Pancreas Transplantation Committee
March 14, 2012
Chicago, Illinois
Interim Report

This report includes items addressed by the Pancreas Transplantation Committee (the Committee) at its meeting held on March 14, 2012.

1. Pancreas Program Specific Reports

Sally Gustafson, MS and Peter Stock, MD, PhD, SRTR liaisons to the Committee, presented updated pancreas program-specific report (PSR) models to the Committee **(Exhibit A)**. Pancreas program outcomes are currently not formally reviewed by the MPSC. The PSRs contain observed outcomes for all pancreas transplant recipients, presented separately for SPK recipients. Expected outcomes are provided in the reports for SPK recipients only. The Pancreas Committee and MPSC have requested outcomes models to evaluate all pancreas transplants within a program (PTA (Pancreas Transplant Alone), PAK (Pancreas after Kidney), and SPK (Simultaneous Pancreas-Kidney) combined).

The selected approach for building these models is to:

- Build a predictive model within each pancreas transplant subtype (PTA, PAK, SPK).
- Predict expected events (graft failures and patient deaths) within each subtype.
- Pool the transplant subtypes within program, and compare total events (PTA, PAK, and SPK combined) to total predicted events using 3 PSR metrics.

An alternative approach would be to combine all transplant subtypes into one model and stratify based on subtype. This approach allows for an increased sample size, which increases the predictive power of the model. However, this stratified approach assumes that the covariates included in the model have a similar effect on the outcome across all transplant subtypes. The SRTR chose to build one model for each transplant type using an extended time window. A larger cohort allows greater precision in the estimated effects of the risk adjusters.

PSRs are generated every 6 months. They evaluate programs based on 2 separate cohorts, each 30 months (2.5 years) long. For model development, the SRTR doubled the cohort to be 5 years wide, but created a "period" variable that indicates if the transplant occurred in the first or second half of the 5-year time period. Model estimates were obtained from period 1 plus period 2 data. The "period" variable allows the model to estimate expected outcomes within periods 1 and 2 separately. Only period 2 data are used to evaluate programs.

For 1-year outcomes models, the cohort included all SPK, PAK, and PTA transplants performed between 7/1/2005 and 6/30/2010. Recipients transplanted prior to 1/1/2008 were designated as period 1; recipients transplanted on or after that date were period 2. For 3-year outcomes models, the cohort included all SPK, PAK, and PTA transplants performed between 1/1/2003 and 12/31/2007. Recipients transplanted prior to 7/1/2005 were designated as period 1; recipients transplanted on or after that date were period 2. All transplants were included in graft failure models; only primary transplants were included in patient survival models.

Table 1 provides the definition of the outcome being assessed for each model cohort. For the pancreas graft failure metric, the transplant program reports when the pancreas graft has failed. It is not based on a specific clinical metric such as c-peptide or insulin usage. Therefore, how pancreas graft failure is reported may vary across programs. When the MPSC begins using these models, a transplant program's outcomes could be affected by how the program reports pancreas graft failure.

Table 1: Outcomes Definitions

Cohort	Event	Followed Until Earliest Of:
1 year	**Graft failure**	Pancreas graft failure; pancreas re-transplant; patient death; 1-year post-transplant
1 year	**Patient death**	Patient death; 1-year post-transplant
3 year	**Graft failure**	Pancreas graft failure; pancreas re-transplant; patient death; 3-year post-transplant
3 year	**Patient death**	Patient death; 3-year post-transplant

Table 2 shows the observed survival rates for each outcomes model.

Table 2: Observed Survival Rates

Outcome	1-year survival rate	3-year survival rate
Cohort	Transplanted January 1, 2008 - June 30, 2010	Transplanted July 1, 2005 – December 31, 2007
Graft Survival		
SPK	87.9% (86.4, 89.2)	79.0% (77.3, 80.6)
PAK	81.4% (77.6, 84.6)	68.0% (64.4, 71.2)
PTA	77.7% (72.1, 82.2)	63.4% (57.4, 68.9)
Patient Survival		
SPK	96.0% (95.1, 96.8)	92.3% (91.1, 93.4)
PAK	95.4% (92.6, 97.2)	94.0% (91.5, 95.6)
PTA	96.5% (93.2, 98.3)	92.5% (88.3, 95.2)

Table 3 shows the c-statistic for each pancreas outcomes model. The c-statistic is the model's ability to correctly rank patients based on their estimated risk. A c-statistic of 0.50 is roughly equal to random guessing.

