Interim Report
Pancreas Transplantation Committee

October 20, 2011
Live Meeting/ Teleconference

October 26, 2011
Chicago, Illinois

This report includes items addressed by the Pancreas Transplantation Committee (the Committee) at its meetings held on October 20, 2011 and October 26, 2011.

1. Review of Pancreas Variance Applications

On October 26, 2011, Jonathan Fridell, MD, chair of the Pancreas Allocation Subcommittee, presented two variance applications and the Pancreas Allocation Subcommittee's recommendations on these applications. As part of the recent pancreas allocation proposal, there was a provision that groups with existing variances would have the opportunity to apply to continue their variances under the new allocation system, provided that they met the requirements for a variance and were consistent with certain elements of the new pancreas allocation system. In the March 2011, the Committee notified all groups with existing kidney-pancreas (KP) or pancreas (PA) variances of the deadline for variance applications to be submitted. The deadline for application submission was May 2011. The MNOP group chose not apply to continue its variance **(Exhibit A)**. The MNOP variance will be dissolved when the new pancreas allocation system is implemented.

Both the NCNC and Tennessee Statewide groups submitted applications for consideration. In July 2011, the Pancreas Allocation Subcommittee met to review variance applications for completeness. In August 2011, the subcommittee's feedback was provided to the applicants with the opportunity to submit revised applications by September 19, 2011. The subcommittee met again on October 6, 2011 to review the revised variance applications and develop recommendations for the full Committee.

The Committee must notify the applicants of its decision within 10 business days. If the applicant intends to appeal the decision, the applicant must notify the Committee in writing within 30 days of the Committee's communication of its decision. The Committee reviews only new information on the appeal. The applicant may participate in discussion. Then, the Policy Oversight Committee would review the appeal, and the Board would vote on the variance appeal.

The subcommittee reviewed each application for the following elements (the reference for each element is in parentheses):

a. Research design (Final Rule, Application)
b. Data collection plan (Final Rule, Policy, Application)
c. Analysis plan (Final Rule, Policy)
d. Time-limited/ defined endpoint (Final Rule, Policy, Application)
e. Indication of support or opposition from each OPO or transplant center that is to take part in the variance (Policy, Application)
f. If not unanimous, statements of support or opposition (Policy)
g. Statement of purpose, incorporating a review of the method for improving organ allocation or distribution (Policy)
h. How the system is intended to accomplish this purpose (Policy)
i. Why the current, national allocation system does not sufficiently address the needs of the transplant professionals or candidates that your organization serves (Application)

j. What is the target audience/population? (Application)
k. Predicted outcomes (Application)

Review of NCNC Application ***(Exhibit B)***

This variance allows candidates who are ABO identical and a 0 to 2 ABDR mismatch with the donor to have priority over KP candidates at the local level. All other local PA candidates come after the KP candidates on the match run. The rest of the allocation scheme is consistent with the old pancreas allocation system; there were no updates to make the variance consistent with the new pancreas allocation system as required in the pancreas allocation proposal. Four pancreas programs and one OPO voted in favor of the application. The NCNC applicants did not submit any additional or revised information based on the subcommittee's feedback in August 2011. Table 1 shows the Committee's assessment of the NCNC application for each variance criteria.

Table 1: Assessment of NCNC Pancreas Variance Application

Criteria	Reference	Notes
Research design	Final Rule, Application	Not included in detail
Data collection plan	Final Rule, Policy, Application	Included on page 2 of the application, but fields are not specific
Analysis plan	Final Rule, Policy	Not included
Time-limited/ defined end point	Final Rule, Policy, Application	Included on page 2 of the application
Indication of support or opposition from each OPO or transplant center that is to take part in the variance	Policy, Application	Ballots included
If not unanimous, statements of support or opposition	Policy	N/A
Statement of purpose, incorporating a review of the method for improving organ allocation or distribution	Policy	Not present
how the system is intended to accomplish this purpose	Policy	Included in Attachment B but explanation is limited
Why the current, national allocation system does not sufficiently address the needs of the transplant professionals or candidates that your organization serves	Application	Included in Attachment C Application states anecdotal evidence is not sufficient.
What is the target audience/population?	Application	Included on page 2 of the application
Predicted outcomes	Application	Included on page 2 of the application
A combined SPK and PA match run	Pancreas proposal	In Attachment B of the application, but PA and KP candidates are sometimes in separate classifications.

		High CPRA statewide candidates follow 0MM high CPRA regional and national candidates (in national policy, high CPRA local candidates comes before 0MM high CPRA regional and national candidates). Differences for islet candidates based on donor type not noted.
SPK qualifying criteria	Pancreas proposal	Not included
Pancreas allocation disentangled from kidney allocation	Pancreas proposal	Not included

The subcommittee thought the application was not complete enough to be implemented. The subcommittee voted to recommend that the full Committee not approve this variance to continue under the new pancreas allocation system. The subcommittee vote to support continuing the variance was 0-Support, 7-Oppose, 0-Abstain. The Committee voted to support the subcommittee's recommendation not to continue the NCNC variance. (13-Support, 0- Oppose, 2-Abstain) Two Committee members from region 11 abstained because their organizations could be impacted by the variance decision. The Committee did think that it would be worth investigating the impact of matching on solitary pancreas transplantation outside of the variance context.

Review of Tennessee Statewide Application ***(Exhibit C)***
This variance combines the two OPOs in the state into a single allocation unit. Two OPOs support the AAS. Two active pancreas programs and three inactive pancreas programs support the AAS. One active pancreas program opposes the AAS. The Tennessee Statewide applicants submitted a revised application that addressed all the recommendations. Table 2 shows the Committee's assessment of the Tennessee Statewide application for each variance criteria.

