At-a-Glance

- **Proposal to Develop an Efficient, Uniform National Pancreas Allocation System**

- **Affected Policies:** Policy 3.8 (Pancreas Allocation Policy), Policy 3.5 (Kidney Allocation Policy), Policy 3.2 (Waiting List), Policy 3.3 (Acceptance Criteria), Policy 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation), and Policy 3.9 (Allocation Systems for Organs not Specifically Addressed)

- **Pancreas Transplantation Committee**

  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.

- **Affected groups**
  Directors of Organ Procurement, OPO Executive Directors, OPO Medical Directors, OPO Coordinators, Transplant Administrators, Transplant Data Coordinators, Transplant Physicians/Surgeons, PR/Public Education Staff, Transplant Program Directors, Transplant Social Workers, Organ Candidates, Living Donors, Donor Family Members, General Public

- **Specific requests for comment**

  1. Are the specific objectives of the proposed allocation system for pancreas transplantation appropriate? Are there other objectives that should be considered?
  2. Is the methodology to achieve the specific objectives reasonable?
  3. Do you believe that the design for allocation of pancreata gives pediatric and adult kidney-only candidates sufficient access to transplant? Do you agree that the medical qualifying criteria relating to renal dysfunction and diabetes for SPK candidates are objective and reasonable?
  4. Should the new policy apply to patients currently listed for SPK or PA transplantation?
  5. Does clinical evidence sufficiently support the proposal to combine the two pancreas allocation lists and is the proposal well justified under UNOS/OPTN policy development guidelines?

  Please consider and comment on the entire proposal. Do not feel limited to the focused questions. They simply point out key issues within the proposal that may specifically interest some readers.

Proposal to Develop an Efficient, Uniform National Pancreas Allocation System

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Pancreas Transplantation Committee

Summary and Goals of the Proposal:

This purpose of this proposal is to improve the pancreas allocation system. This improvement is consistent with the OPTN long-range strategic goals and priorities:

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

Depending on where a transplant candidate lives, some candidates may have to wait longer than others for a pancreas transplant. The first goal of the proposed pancreas allocation system reduces the geographic inequities related to deceased donor pancreas utilization, access to transplantation, and how long the candidates wait. Accomplishing these goals would mean instituting a consistent national system. Under this system, if a diabetic, uremic candidate on the list for a simultaneous pancreas kidney (SPK) transplant is allocated a pancreas from a local deceased donor and accepts it, then that candidate would also receive a kidney from the same deceased donor.

The second goal is to maximize capacity by improving the opportunity for pancreas candidates to receive a transplant. The Pancreas Transplantation Committee (the Committee) would accomplish this goal by combining simultaneous pancreas-kidney (SPK) and pancreas-alone (PA)[1] candidates onto a single match run list. On a single list, candidates for both categories of pancreas transplants would have an equal opportunity to receive offers of high quality organs. A single list for all pancreas candidates would be operationally efficient for OPOs. It would also retain some high quality kidneys for the kidney allocation system in the situations in which a pancreas graft is allocated for pancreas-alone transplantation. Right now, diabetic, uremic candidates are not motivated to receive a kidney from a living donor and then wait on the list for only a pancreas because most donation service areas (DSAs) allocate organs to SPK candidates before allocating them to PA candidates. In this situation, if a candidate chose to take a living donor (LD) kidney and then wait on the list for a pancreas, that candidate would receive a local pancreas offer only if all the local SPK candidates had turned down that pancreas. This process results in additional waiting time for pancreas-after-kidney transplantation compared to declining a LD kidney and continuing to wait for the SPK transplant. Also, in many circumstances, these pancreata that are refused by all the SPK candidates are of lower quality than the pancreata the candidate would be able to receive if he or she had waited for an SPK rather than taking the living donor kidney. This situation discourages candidates who need both a kidney and a pancreas to take a living donor kidney followed by a deceased donor pancreas. The proposed allocation change would mean that candidates may be more inclined to accept a kidney from a living donor.

[1] PA includes both pancreas after kidney (PAK) and pancreas transplant alone (PTA).

The third goal is to enhance efficiency and minimize complexity of implementing and maintaining the operational requirements of a new pancreas allocation system. The proposed method would allocate deceased donor pancreata separately from the current kidney allocation system. This method would effectively disentangle the system of a pancreas allocation from kidney allocation. There appear to be enough deceased donor kidneys (both standard and expanded criteria) available to accommodate this allocation change without adversely affecting pediatric or adult kidney transplant activity. Importantly, this process would result in a faster and more efficient method of allocating organs. It would also be less costly to implement and maintain.