Table 3: C-statistics by Pancreas Outcomes Model

Model Type	C-statistic for Period 2	C-statistic for combined models, Period 2
1-year SPK GF	0.64 (0.60, 0.67)	0.65 (0.63, 0.68)
1-year PAK GF	0.64 (0.58, 0.69)	
1-year PTA GF	0.66 (0.61, 0.70)	
1-year SPK PS	0.65 (0.60, 0.71)	0.68 (0.63, 0.73)
1-year PAK PS	0.75 (0.62, 0.88)	
1-year PTA PS	0.78 (0.58, 0.98)	
3-year SPK GF	0.59 (0.56, 0.62)	0.62 (0.60, 0.64)
3-year PAK GF	0.61 (0.57, 0.64)	
3-year PTA GF	0.66 (0.61, 0.71)	
3-year SPK PS	0.65 (0.61, 0.69)	0.67 (0.63, 0.70)
3-year PAK PS	0.68 (0.59, 0.77)	
3-year PTA PS	0.76 (0.66, 0.86)	

Table 4 shows the c-statistics for outcomes models for other organs.

Table 4: Outcomes Model C-Statistics

Transplant Type	1-yr graft failure model: Average c-statistic	1-yr patient survival model: Average c-statistic
Kidney: Deceased Donor	66.1%	71.1%
Kidney: Living Donor	64.7%	75.0%
SPK: Kidney	59.2%	58.4%
SPK: Pancreas	58.6%	58.4%
Proposed Models	**1-yr combined graft failure model: C-statistic**	**1-yr combined patient survival model: C-statistic**
Pancreas	65.4%	68.2%

Calibration shows how well a model's predictions agree with reality across different levels of risk. Calibration is assessed by comparing number of events (graft failures/deaths) predicted by the model with the number observed in reality. Table 5 shows the calibration by decile of risk for the SPK, PAK, and PTA models.

Table 5: Calibration for Pancreas Outcomes Models

	SPK			PAK			PTA		
Decile of Risk	N	Predicted Graft Failures	Observed Graft Failures	N	Predicted Graft Failures	Observed Graft Failures	N	Predicted Graft Failures	Observed Graft Failures
1	209	13.49	12	50	3.31	4	26	2.82	3
2	210	16.43	17	51	5.09	8	26	3.54	1
3	210	18.60	9	51	6.55	3	27	3.89	4
4	209	19.50	26	50	7.17	8	26	4.29	5
5	210	21.77	20	51	8.03	9	27	4.94	5
6	210	23.55	26	51	9.75	6	26	5.40	7
7	209	26.0	21	50	10.28	9	27	5.98	4
8	210	28.28	33	51	11.50	14	26	7.15	7
9	210	32.99	36	51	13.17	17	27	7.49	10
10	209	53.41	54	50	19.14	16	26	13.49	13

The Committee asked whether a program could enter their patient data into these models to get a prediction of risk. These models cannot be used for that purpose. However, the pancreas donor risk index could be used for such a purpose. These models are cohort models and do not directly translate for risk assessment for individual patients.

1-Year SPK Graft Survival Model

Between January 1, 2008 and June 30, 2010, 2096 SPK transplants were performed. 87.9% of recipients (n=1842) were censored at one year post-transplant; 12.1% of recipients (n=254) experienced pancreas graft failure or died prior to the end of follow-up. Table 6 shows the covariates included in the 1-year SPK graft survival model with their associated hazard ratios and p-values.

Table 6: Covariates Included in the 1-year SPK Graft Survival Model

Covariate	Hazard Ratio	P-value
Pancreas Donor Risk Index, linear	1.65	<0.0001
Recipient BMI	<20: 0.81 20-25: 0.68 26-30: 0.71 30+: 1 (reference)	0.02
Cold ischemic time	0-6 hours: 0.65 6-10 hours: 0.62 10-15 hours: 0.74 15-20 hours: 0.75 >20 hours: 1 (reference)	0.01
Recipient race	Caucasian: 1 (reference) African-American: 1.1 Hispanic: 0.7 Other: 1.09	0.07
Hospitalization at transplant	2.7	<0.0001
Hospitalization in 90 days preceding transplant	1.5	0.01
CPRA/PRA, per 10 units	1.05	0.002
Recipient working for income prior to transplant	0.88	0.16
Age at diabetes diagnosis >35	1.08	0.04
Kidney received on ice versus pump	1.46	0.04

The c-statistic for the 1-year SPK graft survival model is 0.64 (95% CI = 0.60, 0.67).