Table 2: Assessment of Tennessee Statewide Pancreas Variance Application

Criteria	Reference	Notes
Research design	Final Rule, Application	Included on page 2 of the application and Attachment E
Data collection plan	Final Rule, Policy, Application	Included on page 2 of the application and Attachment D
Analysis plan	Final Rule, Policy	Included on page 2 of the application and Attachment E
Time-limited/ defined end point	Final Rule, Policy, Application	Included on page 2 of the application and Attachment E
Indication of support or opposition from each OPO or transplant center that is to take part in the variance	Policy, Application	Ballots submitted
If not unanimous, statements of support or opposition	Policy	Statement provided.
Statement of purpose, incorporating a review of the method for improving organ allocation or distribution	Policy	Included on page 2 of Attachment C for

How the system is intended to accomplish this purpose	Policy	Included in Attachment B and Attachment C
Why the current, national allocation system does not sufficiently address the needs of the transplant professionals or candidates that your organization serves	Application	Included in page 1 of Attachment C How is item 1 (remove the disincentive for patients to pursue LRD kidney followed by PA) different from the national system?
What is the target audience/population?	Application	Included on page 2 of the application and Attachment E
Predicted outcomes	Application	Included on page 2 of the application and Attachment E
A combined SPK and PA match run	Pancreas proposal	Included on page 3 of Attachment B
SPK qualifying criteria	Pancreas proposal	Included on page 4 of Attachment B (same as the national system)
Pancreas allocation disentangled from kidney allocation	Pancreas proposal	Included on page 3 of Attachment B

The pancreas program who opposed continuing the variance under the new pancreas allocation system provided the following rationale:

1. "Our understanding of the new national pancreas allocation system is that it is essentially the same as TN AAS [Alternative Allocation System], i.e. pancreas allocated according to wait-time within blood group, kidney follows pancreas. This obviates the need to have a separate AAS.
2. As we have from our kidney AAS, there may be unintended, potentially adverse, consequences when one departs from a thoroughly vetted nationally approved system.
3. The new national system promotes wider, regional sharing, compared to current TN AAS."

The subcommittee noted that there is precedent from the Liver and Intestinal Organ Transplantation Committee and the Board of Directors that sharing in a unit smaller than the region is not broader sharing. There was also concern that one of three active programs opposed the variance. The subcommittee noted that addressing racial/ethnic disparities is important, but the variance would only address disparities within the state, not within the region which may have other OPOs with similar disparities. The subcommittee thought the OPO should have a prospective study of racial and ethnic disparities, in particular the impact of not having this variance in effect, and bring the results back to the Committee. The subcommittee voted to recommend that the full Committee not approve this variance to continue under the new pancreas allocation system. The subcommittee vote to support continuing the variance was 0-Support, 6-Oppose, 1-Abstain. The subcommittee member from Region 11 abstained from voting because his program could be affected by the variance.

The Committee noted that the state is currently a net exporter of pancreata, so it is not clear that the removal of the variance would negatively impact the ability for candidates in Tennessee to receive pancreas offers. The Committee voted to support the subcommittee's recommendation not to continue the NCNC variance. (17-Support, 0- Oppose, 1-Abstain) One Committee member from region 11 abstained from voting because his organization could be impacted by the variance decision.

Pancreas Allocation Subcommittee Minutes can be found in **Exhibit D.**

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

Background on the data request

On October 26, 2011, David Axelrod, MD, MBA, chair of the Committee, provided background on why the Committee is investigating PAK outcomes. Public comment for the proposal for a new pancreas allocation system included much feedback about having a combined list of SPK and PAK recipients. Two themes of the feedback were the desire for SPK candidates to have priority over all other types of pancreas candidates and the desire for PAK candidates who received a living donor kidney to have priority over all other types of pancreas candidates.

Whereas living donor kidney transplant outcomes may be superior to deceased donor kidney transplant outcomes for kidney-alone recipients, the case is more complicated for candidates who need both a kidney and a pancreas. For pancreas graft survival, the 1 year outcomes for SPK transplant (84.8%) and for PAK transplant (80.0%) are similar, but at 5 years, the outcomes for PAK (53.4%) are worse than SPK outcomes (73.4%). The kidney graft survival outcomes for SPK and PAK are similar at 1 year and 5 years (2009 OPTN/SRTR Annual Report, Table 1.13). Therefore, the data do not support a statement that a living donor kidney is a better option for candidates who also need a pancreas. There are some single center studies that show better outcomes for PAK recipients, but the improvements have not been shown at the national level to date.

As a result of this feedback from public comment, the Committee decided to investigate the factors that influence improved PAK outcomes at the national level. The Committee began reviewing these data at its March 17, 2011 meeting. On April 13, 2011 the subcommittee requested additional data, including additional years of patients, additional variables, and rates of graft loss for PAK recipients after living donor kidney transplant:

- Continue analyses of donor and recipient factors that are associated with patient and graft survival for PAK recipients.
    - As an additional analysis, rerun/rebuild models using an expanded cohort of PAK recipients from 2000-2009.
    - Report average follow-up time when presenting Kaplan-Meier survival analyses.
    - Investigate use of PDRI, eGFR of recipient, donor type (living vs. deceased donor), and interaction terms in the models.
    - Compare methods of calculating graft failure. Examine all-cause graft failure.
    - Examine outcomes for PAK transplant with „ideal' recipients and donors, showing estimated 5-year outcomes from the models for combinations of characteristics.

The SRTR data analyses can be found in **Exhibit E**.

Methods

Study population

2349 PAK transplant recipients who underwent pancreas transplants between January 1, 2000, and December 31, 2009, were included. Only the first pancreas transplant during this period was considered. Additionally, 467 patients who had previously undergone SPK transplant (as opposed to kidney-alone transplant) were excluded from this analysis to simplify follow-up of the various graft statuses. Patients who were denoted as having undergone a previous kidney transplant but had no record of the transplant were excluded. Multiple prior kidney transplants were possible; the most recent kidney transplant before the pancreas transplant was considered for the outcomes analysis.

Average pancreas donor risk index (pDRI) has decreased from 2000 to 2009 as has average cold ischemic time for pancreas transplant. The Committee thought this trend was related to transplant hospitals taking

less risk with pancreata. The pressure to show better outcomes for PAK may have caused this change in behavior.

Analytical approach

The Cox proportional hazards model was used to model five outcomes in the PAK cohort: all-cause pancreas graft failure, death-censored pancreas graft failure, all-cause kidney graft failure, death-censored kidney graft failure, and patient death. Observation time for all models began at the time of the pancreas transplant. Multiple covariates were examined separately and together to best determine the predictors for each type of outcome. If a covariate by itself was not significantly predictive of the outcome (with a significance level of $P < 0.10$), it was not considered in the final multivariate model. Backwards selection was used to create the final model. If model fit worsened significantly (with a selection criterion of $P < 0.10$) with the covariate's exclusion, the covariate was retained. Otherwise, the covariate was removed. Appropriate functional form of each covariate was considered separately for each univariate and multivariate model. Linear, quadratic, cubic, and logarithmic parameterizations were variously tested to assess form. Furthermore, the proportional hazards assumption was assessed for all covariates included in the final model, and stratification was used to control for strong violations of this assumption. For a covariate to satisfy this assumption, the magnitude and direction of its effect cannot significantly vary during follow-up.