The fourth goal is to 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. This goal would be accomplished by instituting objective medical qualifying criteria relating to renal dysfunction and diabetes for SPK candidates. SPK candidates would be eligible to accrue SPK waiting time only if they meet qualifying criteria based on renal and metabolic function. The kidney function criteria for qualifying includes either being on dialysis, having a creatinine clearance (CrCl) less than or equal to 20 mL/min, and/or having a glomerular filtration rate (GFR) less than or equal to 20 mL/min. Qualifying pancreas function criteria includes either being on insulin and having a c-peptide values less than or equal to 2 ng/mL or being on insulin with glycemic intolerance with a c-peptide value greater than 2 ng/mL and a body mass index (BMI) less than or equal to 30 kg/m^2. In addition, a single list for all pancreas transplant candidates would retain some high quality kidneys for the kidney allocation system. Finally, the proposal includes a system to 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.

Background and Significance of the Proposal:

The Committee has spent several years developing a national pancreas allocation system to better address the needs of patients with diabetes with and without concurrent renal failure. The policy revisions outlined in this proposal are particularly important in light of potential changes to policy regarding kidney allocation that the Kidney Transplantation Committee (Kidney Committee) is currently considering. One of the possible components of a revised kidney allocation system is to disentangle SPK allocation from kidney allocation which would allow pancreata and kidneys to be allocated together for those candidates needing simultaneous pancreas-kidney transplantation.

Concerns with the Current Pancreas Allocation System

The Committee has several concerns with the way pancreata are currently allocated. First, there is no nationally established allocation practice for patients with diabetes and renal failure. Current pancreas allocation policy (Policy 3.8) allows OPOs several choices on pancreas (PA) allocation practice:

- The candidates can be listed on separate or combined SPK / PA waiting lists,
- The kidney may be allocated to SPK candidates based upon the kidney-pancreas match run, the kidney-alone (KI) match run, or a combination of match runs.

Consequently, waiting time for SPK transplant varies widely across the country because of local or regional allocation decisions. Furthermore, current practice does not seek to maximize the utilization of the pancreas. SPKs receive offers after other renal/extra-renal multi-organ transplants, kidney paybacks, and zero mismatch kidney-alone candidates. This allocation order leads to discard of grafts that would likely be used if offered in the context of SPK transplantation but are declined for PA transplants. Under the current system, 66% of pancreata are used for SPK transplant candidates;

however, there are no specific listing criteria for SPK transplants with respect to the degree of pancreas dysfunction necessary to qualify to receive waiting time for an SPK transplant.

Why Now?

The current environment in pancreas transplantation provides an appropriate context for a change to the national pancreas allocation system. The pancreas is the only organ that does not have a consistent national system for allocation in the context of simultaneous pancreas/kidney transplantation. Additionally, changes to the kidney allocation system, specifically the possibility for the kidney to follow the pancreas in allocation (i.e. allocating from the PA or SPK list before allocating from the KI list), are not feasible without changes to pancreas allocation. The Committee was thus challenged to develop a national pancreas allocation system that will be acceptable to the pancreas transplantation community, the kidney transplantation community (adult and pediatric), and the other major stakeholders, and that would meet the policy objectives outlined in the OPTN long range strategic goals and priorities. As part of its development of a new kidney allocation system, the Kidney Committee requested that the Pancreas Committee investigate the development of a pancreas allocation policy where the kidney follows the pancreas locally to accompany the new kidney allocation system and, specifically, to define appropriate of SPK qualifying criteria.

Goals of a New National Pancreas Allocation System

- establish a uniform, national system to govern how pancreas allografts are allocated;
- reduce geographic inequities of access and waiting time;
- increase utilization of the pancreas allografts;
- maximize capacity of pancreas transplantation to allow more pancreas transplant candidates to have an opportunity for transplantation;
- standardize the pancreas allocation process to increase access to organs and reduce waiting times for both SPK and PA candidates without significantly adversely affecting access and waiting times for pediatric and adult KI recipients, including impact on ethnicity, age, and gender of KI recipients;
- develop appropriate qualifying criteria for candidates waiting for an SPK transplant;
- promote appropriate utilization of SPK transplantation if/when a new kidney allocation system is developed;
- enhance operational efficiency, reduce computer programming requirements, and decrease OPO and OPTN administrative costs for pancreas allocation by disentangling it from the kidney allocation system.

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.

Read more below on how each of these concepts were developed and what alternatives were considered.

Combined SPK and PA List

Outcomes for pancreas transplant alone (PTA) and pancreas after kidney (PAK) transplants have been steadily improving. Pancreas graft survival rates for recipients of solitary grafts are similar to the pancreas graft outcomes of SPK transplant recipients. Therefore, the Committee has considered combining the SPK and PA waiting list. The Committee noted several advantages to combining the SPK and PA waiting lists:

- A single list for all pancreas candidates eliminates complexities in pancreas allocation;
- Candidates for all types of pancreas transplants have an equal opportunity to receive offers for high quality pancreata;
- Increased national consistency in pancreas allocation;
- Does not discourage the use of living kidney donors for appropriate candidates with PAK to follow;
- Retains high quality kidneys within the kidney allocation system in cases in which the pancreas is used for solitary transplant;
- Is consistent with the allocation of kidney allografts with other extra-renal organs.