Usually, missing variables were grouped with the "no" category for each covariate. Time on dialysis, previous transplantation, and eGFR at transplant did not have a statistically significant effect on graft survival in the SPK model. The Committee asked whether the dialysis covariate is co-linear with donor type (living vs. deceased). The Committee suggested dropping the race variable from the model because it may not be reliable. The Committee also noted that the statistical significance of the kidney received on ice versus pump may be a center effect. Additionally, such a covariate could be a result of technique, which should not be adjusted out of the model. The Committee also suggested that transplant programs be provided with the hazard ratio for each covariate so they can understand the importance of accurately reporting data, which allows these models to assess risk more accurately. The Committee wondered whether the hospitalization covariate was really a proxy for re-transplantation. There was also concern that the hospitalization status could be 'gameable', meaning that a program could base clinical decisions or reporting practices on the effect it would have on the program's PSRs. The Committee suggested using pancreas donor risk index (DRI) instead of individual factors in the PAK and PTA models.

1-Year PAK Graft Survival Model

Between January 1, 2008 and June 30, 2010, 504 PAK transplants were performed. 81.4% of recipients (n=410) were censored at one year post-transplant; 18.6% of recipients (n=94) experienced pancreas graft failure or died prior to the end of follow-up. Table 7 shows the covariates included in the 1-year PAK graft survival model with their associated hazard ratios and p-values.

Table 7: Covariates Included in the 1-year PAK Graft Survival Model

Covariate	Hazard Ratio	P-value
Recipient age. linear	0.97	0.0002
Donor age, linear	1.02	0.0005
Previous pancreas transplant	1.6	0.008
Female donor	0.68	0.01
Years of renal replacement therapy	0-10 years: 1.07 10-20 years: 0.67	0.05 0.07
Hospitalized in 90 days prior to transplant	1.6	0.01
HLA mismatches at kidney transplant	1.08	0.04
HLA-DR mismatches at pancreas transplant	0 mismatch: 0.69 1 mismatch: 1.33 2 mismatch: 1	0.01

The c-statistic for the 1-year PAK graft survival model is 0.64 (95% CI = 0.58, 0.69).

1-Year PTA Graft Survival Model
Between January 1, 2008 and June 30, 2010, 264 PTA transplants were performed. 77.7% of recipients (n=205) were censored at one year post-transplant; 22.3% of recipients (n=59) experienced pancreas graft failure or died prior to the end of follow-up. Table 8 shows the covariates included in the 1-year PTA graft survival model with their associated hazard ratios and p-values.

Table 8: Covariates Included in the 1-year PTA Graft Survival Model

Covariate	Hazard Ratio	P-value
Recipient age	< 40 years: 0.94 >40 years: 1.04	0.002 0.03
Recipient BMI	15-25: 0.92 >25: 1	0.06
Donor BMI	1.03	0.15
Previous pancreas transplants	0: 0.48 1: 1.00 2+: 3.72	<0.0001
Type 1 diabetes	0.61	0.13
Working for income prior to transplant	0.73	0.11

The c-statistic for the 1-year PTA graft survival model is 0.66 (95 % CI = 0.61, 0.71).

Large volume programs are defined as programs performing 10 or more transplants in 2.5 year period. The SRTR provides the analyses for 1-year post-transplant graft and patient outcomes. Programs must meet all three criteria below to be considered "flagged" as experiencing lower than expected outcomes:

- Observed – Expected Events > 3
- Observed/Expected Events >1.5
- One-Sided P-Value <0.05

An event is a graft failure or a death. The model serves as a trigger of inquiry or review but it is not the sole factor in decision-making.

Small volume programs are defined as programs performing 9 or fewer transplants in 2.5 year cohort. All small programs that experienced at least 1 event in the 2.5 year cohort are reported to the MPSC by the SRTR. UNOS Staff then review raw data in more recent years for each program. If an event occurred in the subsequent 6 months, the program will receive an MPSC inquiry.

The SRTR used the proposed models to determine flagging rates using a cohort of pancreas transplant recipients from January 1, 2008 to June 30, 2010. 133 programs performed at least one pancreas transplant during that time period. 88 large-volume programs (66.2%) performed 10 or more transplants; 45 small-volume programs (33.8%) performed 9 or fewer.