Table 3 shows a snapshot of the overall survival rate for all five outcomes examined.

Table 3: Survival Rates by Outcome

Outcome	1-year survival rate (95% CI) as percentages	5-year survival rate (95% CI) as percentages	10-year survival rate (95% CI) as percentages
All-cause pancreas graft failure	78.8 (77.1, 80.4)	56.5 (54.3, 58.8)	39.1 (24.7, 43.5)
Death-censored pancreas graft failure	81.9 (80.3, 83.4)	65.0 (62.8, 67.1)	51.1 (46.0, 56.1)
All-cause kidney graft failure	94.8 (93.8, 95.6)	75.8 (73.8, 77.7)	55.1 (50.7, 59.3)
Death-censored kidney graft failure	98.6 (98.0, 99.0)	86.7 (85.0, 88.3)	71.1 (66.3, 75.4)
Patient survival	96.0 (95.1, 96.7)	84.9 (83.3, 86.4)	67.9 (64.3, 71.2)

Results for the Pancreas Graft Failure Models

In this study, 2349 PAK patients were included. Of those, 997 (42.4%) experienced all-cause pancreas graft failure prior to September 30, 2010. Of those, 229 (9.7%) died prior to graft failure and 768 (32.7%) experienced graft failure prior to death. In addition, 15 patients (0.6%) were lost to follow-up and 1337 (56.9%) were followed to the censoring date without incident.

All-Cause Graft Failure

The average length of follow-up for patients with pancreas graft failure was 688 days (22.6 months), while the average length of follow-up for patients without pancreas graft failure was 1706 days (56 months). The index of concordance for this model was 61.3%, with a 95% confidence interval (CI) of 59.4-63.1%. Table 4 shows the covariates in the all-cause pancreas graft failure model and the related hazard for each covariate.

Table 4: Covariates in the All-Cause Pancreas Graft Failure Model

Covariate	Result
Kidney failure during follow-up, prior to pancreas failure or death	↑ hazard
PDRI, linear	↑ hazard as PDRI ↑
Age < 30	↑ hazard
CNI and mTOR use at pancreas transplant	↑ hazard if neither used or missing
Years between kidney and pancreas transplants	↑ hazard as time ↑
Recipient eGFR at pancreas transplant, quintiles	65-77, ↓ hazard versus others
Peripheral vascular disease (PVD)	↑ hazard if yes
Type 1 diabetes	↑ hazard if yes
Karnofsky score at pancreas transplant	↑ hazard if total assistance
Pancreas procured within OPO	↓ hazard
Pancreas donor eGFR	↓ hazard as eGFR ↑
Transplant year	↓ hazard as year ↑
Recipient BMI	↑ hazard for BMI >31 versus 20-31
Delayed Graft Function of Kidney	↑ hazard if yes

The Committee inquired at what time period between kidney and pancreas transplant the risk of graft failure increases. There is no specific inflection point. The increase in risk is linear. The Committee asked whether there is benefit of performing a PAK in recipients who have a good GFR because of the reduction in diabetic complications. This question is not answered by the PAK analyses requested by the Committee, but other studies have shown a benefit of PAK in kidney function after five years. The Committee asked whether any other immunosuppression factors were tested. The SRTR contractor did examine other immunosuppression factors, but those factors were not significant in the final model.

Table 5 shows the characteristics of sample low risk, medium risk, and high risk PAK candidates and their predicted outcomes using the all-cause pancreas graft failure model.

Table 5: Predicted Outcomes from the All-Cause Pancreas Graft Failure Model

Covariate	Person 1 low risk	Person 2 medium-risk	Person 3 high risk
PDRI, linear	0.80	1.0	1.5
Age	>30	>30	<30
Local pancreas	Yes	No	No
Years between kidney and pancreas transplants	1 year	2 years	3years
Calcineurin Inhibitor and mTOR use at pancreas transplant	Both	CNI only	mTOR only
eGFR at pancreas transplant	65.1-76.8	55.1-65	45.1-55
History of PVD	No	No	No
Delayed graft function of kidney	No	No	Yes
Year of pancreas transplant	2006	2006	2006
Pancreas donor eGFR	110	110	90
Karnofsky functional status	No limitations	No limitations	Some limitations
Diabetes type	Type 1	Type 1	Type 1
Estimated 5-year all-cause pancreas graft survival (95% CI)	68.6 (60,7, 77.5)	55.0 (49.9, 60.8)	29.3 (14.8, 58.0)

Death-Censored Graft Failure

The average length of follow-up for patients with pancreas graft failure was 591 days (19.4 months), while the average length of follow-up for patients without pancreas graft failure was 1606 days (52.8 months). The index of concordance for this model was 61.7%, with a 95% confidence interval (CI) of59.6-63.8%. Table 6 shows the covariates in the death-censored pancreas graft failure model and the related hazard for each covariate.

Table 6: Covariates in the Death-Censored Pancreas Graft Failure Model

Covariate	Result
Kidney failure during follow-up, prior to pancreas failure or death	↑ hazard
PDRI, linear	↑ hazard as PDRI ↑
Age at transplant, linear	↓ hazard as age ↑
CNI and mTOR use at pancreas transplant	↑ hazard if neither used, or missing
T-Cell depleting agent used at pancreas transplant	↓ hazard
Pancreas procured within OPO	↓ hazard
Recipient BMI	↑ hazard for BMI >31 versus 20-24
Type 1 diabetes	↑ hazard versus not-Type 1

Covariates dropped from the all-cause model include: recipient eGFR at pancreas transplant; PVD; Karnofsky score; year of pancreas transplant; pancreas donor eGFR; delayed graft function of kidney; and years between kidney and pancreas transplants.

Table 7 shows the characteristics of sample low risk, medium risk, and high risk PAK candidates and their predicted outcomes using the death-censored pancreas graft failure model.

Table 7: Predicted Outcomes from the Death-Censored Pancreas Graft Failure Model

Covariate	Person 1 low risk	Person 2 medium-risk	Person 3 high risk
PDRI, linear	0.80	1.0	1.5
Age	50	45	30
Local pancreas	Yes	No	No
Calcineurin Inhibitor or mTOR use at pancreas transplant	Both	CNI only	CNI only
Induction agent use	TCD	IL-2-RA only	None
Diabetes type	Type 1	Type 1	Type 1
Recipient BMI	≤ 24	24.1-28	>31
Estimated 5-year death-censored pancreas graft survival (95% CI)	80.8 (76.2, 85.6)	64.6 (60.2, 69.4)	32.0 (22.5, 45.6)

Results for the Kidney Graft Failure Model

Of the 2349 PAK recipients included in the model, 591 (25.2%) experienced an all-cause kidney graft failure prior to September 30, 2010. Of these, 285 (12.1%) died without a reported graft failure and 306 (13.0%) experienced graft failure prior to death. In addition, 199 patients (8.5%) were lost to follow-up, and 1559 (66.4%) were followed to September 30, 2010 without incident. 4 of 591 (0.17%) experienced kidney graft failure before the date of the pancreas transplant and so were not included in this model.