Alternatives Considered

The Committee considered a system where SPK candidates have priority over PA candidates. One argument for this method was that SPK candidates are more likely to die while waiting for a transplant and that they should perhaps receive additional priority. However, the simulation results showed that this option had the potential to have a larger impact on kidney-alone candidates. Furthermore, giving priority to SPK candidates over PTA/PAK candidates disadvantages candidates who wish to pursue living donor kidney transplantation followed by deceased donor pancreas transplantation because they would not have equal access to high quality pancreata. This system discourages patients from considering the option of pre-emptive living donor kidney transplant.

The Committee also discussed a system that gives PA candidates priority over SPK candidates. This approach to prioritization for PA candidates conflicts with data that show that SPK candidates are much more likely to die on the waiting list than PA candidates.

The proposal of having a waiting list that combines SPK and PA candidates also simplifies OPO operations and reduces the programming burden for the OPTN. This efficiency should result in reduced cold ischemic times, decreased confusion caused by the current use of multiple lists, and improved utilization of available pancreatic allografts.

Thus, the Committee concluded that a combined list is the best path forward because it provides all candidates access to a high quality pancreas regardless of their need for a kidney.

SPK Qualifying Criteria

The Committee proposes that candidates must meet objective, medical qualifying criteria relating to both kidney function and glucose intolerance. The candidate must qualify for a kidney transplant based upon the current qualifying criteria defined in Policy 3.5.11.1(Time of Waiting):

1. on dialysis; **OR**
2. GFR ≤ 20 mL/min; **OR** CrCl ≤ 20mL/min

Eligibility to accrue waiting time for an SPK transplant will be restricted to patients with diabetes mellitus who meet one of the following criteria.

1. On insulin **AND** c-peptide ≤ 2 ng/mL; **OR**
2. On insulin **AND** c-peptide > 2 ng/mL **AND** BMI ≤ 30 kg/m^2

These policy changes will not affect eligibility for pancreas transplant alone. These criteria will remove the potential for candidates who are not in renal failure or who could improve their glucose intolerance by other methods from receiving waiting time for an SPK transplant. Candidates who do not meet SPK qualifying criteria may still be eligible to receive waiting time for a kidney-alone or a pancreas-alone transplant.

Candidates who do not meet SPK qualifying criteria will not be eligible to accrue waiting time for an SPK transplant, although they may still receive waiting time for a pancreas-alone transplant. If SPK candidates meet qualifying criteria, their waiting time will begin on the date that they meet the kidney portion of the qualifying criteria (i.e., date of start of dialysis or date of GFR or CrCl test that is 20 mL/min or less). Please note that this method of assigning waiting time is different than the current method of having waiting time begin the date the candidate is listed if they meet the qualifying criteria. The Committee anticipates that the Kidney Committee may adopt this new method in a new kidney allocation system as well. The Committee intends to be consistent with the direction of kidney allocation in this area.

Waiting time for PA candidates will begin at the date of listing. If a candidate is listed for both SPK and PA, waiting times for SPK and PA are independent. Once a candidate qualifies for an SPK transplant, the candidate will remain qualified regardless of later test results. The insulin status, c-peptide, and BMI values must be the values at the time of listing or more recent values.

Pediatric SPK candidates do not have to qualify for an SPK, but if they would gain more waiting time by qualifying, they have that option.

If the qualifying criteria for a kidney-alone transplant changes, the Committee would also adopt those changes for pancreas allocation policy.

Alternatives Considered

The Committee considered proposing the following qualifying criteria:
For the kidney portion:

1. On dialysis
   OR
2. GFR ≤ 20 mL/min
   OR
3. CrCl ≤ 20 mL/min

For the pancreas portion:

1. C-peptide ≤ 2.0 ng/mL
   OR
2. Presence of anti-GAD/anti-insulin antibodies
   OR
3. (HbA1c ≥ 7.0% **OR** Clarke score ≥ 3) **AND** Insulin status= "on insulin" **AND** BMI ≤ 30 kg/m^2 **AND** Age of onset of diabetes ≤ 40

The Committee sought input from leading endocrinologists and pancreas programs on these criteria. The programs thought the criteria were too confusing and included tests that are not commonly performed. The programs suggested instituting less complex qualifying criteria, which the Committee has incorporated into this proposal. The programs also objected to qualifying criteria which specifically included language limiting transplant to Type I diabetes mellitus (DM) as there is established evidence that a small number of non-obese candidates with relatively high c-peptide akin to Type II DM also benefit from this procedure (see supporting evidence section).