Of the 88 large-volume programs, 6 (6.8%) were flagged for 1-year graft survival; 0 were flagged for 1-year patient survival. Of the 45 small-volume programs, 26 (57.8%) had at least 1 graft failure and 8 (17.8%) had at least 1 patient death. Of these, 2 programs had 1 or more graft failures and/or deaths in the following 6 months and would be flagged by the MPSC for review. Currently, the rate of flagging for kidney programs is approximately 5%.

The Committee noted several additional covariates that might be helpful in the model, including prior abdominal surgery and presence of cardiac or vascular disease. However, the models are limited by what data are collected on the OPTN forms submitted by transplant programs. Currently, there are no clinical measures of cardiac or vascular disease on these forms (although symptomatic peripheral vascular disease is collected). The Committee inquired whether there were any interactions with center transplant volume and whether the timing of the previous transplant had an impact on outcomes. The Committee noted that the metrics the MPSC is using for flagging may not be the best way to assess program performance. The Committee also questioned what an appropriate flagging rate is.

The Committee was comfortable that this model is the best that can be achieved with the available data and that the model is adequate for the purpose of flagging larger volume programs for further inquiry. It is not sufficient, however, as a sole metric to assess pancreas transplant program performance. The Committee requested that its suggestions be investigated before presenting these models to the MPSC:

- Use pancreas DRI vs. components of pancreas DRI
- Investigate the impact of time between transplants for previous transplants
- Remove in-hospital at time of offer variable
- Investigate the interaction between donor type and years of ESRD
- Verify that previous abdominal (non-TX) surgery is not available

2. Definition of Pancreas Graft Failure

The Committee discussed the need for a consistent definition of graft failure. Currently, transplant programs may use different criteria to determine when a pancreas graft has failed, particularly as it relates to the need for insulin. Some consider a pancreas as having failed if the patient has to take any insulin. Others only consider a pancreas as having failed if the patient has any hypoglycemic unawareness. Committee members reported that patients view the success of the transplant differently too. In the past, the Committee tried to develop a definition of pancreas graft failure. The definition had five varying levels of function. The Committee considered whether there should be a grade between full graft function and full graft failure. The Committee also questioned how to handle recipients who later develop type 2 diabetes. The Committee agreed that the best solution would be to collect clinical values such as c-peptide, insulin usage, and HbA1c. Then, graft failure could be defined based on these values rather than expecting transplant programs to report graft failure according to a specific definition. The Committee also thought it would be helpful to get input from endocrinologists on this issue. The Committee formed a subcommittee to develop a draft definition for the next full Committee meeting.

3. Plan for Reviewing Pancreas Bylaws

The Committee has an ongoing project to review the bylaws relating to pancreas transplant programs, including both functional inactivity and key personnel requirements for primary pancreas and islet surgeon and physicians. Data on pancreas functional inactivity will be available in the next month. The goal is to have subcommittee recommendations ready for fall full Committee meeting with recommendations sent to the MPSC in the late fall/ winter 2012. The Committee noted that the relative transplant rate is important when considering functional inactivity. If a transplant program is transplanting its patients quickly, then the volume may be less of a concern. The Committee thought the more significant problem might be whether pancreas transplants are not being done even if there are reasonable pancreas offers or if waiting times are long. Some transplant programs have difficulty receiving insurance contracts but serve the patients who are on their list well. This situation is not the same as a transplant program that does not truly intend to do pancreas transplants. The Committee also noted that there is a difference in intent to transplant based on whether the transplant program turns down an offer by phone or after seeing the pancreas in the operating room. The Committee tasked the Allocation Subcommittee with continuing the work on this project.

4. Islet Subcommittee Update

The Islet Subcommittee has been working on revisions to islet policy to require the reporting of every islet infusion to the OPTN Contractor. Currently, islet policy allows an islet candidate to retain waiting time through three infusions. The purpose of allowing the candidate to maintain waiting time was to allow a candidate to have an opportunity to receive enough islets under a single course of induction. Thus, the transplant program only has to remove the candidate from the waiting list after the third islet infusion. The bylaws require that each transplant program submit islet logs accounting for every pancreas accepted for islets at the program, but these logs have never been collected. As a result, the OPTN does not have an official avenue for tracking every islet infusion.