All-Cause Graft Failure

The average length of follow-up for patients with kidney graft failure was 1193 days (39.2 months), while the average length of follow-up for patients without pancreas graft failure was 1804 days (59.3 months). The index of concordance for this model was 65%, with a 95% confidence interval (CI) of 62.6-67.1%. Due to nonproportionality of the hazard over time, the model was stratified by insurance type at pancreas transplant (private versus not private, 50.2% / 49.7%). Table 8 shows the covariates in the all-cause kidney graft failure model and the related hazard for each covariate.

Table 8: Covariates in the All-Cause Kidney Graft Failure Model

Covariate	Result
Recipient BMI	BMI <25 ↑ hazard versus 25-30
Kidney donor age	↑ hazard as age ↑
Recipient eGFR at pancreas transplant	<65 ↑ hazard
Kidney donor eGFR	↑ hazard if ≤ 75 or >115
Race	↓ hazard if Hispanic, ↑ hazard if African-American
Kidney donor type	↑ hazard if deceased
Pancreas failure during follow-up, preceding kidney failure or death	↑ hazard
Total HLA mismatches with kidney donor	↑ hazard if >1
Karnofsky score at pancreas transplant	↑ hazard if total assistance needed
BMI change from kidney to pancreas transplant	↑ hazard if gain >2 units of BMI or if change unknown
Kidney donor BMI	↑ hazard if BMI 35-40, versus 18-35, or >40
Kidney transplant was preemptive (versus >0 dialysis time)	↓ hazard

The Committee noted that the model is based on the kidney donor, which the pancreas surgeon cannot mitigate at the time of PAK. The Committee was interested in removing pancreas graft failure from the model and replacing it with pDRI because the transplant program can know pDRI at the time of pancreas offer. The pancreas program cannot know whether the graft will fail at the time of pancreas offer.

Table 9 shows the characteristics of sample low risk, medium risk, and high risk PAK candidates and their predicted outcomes using the all-cause kidney graft failure model.

Table 9: Predicted Outcomes from the All-Cause Kidney Graft Failure Model

Covariate	Person 1 low risk	Person 2 medium-risk	Person 3 high risk
Recipient BMI at pancreas transplant	25-30	>30	≤ 20
Recipient race	White	African-American	White
Kidney donor age	35	35	50
Karnofsky functional status at pancreas transplant	No limitations	No limitations	Some limitations
Recipient eGFR at pancreas transplant	65.1- 76.8	55.1-65	≤45
Kidney donor type	Living	Living	Deceased
Kidney donor eGFR	101.3- 113.9	101.3- 113.9	101.3- 113.9
Change in BMI from kidney to pancreas transplant	Change of <2 units	Change of <2 units	Gain of >2 units
Kidney donor BMI	18.1-35	18.1-35	<18
HLA mismatches with kidney donor	0-1	2-6	2-6
Insurance type at pancreas transplant	Private	Private	Private
Kidney transplant was preemptive (no dialysis)	Yes	No	No
Estimated 5-year all-cause kidney graft survival (95% CI)	93.0 (90.5, 95.5)	76.3 (67.8, 86.1)	43.9 (27.1, 71.1)

Death-Censored Graft Failure

The average length of follow-up for patients with death-censored kidney graft failure was 1358 days (44.6 months), while the average length of follow-up for patients without pancreas graft failure was 1694 days (55.7 months). The index of concordance for this model was 70.8 with a 95% confidence interval (CI) of 67.7-73.7%. Due to nonproportionality of the hazard over time, the model was stratified by insurance type at pancreas transplant (private versus not private, 50.2% / 49.7%). Table 10 shows the covariates in the death-censored kidney graft failure model and the related hazard for each covariate.

Table 10: Covariates in the Death-Censored Kidney Graft Failure Model

Covariate	Result
Recipient age, linear	↓ hazard as age ↑
Recipient BMI	BMI <25 or >30 ↑ hazard, versus 25-30
Kidney donor age, quadratic	↑ hazard as age ↑
Recipient eGFR at pancreas transplant	<65 ↑ hazard
Kidney donor eGFR	↑ hazard if ≤ 75 or >115
Race	↓ hazard if Hispanic, ↑ hazard if African-American
Kidney donor type	↑ hazard if deceased
Pancreas failure during follow-up, preceding kidney failure or death	↑ hazard
Total HLA mismatches with kidney donor	↑ hazard if 2-6
CNI and mTOR use at pancreas transplant	↓ hazard if CNI only versus both
eGFR post-kidney transplant	↓ hazard for >40, linear
Preemptive kidney transplant	↓ hazard

Covariates dropped from the all-cause model include: **Karnofsky score;** kidney donor BMI; and BMI change.

Table 11 shows the characteristics of sample low risk, medium risk, and high risk PAK candidates and their predicted outcomes using the death-censored kidney graft failure model.

Table 11: Predicted Outcomes from the Death-Censored Kidney Graft Failure Model

Covariate	Person 1 low risk	Person 2 medium-risk	Person 3 high risk
Recipient age at pancreas transplant	45	35	25
Recipient BMI at pancreas transplant	25-30	20-25	>30
Recipient race	White	African-American	White
Kidney donor age	35	45	50
Recipient eGFR at discharge, post-kidney transplant	80	55	35
Recipient eGFR at pancreas transplant	65.1- 76.8	55.1-65	45.1-55
Kidney donor type	Living	Deceased	Deceased
Kidney donor eGFR	101.3- 113.9	101.3- 113.9	101.3- 113.9
CNI and mTOR use at pancreas transplant	CNI only	mTOR only	Both
HLA mismatches with kidney donor	0-1	2-6	2-6
Insurance type at pancreas transplant	Private	Private	Public
Preemptive kidney transplant	Yes	No	No
Pancreas failed during follow-up	No	No	No
Estimated 5-year death-censored kidney graft survival (95% CI)	98.2 (97.2, 99.2)	80.0 (67.2, 95.2)	50.7 (34.6, 74.5)

Results for the Patient Survival Model

Of the 2349 PAK recipients included in the model, 442 (18.8%) died before the end of follow-up and the remaining 1907 (81.2) survived to the end of follow-up. The average length of follow-up for patients who died was 1337 days (43.9 months), while the average length of follow-up for patients who survived to the censoring date was 2163 days (71.1 months). The index of concordance for this model was 73.2%, with a 95% confidence interval (CI) of 70.6-75.8%. Table 12 shows the covariates in the patient survival failure model and the related hazard for each covariate.