The Committee considered a BMI of less than or equal to 32 kg/m^2, but other Committees, including the Kidney Committee, expressed concern that the BMI value could lead to a loophole in policy that would allow candidates who do not have a high life years from transplant (LYFT) score to receive priority for a kidney by being listed for an SPK transplant. LYFT is the difference between a candidate's median projected life span post-transplant minus his projected median wait list survival without a transplant. The Committee does not believe this situation would occur often because it does not currently occur in DSAs with priority for SPK transplant that have no qualifying criteria for SPK transplant. The Committee decided to use the standard definition of obesity as 30 kg/m^2 in the qualifying criteria in order to limit the use of SPK to non-obese, high c-peptide patients most likely to benefit from SPK transplant.

The Committee also considered whether the criteria should be criteria to appear on a match run rather than to accrue waiting time. For kidney allocation, the qualifying criteria are to accrue waiting time. The Committee is specifically seeking feedback during public comment on whether the community supports using qualifying criteria to restrict access to the match list or to allow access to the match run but limit candidates from accruing waiting time.

Pancreas Allocation Disentangled from Kidney Allocation

Local candidates on the combined PA and SPK waiting list will receive offers for pancreata based on waiting time. If the candidate needs both a pancreas and a kidney (SPK candidate), he or she will also receive an offer of a kidney from the same donor (this is what is meant by the kidney following the pancreas). To be able to receive the offer for the kidney, the SPK candidates must meet specific qualifying criteria. This concept will equalize access for SPK candidates across DSAs because SPK candidates will no longer be subject to the disparities in practice related to kidney allocation, such as payback debt. The LYFT analyses show the SPK candidates receive a higher net benefit than other types of kidney recipients (see supporting evidence section). This method decreases complexity for OPOs because OPO staff will no longer spend time arbitrating whether a kidney should be allocated to an SPK or a kidney-alone candidate. It also may reduce the time needed to allocate organs because the OPO only needs to consult one match run rather than three. This method is less costly to both implement and to maintain because changes to kidney allocation will not require related changes to pancreas allocation and vice versa.

Exhibit A shows the order of organ offers to pancreas and kidney candidates under this proposal.

Alternatives Considered

The Committee considered a system that interspersed SPK candidates with kidney-alone candidates, but this system would likely cost more money to implement and maintain. Furthermore, the Kidney Committee has suggested that removing SPK allocation from the kidney allocation is indicated because the SPK candidates have very poor waiting list survival and long life expectancy after transplant. Entangling the two systems further would negate the benefit intended by pulling the SPK candidates out of the kidney allocation system.

The Committee recognizes the community's concern regarding the impact on pediatric kidney candidates. The Committee has considered a system that allows OPOs to offer kidneys to kidney-alone candidates through the local pediatric classification. The OPO would do this before offering organs to candidates on the SPK/PA list when only one kidney from a donor is available at the time the OPO would begin allocating organs to the SPK/PA list (a single kidney contingency). This method would be more operationally complex for OPOs, but it could protect pediatric kidney candidates. **Exhibit A** shows the order of offers to pancreas and kidney candidates under a single kidney contingency. The Committee opted for entirely disentangling pancreas allocation from kidney allocation because the simulations did not show a significant difference in the number of transplants for adult and pediatric kidney transplants with the single kidney contingency (see supporting evidence section), but such a system would be more operationally complex for OPOs. The Committee would support allowing only the pediatric kidney candidates to have priority over SPK candidates, but that system would not be feasible without major changes to kidney allocation, which are not possible at this time and are not within the Pancreas Committee's purview.

The Committee also considered allowing each OPO to decide whether to institute a single kidney contingency. In this case, each OPO would be required to have a formal policy on the single kidney contingency. Another possibility would be for the Committee to propose a Committee-sponsored alternative system for the single kidney contingency. Having a Committee-sponsored system would allow OPOs to opt-in while still tracking how allocation occurs in each DSA. Furthermore, the Committee-sponsored system would provide for a research design and systematic review of the impact on pediatric and adult kidney candidates as well as SPK and PA candidates. This system could then inform future allocation policy decisions.

The Committee appreciates feedback on whether you support this decision to entirely separate pancreas allocation from kidney allocation.

Additional Considerations

If the proposed policy is implemented, current alternative allocation systems (AAS) will be eliminated. If a group with an existing AAS wishes to continue its AAS in the new pancreas allocation system, that group will have the opportunity to re-apply for the AAS. It is expected that any applicants will incorporate the following changes to the national system:

- A combined SPK and PA match run;
- SPK qualifying criteria;
- Pancreas allocation disentangled from kidney allocation.

All applications will be reviewed by the Pancreas Transplantation Committee using the requirements located in policy and in the OPTN Final Rule.

For candidates already listed for SPK transplantation, if their waiting time based on their listing date differs from the waiting time they would have under the new system, they will receive the longer waiting time.

Candidates listed for an SPK transplant who receive a kidney-alone transplant and then list for a pancreas transplant will have the option to transfer their SPK waiting time to a PA listing.