UNOS staff presented the process for removing and automatically relisting an islet candidate to the Committee. When a transplant program removes a pancreas islet (PI) candidate, there is a question asking "Re-List Candidate?" if the number of islet infusions for that candidate's registration is less than three. If the transplant program selects "Yes", then the candidate is added back to the PI waiting list and retains the same waiting time the candidate had upon removal. Therefore, a solution is already programmed that would allow a transplant program to remove a candidate from the PI list after each infusion but still allow the candidate to retain waiting time through three infusions.

The Committee considered the following potential revisions to islet policies and bylaws:

- Require reporting to the OPTN contractor within 24 hours of each infusion (but still allow waiting time to accrue up to three infusions);
- Clarify whether it is three infusions total or three infusions at the program/registration; and
- Remove bylaw language about islet logs.

The Committee's goal is to have a proposal out for public comment in the fall 2012 public comment cycle. UNOS staff will draft policy and bylaw revisions for the Islet Subcommittee to review. Then, the full Committee would vote on the final language in June or July of 2012.

Islet Subcommittee minutes can be found in **Exhibit B.**

5. Pancreas for Technical Reasons Work Group Update

Surgical procedure for the procurement of organs for a multiple organ transplant often includes the procurement of the pancreas regardless of whether the candidate has diabetes or pancreatic deficiency. Therefore, there are some circumstances where a candidate may need a pancreas to facilitate a multiple

organ transplant. Transplant programs are procuring the pancreas for technical reasons as part of a multivisceral transplant. The transplant program is then reporting the organ as not being transplanted. The OPO, on the other hand, is reporting the organ as transplanted. Therefore, the data in the UNOS database do not match because there is no recipient removal for transplant to match the donor disposition stating that the pancreas is transplanted. Transplant programs and OPOs are in disagreement as to whether the pancreas was transplanted. The data need to match, and UNOS staff can create ways for the pancreas to be reported by the OPO and the transplant program as "for technical reasons." However, this removal code for candidates and disposition code for donors must appear either under the set of codes for organs that are transplanted or under the set of codes for organs that are not transplanted. Having the codes in both places will lead to more data errors. Clarification of whether a pancreas procured for technical reasons as part of a multiple organ transplant should be classified as a transplant in the OPTN database is needed.

Please note that this decision does not directly affect how transplant programs will be charged for these organs. CMS determines cost accounting methods for the pancreas independent of any changes to OPTN policy. Additionally, because candidates already receive the pancreas for technical reasons as part of a multivisceral transplant, OPOs already have methods for accounting for the pancreas in these circumstances.

A work group with representation from multiple committees discussed this topic and developed both a programming and non-programming solution that would align the data reported by the transplant program and the OPO. The non-programming solution is:

- Pancreata recovered for technical reasons from a donor weighing less than 35 kg should be reported as not transplanted, and
- Pancreata recovered for technical reasons from a donor weighing more than 35 kg should be reported as transplanted.
- Pancreata recovered for use in a pancreas-alone or SPK transplant should continue to be reported as transplanted (if the organ is transplanted) regardless of the donor weight.

The programming solution would allow OPOs to enter the organ disposition as transplanted for technical reasons and would allow transplant programs to remove the candidate as transplanted for technical reasons. This removal code would not generate pancreas follow-up forms. To use this method, the Committee would also need to define pancreas for technical reasons in policy. In order for UNOS staff to draft such policy language, UNOS staff requested clarification on the different ways a pancreas is used for technical reasons. UNOS staff suggested sending a memo to programs that have done 3 or more pancreata for technical reasons asking them what they do with the pancreas and requested that Committee or a subcommittee help to develop specific questions for this memo.

The Committee thought that the programming solution was a reasonable interim step. The Committee thought that a better approach to this issue would be to define these transplants using standard terminology rather than the term "for technical reasons." For example, the terms "multivisceral" (liver, pancreas, and intestine with or without stomach) and "modified multivisceral" (intestine and pancreas with or without stomach) are commonly used. Other definitions differ based on how the pancreas is used. A standard terminology would need to be developed and defined. Treating the cluster of organs as a bloc rather than as individual organs could solve many of the problems relating to multivisceral allocation and reporting. Additionally, the Committee thought these transplants should be treated as a bloc for reporting purposes instead of trying to decide what should be reported for each organ in the bloc. Committee members volunteered to work with UNOS staff to develop a path forward on this issue that could then be presented to other Committees involved in multivisceral transplantation.