Table 12: Covariates in the Patient Survival Model

Covariate	Result
Kidney or pancreas or both fail during follow-up	↑↑ hazard
Age at transplant, linear	↑ hazard as age ↑
Recipient BMI	BMI <20 ↑ hazard
Private insurance at pancreas transplant	↓hazard
Kidney donor age, linear	↑ hazard as age ↑
Recipient eGFR at pancreas transplant	<65 ↑ hazard
eGFR post-kidney transplant	↑ hazard if <30 or >90
Karnofsky score at kidney transplant	↑ hazard if total assistance needed
Pancreas donor BMI	lowest hazard if BMI 25-27
Pancreas donor eGFR	↓ hazard as eGFR ↑

Table 13 shows the characteristics of sample low risk, medium risk, and high risk PAK candidates and their predicted outcomes using the patient survival model.

Table 13: Predicted Outcomes from the Patient Survival Model

Covariate	Person 1 low risk	Person 2 medium-risk	Person 3 high risk
Age at pancreas transplant	30	45	55
Insurance type at pancreas transplants	Private	Private	Public or other
Recipient eGFR at pancreas transplant	65.1- 76.8	55.1-65	≤45
Recipient BMI at pancreas transplant	20.1-31	>31	≤20
Karnofsky functional status at kidney transplant	No limitations	Some limitations	Some limitations
Kidney donor age	35	45	60
Pancreas donor BMI	27.1-30	20.1-25	≤20
Pancreas donor eGFR	110	100	100
Recipient eGFR at discharge, post-kidney transplant	60-90	30-60	0-30
Kidney or pancreas failure during follow-up	No	No	No
Estimated 5-year patient survival (95% CI)	97.6 (96.5, 98.7)	90.5 (86.6, 94.6)	60.8 (47.3, 78.1)

Summary

Kidney graft failure had a strong negative association with subsequent pancreas graft failure; pancreas graft failure also had a significant negative association with subsequent kidney graft failure. Both effects were much stronger when the outcome was all-cause graft failure versus death-censored.

Kidney and pancreas graft failure were the definitive predictors of patient death. Though the magnitude of kidney failure's effect on death was much higher than that of the pancreas', a pancreas failure alone was a highly significant (P<0.0001) predictor of patient death.

For outcomes that included death, a low recipient BMI generally carried a high hazard; for death-censored graft failure, a low BMI was less detrimental and a high BMI became more hazardous. Immunosuppressant usage was not highly predictive of 10-year outcomes in contrast to a previous analysis; however, *missing* immunosuppression data was found to be highly hazardous. pDRI was highly predictive of pancreas outcomes but not kidney or patient survival. Cold ischemic time did not conform to clinical expectation with a marginally reduced hazard for <6 hours, but no differences among cold times between 6-30 hours. Kidney donor type was not predictive of pancreas outcomes. However, kidney graft failure was predictive of pancreas outcomes, and it is well-established here and elsewhere that kidney donor type is highly predictive of kidney outcomes. Young patients were at significantly higher risk of death-censored graft failure than older patients. The trend diminished for all-cause graft failure, and completely reversed for patient survival.

The Committee discussed the benefit of continuous glucose monitoring versus pancreas transplantation. Continuous glucose monitoring does not greatly improve events of hypoglycemic unawareness, but pancreas transplantation does.

The second request from the Committee was to calculate rates of kidney and pancreas graft loss, timing of loss, and causes of loss for recipients of PAK after living donor kidney transplant (PAK-LKD). The major causes of kidney graft loss were death (47.2% of graft failures) and chronic rejection (22.5% of graft failures). The rates were similar for recipients of PAK after deceased donor kidney transplant (PAK-DKD). The deaths for PAK-LKD were not in the early post-operative period. These data demonstrate that there is not a huge rate of peri-operative and post-operative death and that a PAK is a reasonable procedure. The early causes of graft failure were thrombosis, bleeding, and infection. Recipients of PAK-LKD had better survival of pancreas grafts than recipients of PAK-DKD.

The third request from the Committee was to tabulate the number of tabulate numbers of kidney transplant recipients per year waiting on the PAK list and transplanted off the PAK list, stratified by time between kidney transplant and listing on the PAK list, and kidney donor type. New listings are those who join the list in the index year. New PAK waiting list counts include only patients who were not already listed at a different center prior to the index year. Prevalent listings are those on the list on a particular day that year, December 31for this analysis. Prevalent listings include both "new" and "old" listings. From 2004 to 2010, the average time on the waiting list per year for new PAK candidates is steady at approximately 0.5 years whereas the time on the waiting list for prevalent but not new listing is increasing in that time frame from 2.7 years in 2004 to 4.0 years in 2010. The trend in the number of both new and prevalent listings has decreased from 2004 to 2010. The Committee noted that 2004 was the time when there were several publications questioning the efficacy of PAK, which may have contributed to the decrease in listings. Time to pancreas transplant is similar for LKD and DKD recipients. However, the time to pancreas transplant is much higher for prevalent listings than new listings. Additionally, the time to transplant has increased over time for both new and prevalent listings.

The Committee would like to develop a manuscript for publication on these analyses and present the data at the American Transplant Congress.

Pancreas Outcomes Subcommittee minutes can be found in **Exhibit F**.

3. Retrospective Review of Waiting Time Cases

On October 26, 2011, Joseph Magliocca, MD, chair of the Pancreas Waiting Time Subcommittee updated the Committee on the waiting time transfer cases considered since the March 2011 meeting. There were three candidates who requested a transfer of waiting time between pancreas alone (PA) and pancreas islet (PI) registrations. According to Policy 3.8.2.1 (Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Cell Candidates), any transfer of waiting time between PA and PI registrations require approval by the Committee.