Collaboration

The Committee conducted an extensive consensus building effort during August 2009 through February 2010. The Committee presented the concept for a new pancreas allocation system to all regions. The Committee also solicited feedback from all pancreas programs and from the Committees and external constituent organizations shown in Table 1.

Table 1: Groups Solicited for Feedback

Committees	External Constituent Organizations
Ethics	American Diabetes Association (ADA)
Kidney Transplantation	Association of Organ Procurement Organizations (AOPO)
Minority Affairs	American Society of Transplantation (AST)
Organ Availability	American Society of Transplant Surgeons (ASTS)
OPO	Juvenile Diabetes Research Foundation (JDRF)
Patient Affairs	NATCO
Pediatric Transplantation	
Policy Oversight	
Transplant Administrators	
Transplant Coordinators	

The major themes of the feedback were that the SPK qualifying criteria were too strict with respect to diabetes and there was concern about the potential impact on pediatric kidney candidates. In response to these comments, the Committee revised the SPK qualifying criteria and formed a joint subCommittee with the Pediatric Transplantation Committee. The Committee proposes that it monitor the 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 is also requesting that the community provide comments on the possible alternatives presented in this proposal regarding qualifying criteria and regarding the potential for pediatric kidney candidates to have priority over pancreas candidates when only one kidney is available from a donor.

The Committee voted to send this proposal out for public comment on February 18, 2010. (11-Support, 0-Oppose, 0-Abstain)

Supporting Evidence and Modeling:

What is the current status of pancreas transplantation with respect to the waiting list, number of transplants, outcomes, and deceased donor organ availability?
Approximately 1300 pancreas transplants are performed annually in the United States. This number has remained fairly constant over the past ten years as figure 1 demonstrates.

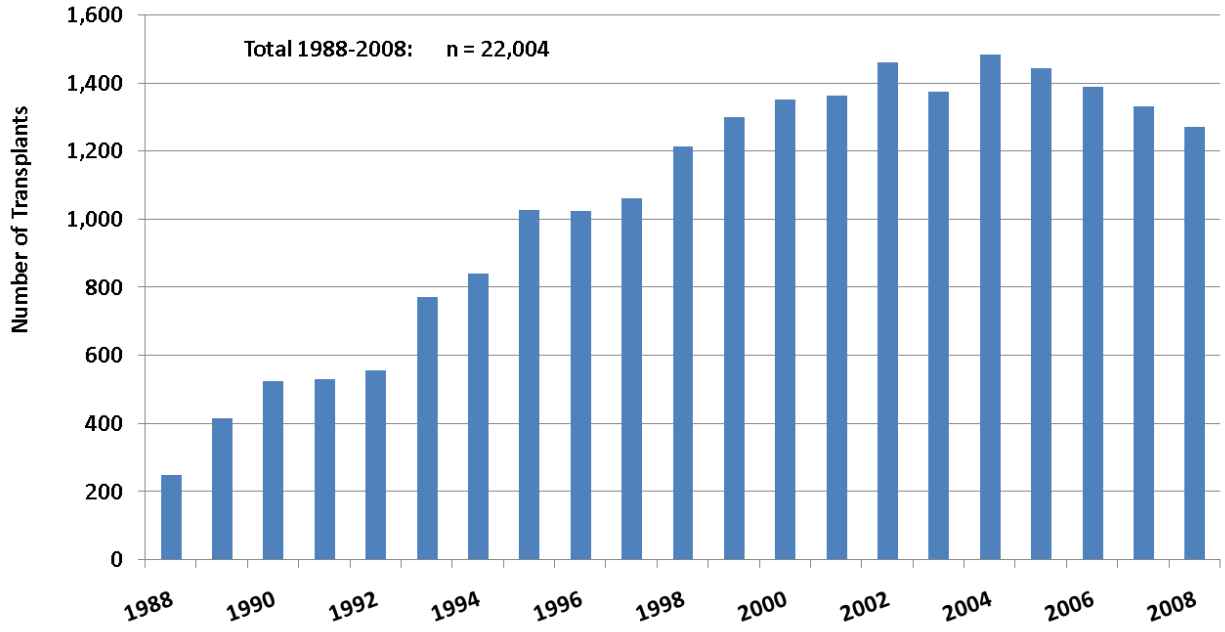


Figure 1: Annual number of pancreas transplants performed in the US 1988-2008

Pancreas transplants are performed in three clinical scenarios: simultaneous pancreas-kidney (SPK) transplantation, pancreas-after-kidney (PAK) transplantation, and pancreas transplant alone (PTA). Approximately 850-900 SPK transplants have been performed annually over the past ten years, as shown in figure 2. (779 SPK transplants were performed in 2009).