6. Kidney Transplantation Committee Update

Richard Formica, MD, vice-chair of the Kidney Transplantation Committee (Kidney Committee), provided an update on the Kidney Committee's progress toward a new kidney allocation system. The current working model for a new kidney allocation system includes the following elements:

- The top 20% kidney donor profile index (KDPI or DPI) kidneys will be allocated to the candidates with the top 20% estimated post transplant survival (EPTS).
- Kidneys with a DPI from 20% to 85% will be allocated under the current rules with a few minor changes.
- Kidneys with a DPI between 85% and 100% will be allocated to candidates who opt-in to receive offers these kidneys.

All of these classifications will come after multi-organ, pediatric, and zero mismatch candidate classifications. Table 9 shows the Kidney Committee's assessment of the limitations of the current kidney allocation system and the concepts the Kidney Committee is considering to address these system limitations.

Table 9: Limitations of Current Kidney Allocation System

Stated Limitation of the Current System	Applicable Concepts
Mismatch between potential survival of the kidney and the recipient	Longevity matching
Variability in access to transplantation by blood group and geographic location	A2/A2B, broader sharing
High discard rates of kidneys that could benefit candidates on the waiting list	KDPI, expedited placement,
Reduce differences in transplant access for populations described in NOTA (e.g., candidates from racial/ethnic minority groups, pediatric candidates, and sensitized candidates).	ESRD time, broader sharing, CPRA sliding scale, maintain peds priority

The Kidney Committee believes that allocation based on longevity matching is accepted and sustains legal scrutiny. The majority of kidneys would still be allocated very similarly to current rules. Waiting time remains the primary determinant of kidney allocation with a more inclusive definition. The proposal improves upon the "ECD" system to address the concerns of older recipients. The "opt in" nature of the system preserves choice. It allows the trade off of a kidney with more longevity for more rapid transplantation. Additionally, regional allocation might improve recovery and placement. Finally, allocation on waiting time alone makes the opt-in system predictable and allows for list management.

The Kidney Committee is currently awaiting final simulation modeling of:

- Sharing for candidates with CPRA>=98%
- Regional sharing of ECD kidneys

The earliest that a proposal could be released for public comment is fall 2012 with earliest Board consideration in June 2013.

The Committee inquired how the Kidney Committee plans to determine the top 20% DPI kidneys. The Kidney Committee continues to discuss this issue. The top 20% DPI kidneys will likely be determined based on data on the national top 20% DPI kidneys each year. Then, the top 20% EPTS candidates will

likely be determined quarterly. The Committee also asked how waiting time will be calculated. Waiting time will begin at the earlier of dialysis initiation date or listing with a GFR less than or equal to 20 mL/min. The Committee asked whether a top 20% DPI kidney will be allocated to local bottom 80% EPTS candidates before being offered to regional top 20% EPTS candidates. Kidneys will be allocated through all local candidates before being offered to any regional candidates.

The Committee inquired whether candidates must be unsensitized to opt-in to the "improved ECD" system. The Kidney Committee does not plan to prevent sensitized candidates from participating in the opt-in "improved ECD" system. The Committee was concerned that allowing sensitized candidates to participate could reduce the predictability of that part of the system, which is one of its advantages. The Committee also wondered how effective the system would be if everyone opted in and asked if there would be any restrictions on participation. The Kidney Committee has not considered any restrictions on participation.

The Committee recommended that the Kidney Committee consider allowing candidates to keep a peak CPRA value for a certain period of time after desensitization so that they could still receive the same priority for offers in the short window where they could accept more offers due to the desensitization procedure. The Committee also noted that list exchange no longer will exist in the new kidney allocation system. The Kidney Committee was concerned that list exchange disproportionately affected blood type O waiting list candidates and thinks that kidney paired donation is a better option for incompatible pairs.

Variance Review
The Kidney Committee has reviewed all existing kidney variances and identified those that it believes could be beneficial if implemented as part of a national kidney allocation policy. The Committee decided to recommend discontinuation of all variances except for:

- Dialysis waiting time study
- A_2/A_2B

The Committee will recommend that these changes take place at the time a new system is implemented. OPOs that currently have a variance not recommended for inclusion:

- May apply for a 1-step transition or
- May apply for a new variance

Details for each option were sent to OPOs which submitted appeals. The Policy Oversight Committee will review the Kidney Committee's recommendations on April 6, 2012. OPOs must submit applications for transition plans by May 15, 2012. The Kidney Committee will update the Board of Directors on its plans for kidney variances at the June 2012 Board of Directors meeting. In addition to distributing the proposal for a new kidney allocation system in fall 2012, the Kidney Committee also hopes to distribute any transition plans for public comment in fall 2012 as well, with Board consideration in June 2013. Then, approved transition plans would be implemented in advance on the implementation of a new kidney allocation system.

