPH	At Large	X
Peter Stock MD, PhD	Ex Officio	X
James Bowman, MD	Ex Officio	X
Kathryn Meyer MS	SRTR Liaison	X
Randall Sung MD	SRTR Liaison	X
Elizabeth Sleeman MHA	Committee Liaison	X
Jennifer Wainright Ph.D.	Support Staff	X
Ciara Samana, MSPH	Support Staff	X
Sally Aungier	Support Staff	X
David Kappus	Support Staff	X