The subcommittee reviewed a waiting time modification request by e-mail on July 21, 2011 through July 26, 2011. A candidate was listed for PA on 05/25/2004. The listing was changed to PI on 12/16/2010. The patient has since become ineligible for PI under the center's clinical trial protocol. The center changed the listing back to PA and requested a waiting time transfer so that the PA waiting time begins on 05/25/2004. The subcommittee voted to modify the candidate's waiting time on the pancreas list to begin on 05/25/2004. (3-Support, 0-Oppose, 0-Abstain)

The subcommittee reviewed two waiting time modification requests by e-mail on October 7, 2011 through October 12, 2011. In both cases, the candidates requested that their waiting time from the PA registration at one center be transferred to a PI registration at another center. The subcommittee voted to approve the transfer of waiting time for the candidate in case 1 (7-Support, 0-Oppose, 0-Abstain) and for the candidate in case 2 (6-Support, 1-Oppose, 0-Abstain).

The Committee voted to endorse the Pancreas Waiting Time Subcommittee's decisions. (16-Support, 0-Oppose, 0-Abstain)

Pancreas Waiting Time Subcommittee minutes and supporting documentation can be found in **Exhibit G**.

4. Review of US Public Health Service Guidelines

On October 20, 2011, the Committee discussed the US Public Health Service guidelines for reducing transmission of HIV, HBV, and HCV through solid organ transplantation. These guidelines are updated from the 1994 guidelines regarding the risk of transmission of HIV. The Committee thought the newly defined risk factors were not adequately data driven and were overly broad. The factors under sexual contact will increase the number of donors classified as increased risk, which could result in organ wastage. Candidates may turn down organs based solely on this designation. Also, the timeframes for increased risk behavior are too wide if NAT testing results are available. If NAT results are available, only increased risk behavior in the previous two weeks is most relevant. Thus, for donors in lower risk categories (e.g. number of sexual contacts, monogamous male homosexual relationship), behavior beyond two weeks should not considered to be high risk. The Committee supports NAT testing for increased risk donors. However, testing for low risk donors will result in false positives that could lead to organ wastage as well as the very small risk of false negatives in very high risk donors (e.g. intravenous drug use which warrants continued use of the high risk label even with a negative NAT test. Requiring testing for all donors may increase the cost of transplantation with little benefit among lower risk donors, and with the real risk that organs will be discarded unnecessarily leading to waiting list death. Furthermore, NAT testing is not widely available. In the case of unstable donors, waiting for NAT testing could result in not being able to use any of the donor's organs. These requirements should be considered in the context of solid organ transplantation where there is a shortage of organs and the impact of discards from false positives is greater than in blood donation. The Committee inquired why the requirements for NAT testing for HBV are inconsistent with the requirements for NAT testing for HIV and HCV.

The Committee thought the requirements for storing samples for future testing on deceased donors should be clarified to indicate that it is the Host OPO**, not the transplant center**, that must store the specimen. For storing living donor samples for future testing, the Committee thought 10 years was too long. There are also HIPAA concerns with storing samples from living donors. Doing so requires consent from the donor. Retaining the records of the testing should be sufficient. There will be cost and labor involved in complying with these requirements. If the requirement is costly, there needs to be evidence that the requirement provides sufficient benefit to justify these decisions. Neither has been demonstrated for these storage requirements.

The Committee inquired whether the infusion of crystalloid and colloid solutions and blood transfusions result in higher false negative results for NAT testing. There should be a prospective study to determine if this is the case.

The Committee was concerned about the requirement that all stored blood vessels from a donor found to be HIV, HBV, or HCV infected should be retrieved and quarantined immediately and either used only for research purposes or destroyed. The Committee believes automatic disposal of vessels will hurt more people than it saves. There is no reason not to use a vessel from a donor found to be infected with HBV, or HCV in a recipient who received an organ from the same donor. Just because a vessel is positive for HBV or HCV does not mean it should be discarded. The use of these vessels should follow the same standards as for HBV or HCV infected organs. It should not be forbidden but rather allowed with appropriate precautions including storage, labeling, pre-implantation time out, and documentation of use or destruction.

5. Islet Subcommittee Update

On October 26, 2011, Ty Dunn, MD, chair of the Islet Subcommittee, provided an update on the Islet Subcommittee. In January 2011, the subcommittee conducted a survey of program directors of active and inactive pancreas islet transplant programs in the US to investigate barriers to pancreas islet procurement and placement. Islet transplant activity in the US contracted dramatically from 2002 to 2008. The survey results suggest that the major barriers are primarily financial in nature. Specifically, handling of organ acquisition charges, transportation costs, and transportation charges are major obstacles. Modification of current financial charge practices or approval of islets by third party payers as reimbursable therapy for Type I diabetes is needed for islet transplantation to expand to its full potential. An abstract has been drafted for submission at professional meetings (e.g., IPITA, ATC, AOPO, NATCO). The subcommittee would like to share these findings with the OPO community.

The Islet Subcommittee is also considering how to track every islet infusion in the OPTN database. Currently, islet infusions are not being reported to the OPTN. Potential solutions include requiring centers to remove a candidate from the pancreas list after each infusion (this option is already programmed but not required) or having islet programs submit logs that include basic information about each islet infusion performed including recipient outcome data as is required for solid organ transplantation.. Policies and bylaws about islet reporting need to be updated based on how the data will be collected. The subcommittee will work on a public comment proposal to require reporting of each infusion and clean up policy and bylaw language.

The Committee also discussed the lack of follow-up forms for pancreas islet infusions. In the past, the Committee had identified several barriers to creating islet follow-up forms. First, there were concerns about how to program islet follow-up forms if islets from multiple donors were infused into a candidate at the same time. Second, the federal government funds another group, the Collaborative Islet Transplant Registry (CITR), to collect data on islet outcomes. Third, if there are multiple infusions for a candidate, it may be difficult to determine which infusion the follow-up forms cover. However, the Committee

strongly believes that this issue warrants further investigation prior to considering the relative position of pancreas allocation for islets compared to whole organ transplant.

6. Referral from the Membership and Professional Standards Committee (MPSC) on Pancreas Program Functional Activity

On October 26, 2011, the Committee considered a referral from the MPSC. The MPSC's Performance Analysis and Improvement Subcommittee (PAIS) conducts routine reviews of all transplant programs' performance by monitoring program outcomes and activity levels. All kidney, liver, heart, lung, and pancreas programs that do not perform a transplant during a specified time period are considered to be "functionally inactive." Pancreas programs are expected to perform at least one pancreas (including kidney/pancreas) transplant every six months. The majority of programs reviewed for inactivity are pancreas programs, and many of these programs have been reviewed for multiple periods of inactivity.