7. Memo from the Policy Oversight Committee and Policy Oversight Committee Update
The Policy Oversight Committee (POC) has been charged with addressing multi-organ allocation policies. Following several meetings held in 2011, the POC is considering policy modifications that would incorporate minimum listing criteria for each organ in circumstances where a patient is being listed for a multi-organ transplant. In addition, the committee is considering expanding beyond the local DSA the zone where multiple organ recipients will take priority. As the POC continues working on this project, they identified four main areas for which the POC would benefit from other committees input: Minimum listing criteria, policy ambiguities, ethical principles, and logistical issues.

The POC requested that the Committee address the following questions:

1) *For those committees with minimum listing criteria: Do you think the minimum listing criteria issues are resolved for your organ and if so, what are the important principles that were used to get there?*

The Committee believes that the minimum listing criteria issues are resolved for kidney-pancreas transplants. The Committee required that the candidate meet minimum requirements for both organs in order to accrue waiting time for a kidney-pancreas transplant. The kidney portions of the criteria are the same as for isolated kidney. There are currently no minimum criteria for pancreas transplantation, so the pancreas portion of the kidney-pancreas criteria are more rigorous than for isolated pancreas.

2) *Are there organ combinations for which minimum listing criteria do not exist but should?*

The Committee thinks that multivisceral transplants should have minimum listing criteria in order to receive allocation priority. The Committee also considered whether there should be criteria for lung-pancreas and liver-pancreas. The Committee thinks that a lung or liver candidate should have to meet the definition of cystic fibrosis-related diabetes or meet the same requirements for the pancreas portion of the SPK criteria in order to receive a pancreas with the first organ.

3) *In order to minimize unnecessary multi-organ transplants, are there adjustments needed to the allocation system that will ensure a candidate who does not receive multiple organs (due to failure to meet minimal listing criteria) could get appropriate priority if subsequent to the transplant of the primary organ he/she develops failure of the second organ?*

The Committee thought that this issue does not apply to kidney-pancreas transplants.

4) *Are there logistical issues regarding waiting list management surrounding multi-organ listing and transplant that need to be addressed?*

The Committee did not identify any specific waiting list management issues around kidney-pancreas transplants but thinks that waiting list management issues around multi-organ transplant should be addressed as part of this discussion.

5) *Are there procurement issues that could be addressed in this process?*

The Committee requested that the procurement of an isolated pancreas and an isolated intestine be considered as part of this process. There are methods that would allow both organs to be procured, but it would require coordination between procurement teams.

6) *If the concept of lifesaving organ is removed, are there key ethical principles your committee feels should be included in a framework for allocating the second organ based on a balance between equity and utility.*

The Committee did not have a comment on this question.

8. Overview of Pancreas Committee Projects

The Committee has requested to continue working on the following projects in the 2012-2013 Committee year:

- Implement pancreas allocation system approved by the Board in November 2010
- Islet infusion reporting
- Pancreas for technical reasons
- Review pancreas primary physician/surgeon bylaws
- Investigating characteristics resulting in improved PAK outcomes

The Committee has also requested to begin work on the following new projects in the 2012- 2013 Committee year:

- Defining pancreas graft failure
- Review of facilitated pancreas allocation
- Investigating sources of pancreas discards
- Investigating DCD pancreas outcomes
- Best practices for isolated pancreas recovery with an isolated intestine recovery

The POC will review these projects and forward a recommendation to the Executive Committee, which will decide on the Committee's projects for the upcoming Committee year.

9. Isolated Pancreas Recovery with Isolated Intestine Recovery

The Committee discussed whether there were any methods for recovering an isolated pancreas and an isolated intestine from the same donor. A Committee member shared his work on this topic. If the project is approved by the Executive Committee, the Committee would like to work with other Committees to establish best practices in this area with the goal of reducing pancreas discards when an isolated intestine is recovered.