Approximately two-thirds of the pancreas transplants performed annually are SPK. PAK transplantation is the next most commonly performed pancreas transplant procedure. Approximately 200-300 cases are performed each year. Recipients of a PAK transplant have previously received a living donor kidney in approximately 60% of cases. The final category is PTA recipients, which number approximately 200 per year.

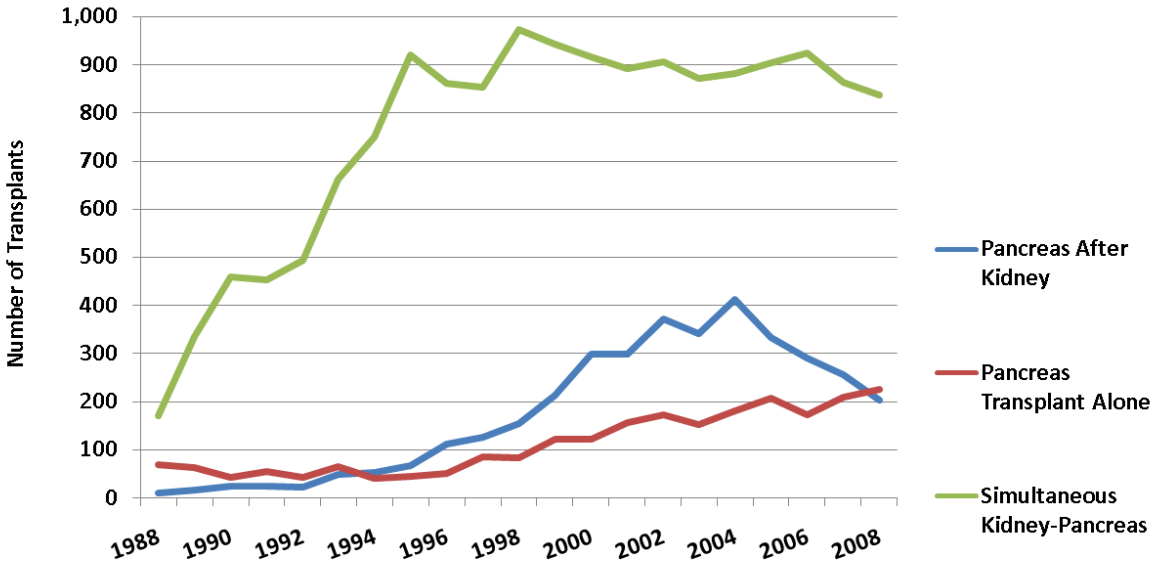


Figure 2: Annual number of SPK, PAK and PTA transplants performed in the US 1988-2008

The number of patients listed for SPK and solitary (PAK and PTA) pancreas transplants on the waiting list as of September 30, 2009 were 2,187 and 1,487, respectively. The proportion of individuals on the waiting list between ages 18-49 years is 76% for SPK and 69% for solitary pancreas transplantation. (It is 39% for a kidney-alone transplant). Over the past decade there has been little change in the total number of individuals on the waiting list for SPK transplantation. However, the number of candidates on the waiting list for a solitary pancreas transplant more than doubled from 1999 to 2009.

Pancreas graft function in the three categories of pancreas transplant recipients are shown in figure 3. These outcomes represent recipients of a primary graft transplanted between 1/1/2004 and 12/31/2008, all receiving anti-T-cell induction therapy and the combination of tacrolimus and mycophenolate maintenance immunosuppression (the most common immunosuppressive combination used in pancreas transplantation).