On behalf of the MPSC, the PAIS requested that the Committee consider modifying the pancreas functional inactivity threshold and provide the MPSC with a summary of the final outcome of the discussions. The PAIS has expressed concerns on several occasions that this level of activity seems too low for a program to remain current both with surgical skills and programmatic administrative competence. With these current activity levels, the PAIS cannot recommend voluntary inactivation, for instance, for these programs experiencing multiple periods of inactivity.

The Committee tasked the Pancreas Outcomes Subcommittee with requesting the necessary data to evaluate this situation and with drafting a response to the MPSC. The Committee requested that the bylaws relating to pancreas programs be provided to the Committee. Among the data collected will be the impact of program closure on access to transplant, number of candidates listed for transplant at centers not performing pancreas transplants, and the impact of recent changes in the kidney payback system that facilitate SPK transplant.

7. Kidney Transplantation Committee Update

On October 26, 2011, Richard Formica, MD, vice chair of the Kidney Transplantation Committee (Kidney Committee) provided the Committee with an update on the Kidney Committee's activities. In early 2011, the Kidney Committee released a concept document for a new kidney allocation system which contained the following potential elements:

- Utilize a kidney donor profile index (KDPI) to better characterize donor kidneys and to provide additional clinical information for patients and providers to consider during the transplant evaluation process and organ offer process.
- Allocate the majority of organs (80%) by age matching so that candidates within 15 years (older and younger) of the donor are prioritized.
- Allocate some kidneys (20%) by a kidney donor profile index (KPDI) and estimated recipient post-transplant survival.

The Kidney Committee received feedback in response to the concept document that there is general agreement with longevity matching for some kidneys and support for use of KDPI as a clinical tool and in allocation. However, there were also concerns over use of age matching (+/-15 years). As a result, the Kidney Committee decided not to move forward with age matching. The Kidney Committee plans to move forward with a proposal that incorporates the following elements:

- Using longevity matching for top 20% of donor kidneys;
- Applying the A_2/A_2B committee-sponsored alternative system nationally;
- Incorporating ESRD time in addition to waiting time

- Using KDPI as an allocation tool;
- Creating a sliding scale for CPRA points;
- Allowing expedited placement for high KDPI kidneys; and
- Promoting broader sharing for the most highly sensitized candidates (CPRA >=98%).

In the proposed system, the top 20% KDPI kidneys will be allocated to the candidates with the top 20% estimated post transplant survival. 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.

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 Pancreas Transplantation Committee asked whether the top 20% would be in the local unit, across the region, or nationally. Those options are being modeled. Additionally, the Kidney Committee is still considering whether candidates remain in the top 20% once they reach the top 20% or if it is the top 20% of candidates at the time of the match. The Committee was concerned about the impact this policy could have on living donation for younger candidates. Dr. Formica explained that the Kidney Committee expects waiting time to remain similar because even the top 20% will not have access to all of the kidneys. Some Committee members were concerned that this policy would give priority to the younger candidates who often are less likely to be compliant or to have insurance. The Committee also thought candidates who were at high risk for waiting list mortality because they are on immunosuppression should qualify for the top 20%, including those who have previously undergone pancreas or liver transplantation and now have significant reductions in renal function. Committee members recommended defining the top 20% at the regional level with matches between a candidate and donor in the same local unit receiving more points to reduce cold ischemic time. The Committee inquired whether list exchange will be included in the new kidney allocation system. Some arguments have been made that list exchange disadvantages blood type O candidates, and the Kidney Committee's plan is currently not to include list exchange.

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 Kidney Committee has sent letters to each OPO regarding the Kidney Committee's recommendations on whether the variance will be included in national kidney allocation policy. OPOs that wish to propose that its variance be reconsidered for national allocation policy will be asked to submit a brief rationale. OPOs involved in alternative local units or sharing arrangements who wish to maintain variances due to unique geographical constraints will be asked to submit a rationale as well. The Committee will review any responses to its letters before making final recommendations to the Board of Directors either to incorporate the variance into national kidney allocation policy, to acknowledge that the OPO has a permanent need for an alternative arrangement and to codify this variance in policy, or to discontinue the variance.

8. Policy Oversight Committee Update

On October 26, 2011, Dr. Axelrod and Dr. Fridell updated the Committee on the activities of the Policy Oversight Committee (POC). The POC is currently providing oversight to the policy rewrite project, which is translating policy into a better structured, more reader-friendly format. The POC also evaluates committee activities and makes recommendation to the Executive Committee on whether the activities should be approved. The POC is working on multi-organ allocation, specifically liver/kidney, heart/kidney, and kidney/pancreas. There has been some discussion of listing criteria for these organ combinations with a safety net for candidates who do not meet the listing criteria but then have ongoing renal failure.

9. Public Comment

a. Proposal to Clarify Requirements for Waiting Time Modification Requests

Kidney Transplantation Committee

Current OPTN policies regarding submission of waiting time modification requests are not clear, leading to wasted time for the transplant centers that submit requests, for OPTN Contractor staff who process requests, and for the Committees that review requests. Required documentation is often missing and results in delays for transplant candidates to receive the waiting time that they may be entitled to receive under OPTN policy. With these proposed clarifications, the Committee believes that it will receive fewer submissions of incomplete requests and be able to act on approved requests more quickly.

The Committee considered this proposal on October 26, 2011. The Committee voted to support the proposal as written. (14-Support, 0-Oppose, 0-Abstain)

b. Proposal to Clarify and Improve Variance Policies

Policy Oversight Committee (POC)

The OPTN Contractor has initiated a plain language rewrite of the OPTN policies and bylaws. During the evaluation of the policies it was noted that significant changes to the variance policies were needed in order for members to better comply with the variance policies, create uniformity in how members apply for any type of variance, and promote reliability in the category of information provided with each variance application. As such, the following modifications are proposed:

- Elaboration of existing variance policies to provide clearer guidance to the community on how to apply for, modify, or dissolve a variance;
- Gathering all requirements into one policy category for the variance application, review, approval, modification, dissolution, and appeal processes;
- Eliminating redundancy in existing variance policies; and,
- Rewriting the variance policies using plain language.

The Committee considered this proposal on October 26, 2011. The Committee voted to support the proposal as written. (15-Support, 0-Oppose, 0-Abstain)

c. Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions

Ad Hoc International Relations and Ethics Committees

This proposal clarifies the data collected about the citizenship and residency of donors and recipients. The proposal also amends the audit trigger policy, allowing the Ad Hoc International Relations Committee to review the circumstances of any transplant of non-US residents/non-US citizens and make a public report. The proposal also contains technical amendments and removal of requirements that are not enforceable.

