Interim Report
Pancreas Transplantation Committee

February 18, 2010
Live Meeting/ Teleconference

The following is a summary of the Pancreas Transplantation Committee meeting on February 18, 2010 held via Live Meeting and Teleconference.

1. Public Comment Proposal for an Efficient, Uniform Pancreas Allocation System

The Committee reviewed the draft public comment proposal for an efficient, uniform pancreas allocation system. The final version of this proposal is attached as **Exhibit A**. The purpose of this proposal is to improve the national pancreas allocation system. This improvement is consistent with the OPTN long-range strategic goals and priorities:

- to increase geographic equity in access and waiting time to deceased donor organs for transplantation;
- to maximize capacity of deceased donor organ transplantation;
- to achieve operational efficiency and cost-effectiveness of implementing and maintaining the organ allocation system.

Specific objectives of the proposed allocation system for pancreas transplantation:

- reduce geographic inequities of pancreas utilization, access to transplantation, and transplant waiting time;
- maximize capacity by improving the opportunity for pancreas candidates to receive a transplant;
- enhance efficiency and cost-effectiveness, and minimize complexity of implementing and maintaining the operational requirements of a new pancreas allocation system; and
- optimize pancreas transplant access without adversely affecting kidney transplantation. Specifically, the committee evaluated the transplant volume for adult and pediatric kidney recipients as well as ethnicity, age, and gender of recipients.

Methodology to achieve these objectives:

- combine pancreas-alone (PA) and simultaneous pancreas-kidney (SPK) candidates onto a single match run list;
- allow local candidates who are allocated a pancreas from the combined list but who also require a kidney transplant, to receive a kidney independently of the kidney-alone match run if they meet specific qualifying criteria;
- institute objective medical qualifying criteria relating to renal dysfunction and diabetes for SPK candidates to accrue waiting time;
- allocate deceased donor pancreata separately from the current kidney allocation system so that pancreas candidates are allocated organs that precede kidney paybacks and pediatric and adult kidney-alone (KI) recipients
- monitor allocation of standard criteria deceased donor kidneys for pediatric and adult KI recipients and SPK recipients with respect to donor ages ≤35 and >35 years, as well as ethnicity, age and gender.

Proposal

In order to reach these goals, the committee proposes:

1. Combining PA and SPK candidates onto a single match run list;

2. Allowing local candidates who are allocated a pancreas from the combined list but who also require a kidney transplant, to receive a kidney independently of the kidney-alone match run if they meet specific qualifying criteria;

3. Establishing specific qualifying criteria for a diabetic uremic patient to accrue SPK waiting time:
    a. The candidate must qualify for a kidney transplant based upon the current qualifying criteria as defined by Policy 3.5.11.1(Time of Waiting):
        i. on dialysis; **OR**
        ii. GFR ≤ 20 mL/min; **OR** CrCl ≤ 20mL/min
    b. Eligibility for SPK waiting time will be restricted to patients with diabetes mellitus who meet one of the following criteria:
        i. On insulin **AND** c-peptide ≤ 2 ng/mL; **OR**
        ii. On insulin **AND** c-peptide > 2 ng/mL **AND** BMI ≤ 30 kg/m^2
    c. Listing criteria for pancreas-alone transplantation will remain the same. See Policy 3.2.7 (Pancreas Waiting List Criteria) below:

3.2.7 Pancreas Waiting List Criteria. Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.

4. Allocating deceased donor pancreata separately from the current kidney allocation system such that pancreas candidates are allocated organs that precede kidney paybacks and pediatric and adult kidney-alone (KI) recipients;

5. Having the committee monitor allocation of standard criteria deceased donor kidneys for pediatric and adult KI recipients and SPK recipients with respect to donor ages ≤35 and >35 years.