10. Recognition of Outgoing Members

David Axelrod, MD, MBA, chair of the Committee, recognized the following Committee members with terms ending on June 30, 2012:

- Ty Dunn, MD- Region 7 Representative
- Charles Bratton, MD- Region 11 Representative
- Nicole Beauvais, PA-C- At Large Representative
- Anissa Cole- At Large Representative
- Barry Friedman, RN, BSN, MBA, CPTC- At Large Representative
- Danielle Neidfeldt, JD, RN- At Large Representative

11. Public Comment

a. **OPTN Bylaws Substantive Rewrite of Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs**

Membership and Professional Standards Committee

This rewrite affects the current Appendix *A: Application and Hearing Procedures for Members and Designated Transplant Programs.* This represents a substantive rewrite of the process and procedures for reviewing potential violations of and non-compliance with OPTN obligations. All content of the former Appendix A also underwent a plain language rewrite and reorganization for clarity and usability, and will be presented as the new *Appendix L: Reviews, Actions, and Due Process.*

The Committee considered this proposal on March 14, 2012. The Committee voted to support the proposal with no additional comments. (16-Support, 0-Oppose, 0-Abstain)

12. New Business

A Committee member requested clarification on two pancreas allocation questions. There was a situation where a blood type B candidate was listed for both a kidney and an SPK. The candidate received an offer for the kidney but did not appear on the SPK match run because the donor's blood type was O. Kidney policy allows blood type B candidates who are a zero mismatch with the donor to receive blood type O kidney offers. However, pancreas policy only allows blood type O SPK candidates to receive blood type O kidney-pancreas offers. Blood type B pancreas-alone candidates can receive blood type O pancreas

offers. Therefore, this candidate was eligible to receive blood type O kidney and pancreas offers but not blood type O SPK offers. The Committee agreed that the intent was to be consistent in how the kidney is allocated and that kidney and pancreas allocation policy should be consistent. The Committee would like to correct this inconsistency in policy. The Committee tasked Allocation Subcommittee with looking into this issue further.

The second situation is that there was a local donor with a common HLA, which resulted in a number of candidates appearing in the zero mismatch classifications. An offer went to a regional zero mismatch candidate with a CPRA greater than 80% rather than the local candidate who was a zero mismatch but had a CPRA less than 80%. The Committee was comfortable with these allocation rules because the priority is designed to improve access for highly sensitized candidates.

Table 10: Pancreas Transplantation Committee Attendance

PANCREAS COMMITTEE		JANUARY 1, 2012 - JUNE 30, 2012
	MONTH	MARCH
	DAY	14
	FORMAT	In Person
NAME	COMMITTEE POSITION	
David Axelrod, MD, MBA	Chair	X
Jonathan Fridell, MD	Vice Chair	X
Sayeed Malek, MD	Regional Rep.	X
James Lim, MD	Regional Rep.	
Joseph Magliocca, MD	Regional Rep.	
John Duffy, MD	Regional Rep.	X
Jonathan Fisher, MD, FACS	Regional Rep.	X
Nelson Goes, MD	Regional Rep.	X
Ty Dunn, MD	Regional Rep.	
Michael Morris, MD	Regional Rep.	X
Bernd Schroppel, MD	Regional Rep.	X
Edmund Sanchez, MD	Regional Rep.	X
Charles Bratton, MD	Regional Rep.	X
Nicole Beauvais, PA-C, MMS	At Large	X
Lisa Chronis, RN	At Large	
Anissa Cole	At Large	X
Barry Friedman, RN, BSN, MBA, CPTC	At Large	
Monica Grafals, MD	At Large	X
Albert Hwa, PhD	At Large	X
Danielle Niedfeldt, JD, RN	At Large	X
Jason Wellen, MD	At Large	X
Dixon Kaufman, MD, PhD	Ex. Officio	
James Bowman III, MD	Ex. Officio	X
Monica Lin, PhD	Ex. Officio	By phone
Ba Lin, MS, MPH	Ex Officio	By phone
Raja Kandaswamy, MD	SRTR Liaison	
Sally Gustafson, MS	SRTR Liaison	X
Peter Stock, MD, PhD	SRTR Liaison	X
Jon Snyder, PhD, MS	SRTR Liaison	By phone
Elizabeth Sleeman, MHA	Committee Liaison	X
Jennifer Wainright, PhD	Support Staff	X
Manny Carwile	Support Staff	X