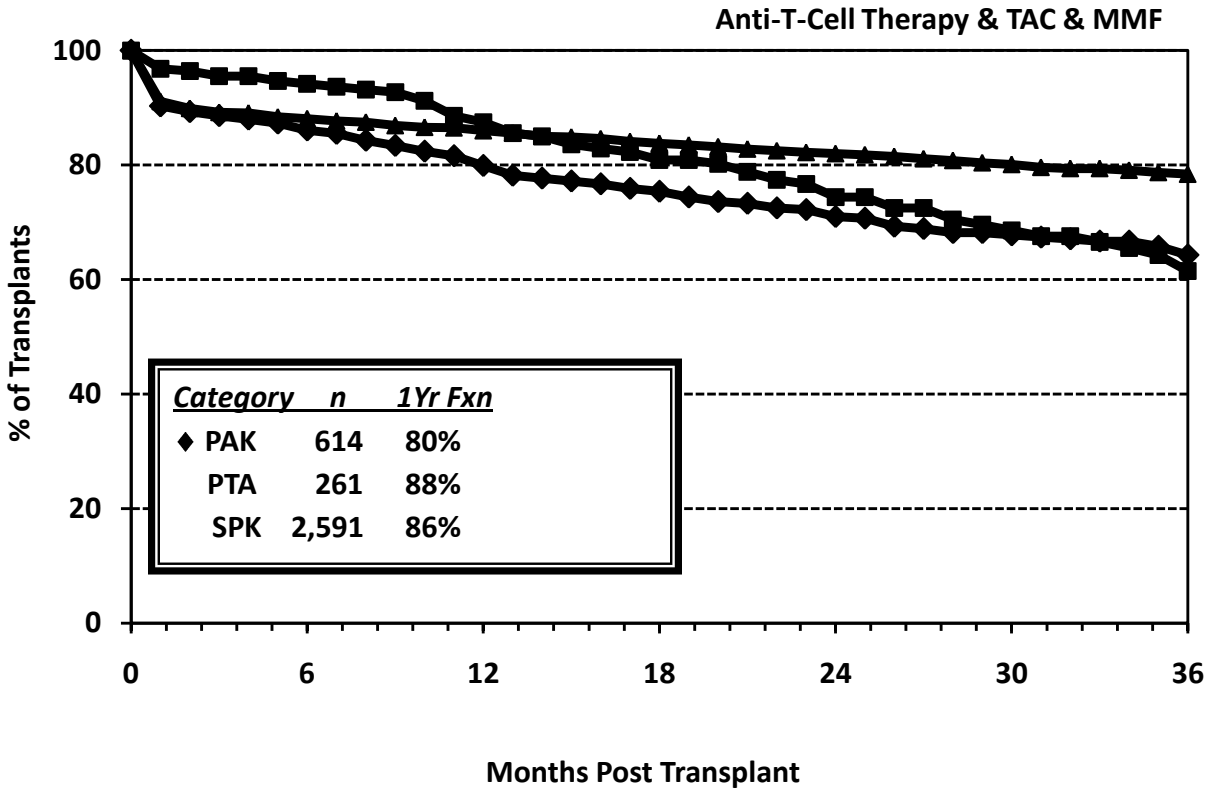


Figure 3: Pancreas graft function according to pancreas transplant type
Deceased Donor Primary Pancreas Transplants in the US 1/1/2004 – 12/31/2008[1]

There are statistically significant differences in outcomes among the groups, with the best outcome of the pancreas in recipients of an SPK transplant. At one year post-transplant, there are minor differences in outcomes among the three groups. Importantly, at three years post-transplant the outcomes are even more different. The pancreas graft survival rates are approximately 80% in recipients of SPK transplants versus 60-65% in those with a solitary pancreas transplant.

There are important survival risks for patients being on the pancreas transplant waiting list. Figure 4 shows the 5-year patient survival rates for individuals who are awaiting a pancreas transplant according to the three categories of pancreas transplantation with the SPK group further stratified according to whether the transplant center categorized the recipient as having type 1 or type 2 diabetes.

[1] Figure and data provided by the International Pancreas Transplant Registry.

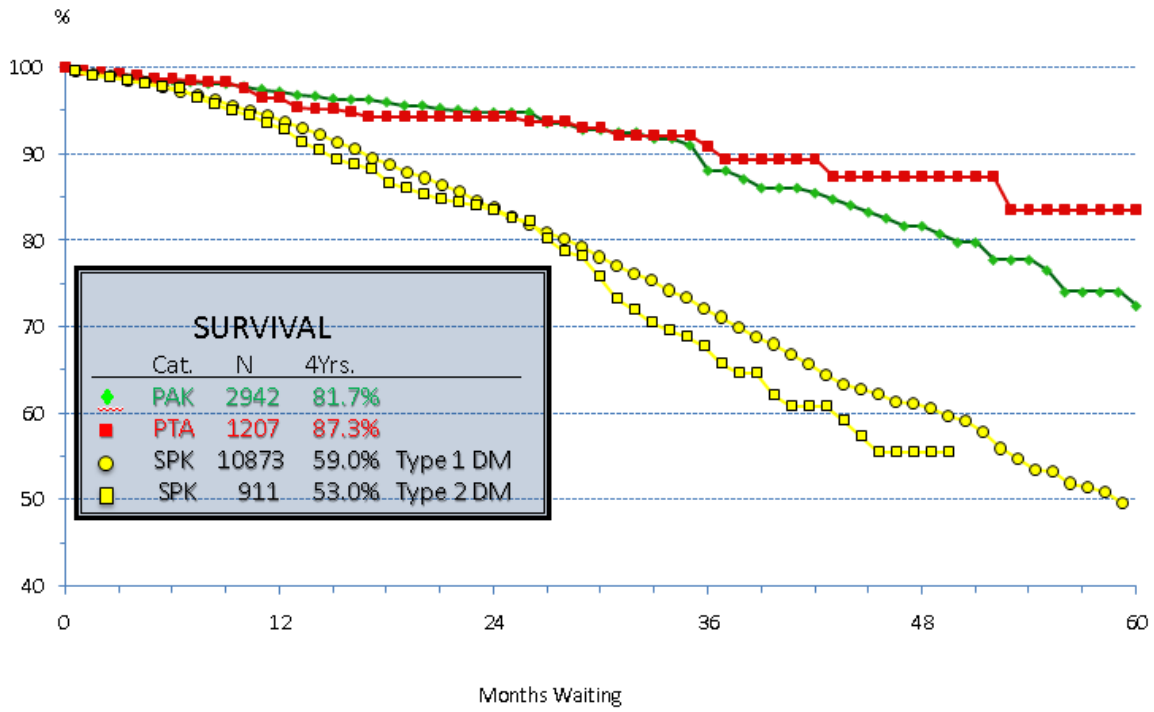


Figure 4: Patient survival while on the waiting list for pancreas transplantation according to pancreas transplant type
Pancreas Waiting List 1/1/1995 – 5/31/2003[1]