The Committee also reviewed the supporting evidence section in detail. The Committee specifically voted to support option 9, which is a combined SPK and PA list that comes before all kidney-alone candidates in allocation. (11-Support, 0-Oppose, 0-Abstain) The Committee discussed the SPK qualifying criteria and noted that the most controversial point would likely be the BMI cut-off. The Committee also voted to endorse the SPK qualifying criteria as written. (11-Support, 0-Oppose, 0-Abstain) The Committee reviewed the simulation results for specific groups. For African American kidney candidates, the increase between the current system (2791 ±22) and option 9 (2872 transplants ±26) is more than four times greater than the between run standard deviation and is unlikely to be caused by random variation. The number of pediatric kidney transplants increase from the current system to option 9, but the difference is not greater than the between run standard deviation. The Committee voted to send the proposal for an efficient, uniform pancreas allocation system out for public comment. (11-Support, 0-Oppose, 0-Abstain)

2. Proposal from the Histocompatibility Committee to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers.

Lori Gore, liaison to the Histocompatibility Committee, reviewed the Histocompatibility Committee's proposal to require that deceased donor HLA typing be performed by DNA methods and identify additional antigens for kidney, kidney-pancreas, pancreas, and pancreas islet offers. This proposal would require that OPOs and their associated laboratories perform HLA typing of deceased donors by DNA methods and identify the HLA-A, -B, -Cw, -DR and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers. The Histocompatibility Committee plans to send this proposal out for public comment in the spring 2010 public comment cycle and wanted the Pancreas Transplantation Committee's input before public comment.

The Committee inquired whether the DNA methods could be completed before pancreas offers are made. DNA methods take less time than serological methods and can be completed before placement and procurement if the lab has the staff trained to do the DNA tests at all times (including nights and weekends). Additionally, DNA methods can be done on peripheral blood unlike serological testing. Most labs (95%) already have the ability to do these tests, so the extra costs would likely be around training and staffing. Only a very few labs would need to purchase equipment. Many labs are not performing DNA testing at all times, such as nights or weekends. For the match run, the labs are performing serological testing, but they are submitting the DNA results for the histocompatibility forms. The Histocompatibility Committee has identified discrepancies between the serological results on the match run and the DNA results on the histocompatibility forms, meaning that organs may be being placed with inaccurate tissue typing. The Committee supported the proposal. (9-Support, 0-Oppose, 0-Abstain)

Table 1: Pancreas Committee Attendance

PANCREAS COMMITTEE		JANUARY 1, 2010 - JUNE 30, 2010
	MONTH	February
	DAY	18
	FORMAT	Live Meeting/ Teleconference
NAME	COMMITTEE POSITION	
Dixon Kaufman MD, PhD	Chair	X
David Axelrod MD, MBA	Vice Chair	X
James Markmann MD, PhD	Regional Rep.	
Stuart Geffner MD	Regional Rep.	
Rubin Zhang MD, PhD	Regional Rep.	
Jacqueline Lappin MD	Regional Rep.	
Horatio Rilo MD	Regional Rep.	
David Scott MD	Regional Rep.	X
Brian Flanagan PhD	Regional Rep.	X
Ahmad Abdulkarim MD, PhD	Regional Rep.	X
Mark Laftavi MD, FACS	Regional Rep.	
Jonathan Fridell MD	Regional Rep.	X
Leonard Cortese	Regional Rep.	X
Chris Chiarello	At Large	
Mary Beth Drangstveit RN	At Large	X
Albert Hwa PhD	At Large	
Christian Kuhr MD	At Large	
Patricia Niles RN, BS, CPTC	At Large	
Meg Rogers	At Large	X
Paul Volek MPH	At Large	X
Rainer W. Gruessner MD	Ex. Officio	
James Bowman III, MD	HRSA	
Elizabeth Ortiz-Rios MD, MPH	HRSA	X
Emily Messersmith PhD	SRTR Liaison	X
Maria Larkina, MS	SRTR Liaison	X
Randall Sung MD	SRTR Liaison	X
Elizabeth Sleeman MHA	Committee Liaison	X
Jennifer Wainright PhD	Support Staff	X
Kerrie Cobb	Support Staff	X
Lori Gore	Support Staff	X