The Committee considered this proposal on October 26, 2011. The Committee was very concerned about the implications of this proposal. There was not support for an audit to be conducted by a group other than the MPSC. The Committee was uncomfortable with allowing a group to conduct an audit with no defined purpose of the audit. Additionally, the Committee did not find the new definitions useful, especially since they are not consistent with any existing residency definitions. Candidates will self-report their residency status so the data may not be accurate. Furthermore, trying to define immigration status in the current political climate may be misinterpreted by the general public. The Committee thought that there should be no restriction on who can receive pancreata because there is not a pancreas shortage. The Committee recommended not having any residency definitions and entirely removing the audit requirements. The Committee did support the technical changes to the policy to clean up outdated language. The Committee tasked the Pancreas Outcomes Subcommittee with developing a response to this proposal regarding the audit requirements and residency definitions.

d. **Proposed Update to the Calculated PRA (CPRA)**

Histocompatibility Committee

The purpose of this proposal is to update CPRA so it can better reflect current laboratory practices as well as the current donor pool. These revisions include updating the HLA frequencies used to calculate CPRA, the addition of the antigen HLA-C to the calculation, and the addition of a question to the waiting list to better interpret 0% default CPRA value.

The Committee considered this proposal on October 26, 2011. The Committee suggested that the option for whether a candidate was tested for anti-HLA antibodies be re-worded from "yes, antibodies detected" to "yes, clinically significant antibodies detected" and from "yes, no antibodies detected" to "yes, no clinically significant antibodies detected". The Committee also requested more information on how the Histocompatibility Committee plans to handle desensitized candidates so that they can still receive priority for zero mismatch organs even if candidate does not have enough unacceptable antigens entered to yield a CPRA of greater than or equal to 80% after desensitization. The Committee voted to support the proposal. (15-Support, 0-Oppose, 0-Abstain)

10. Committee Orientation

On October 26, 2011, Dr. Axelrod welcomed the new Committee members, and James Bowman, III, MD, HRSA representative on the Committee, welcomed the Committee on behalf of the Health Resources and Services Administration. The Committee requested that HRSA provide ongoing guidance on how to deal with the conflicting incentives created by the organs transplanted per donor metric for OPOs from the Centers for Medicare and Medicaid Services (CMS) and the graft outcomes metrics for transplant hospitals. Additionally, the Committee was interested in working with HRSA to pursue discussions with the CMS on islet standard acquisition charges.

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

Pancreas Transplantation Committee Charge

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

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

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

2010-2011 Pancreas Transplantation Committee Work Plan:

1. Implement the Pancreas Allocation System: (approved by the Board in November 2010) that will increase utilization of the pancreas, increase access for SPK and PA candidates, reduce waiting time for all pancreas candidates without adversely affecting adult and pediatric renal transplantation candidates, and reduce geographic inequities of access and waiting time.
2. Pancreas for technical reasons: It is not clear how pancreata used for technical reasons should be reported. Transplant centers and OPOs do not always agree on the appropriate disposition code (transplanted or not transplanted) for pancreata that are used for technical reasons as part of multi-organ transplants, so the disposition can be reported differently. This discrepancy in reporting results in data errors.
3. Review Pancreas Primary Physician/ Surgeon Bylaws: The bylaw requirements for primary pancreas physicians and surgeons stands to be reviewed for currency and improvements.
4. Report Islet Infusions: There is currently no OPTN tracking of islets once they have been infused. There is a mechanism for report islet infusions in UNet℠, it is just not required in policy.

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

- Committee System and Member Roles and Responsibilities by Elizabeth Sleeman
- Overview of Policy Development Process and Process for Developing Committee Strategic Priorities by Elizabeth Sleeman
- Introduction to the UNOS Research Department by Jennifer L. Wainright, PhD
- Overview of the Scientific Registry of Transplant Recipients (SRTR) by Sally Gustafson, MS, and Raja Kandaswamy, MD
- Current Activities and Subcommittees by David Axelrod, MD, MBA

The Committee inquired whether c-peptide will be collected in the new pancreas allocation system. C-peptide will be collected in the Waitlist℠ application in order for a kidney/pancreas candidate to accrue waiting time, but the field was not approved for data collection on registration and follow-up forms. The Committee noted the need for further discussion on how to define and report pancreas graft failure.

The Committee discussed what they would like evaluate when the new pancreas allocation system is implemented, including:

- Change in waiting list mortality;
- Pancreas utilization rates;
- Impact, if any, on patient and graft survival;
- The appropriate c-peptide and BMI values for a candidate to qualify to accrue waiting time for a kidney/pancreas registration; and
- Cardiovascular outcomes.

The Pancreas Allocation Subcommittee will begin developing a thorough evaluation plan.

Table 13: Pancreas Transplantation Committee Attendance

PANCREAS COMMITTEE		JULY 1, 2011 - OCTOBER 31, 2011	
	MONTH	OCTOBER	OCTOBER
	DAY	20	26
	FORMAT	Live Meeting/ Teleconference	In Person
NAME	COMMITTEE POSITION		
David Axelrod, MD, MBA	Chair	X	X
Jonathan Fridell, MD	Vice Chair	X	X
Sayeed Malek, MD	Regional Rep.		
James Lim, MD	Regional Rep.		
Joseph Magliocca, MD	Regional Rep.	X	X
John Duffy, MD	Regional Rep.		X
Jonathan Fisher, MD, FACS	Regional Rep.	X	X
Nelson Goes, MD	Regional Rep.	X	X
Ty Dunn, MD	Regional Rep.		X
Michael Morris, MD	Regional Rep.	X	X
Bernd Schroppel, MD	Regional Rep.		X
Edmund Sanchez, MD	Regional Rep.	X	X
Charles Bratton, MD	Regional Rep.	X	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		By phone
Monica Grafals, MD	At Large		X
Albert Hwa, PhD	At Large		
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	X
Monica Lin, PhD	Ex. Officio		
Ba Lin, MS, MPH	Ex Officio	X	By phone
Raja Kandaswamy, MD	SRTR Liaison		X
Sally Gustafson, MS	SRTR Liaison		X
Bertram Kasiske, MD, FACP	SRTR Liaison		By phone
Elizabeth Sleeman, MHA	Committee Liaison	X	X
Jennifer Wainright, PhD	Support Staff	X	X
Rich Endert	Support Staff		X