It is striking to note that there is a less than 50% 5-year patient survival rate for the diabetic, uremic patient awaiting SPK transplant. Furthermore, the relatively poor waiting list survival rate is nearly the same for type 2 diabetic patients as for type 1 diabetic patients. These survival rates are among the worst waiting list patient survival rates of any category of uremic patients.

The outcomes for SPK transplantation for the diabetic, uremic patient when defined using the life years from transplant (LYFT) metric are among the best of all kidney transplants. LYFT is the difference between a candidate's median projected life span post-transplant minus his projected median wait list survival without a transplant. Figure 5 shows the LYFT results in the diabetic SPK transplant recipient compared to kidney-alone recipients that are either diabetic or non-diabetic.

[1] Figure and data provided by the International Pancreas Transplant Registry.

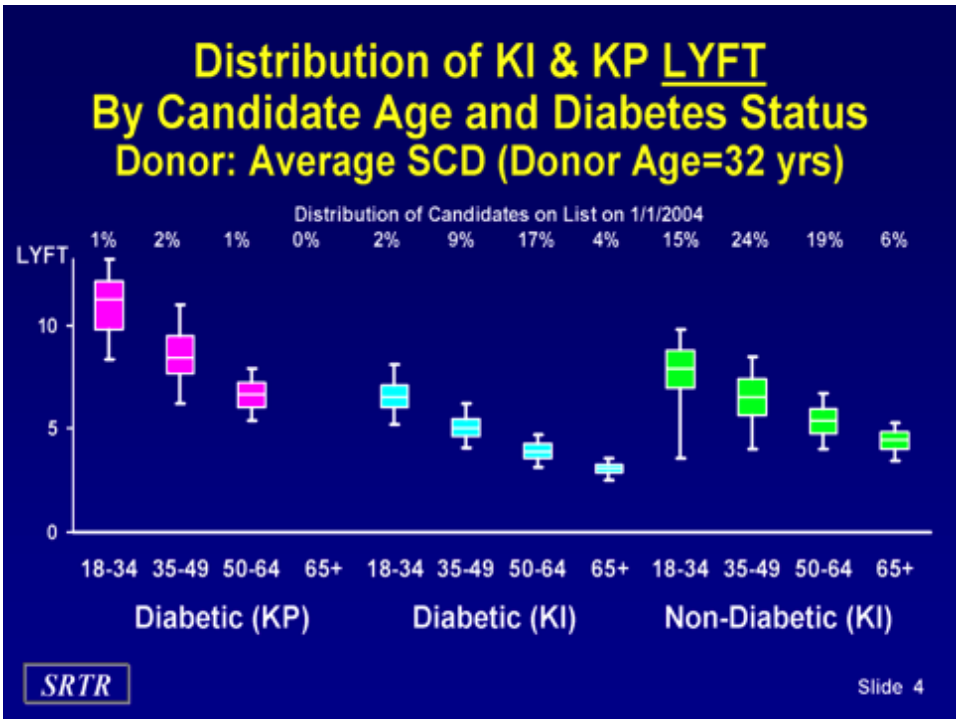


Figure 5: Life years from transplant (LYFT) according to transplant type, diabetes status, and age

The diabetic, uremic SPK transplant category comprised a small proportion of all kidney transplant recipients. The LYFT was higher in each of the three age groups (18-34, 35-49, and 50-64), than the respective counterparts of diabetic or non-diabetic kidney-alone recipients. These data emphasize the detriment in waiting for a SPK transplant in a diabetic, uremic patient and the significant benefit in patient survival when those individuals receive an SPK transplant. It is important to note that the candidates in this analysis include a small number of high c-peptide diabetic patients.

In 2008, there were 7,990 deceased organ donors in the U.S. There were 14,278 deceased donor (DD) kidneys recovered and 1,829 pancreata recovered. There were 11,670 DD kidneys transplanted and 1,309 pancreata transplanted.

Multi-organ renal/extra-renal transplants

Multi-organ transplants involving renal/extra-renal transplants occurred in approximately 12% of kidney transplants. Figure 6 shows the proportion of multi-organ kidney transplants for the years 2005 through 2007.

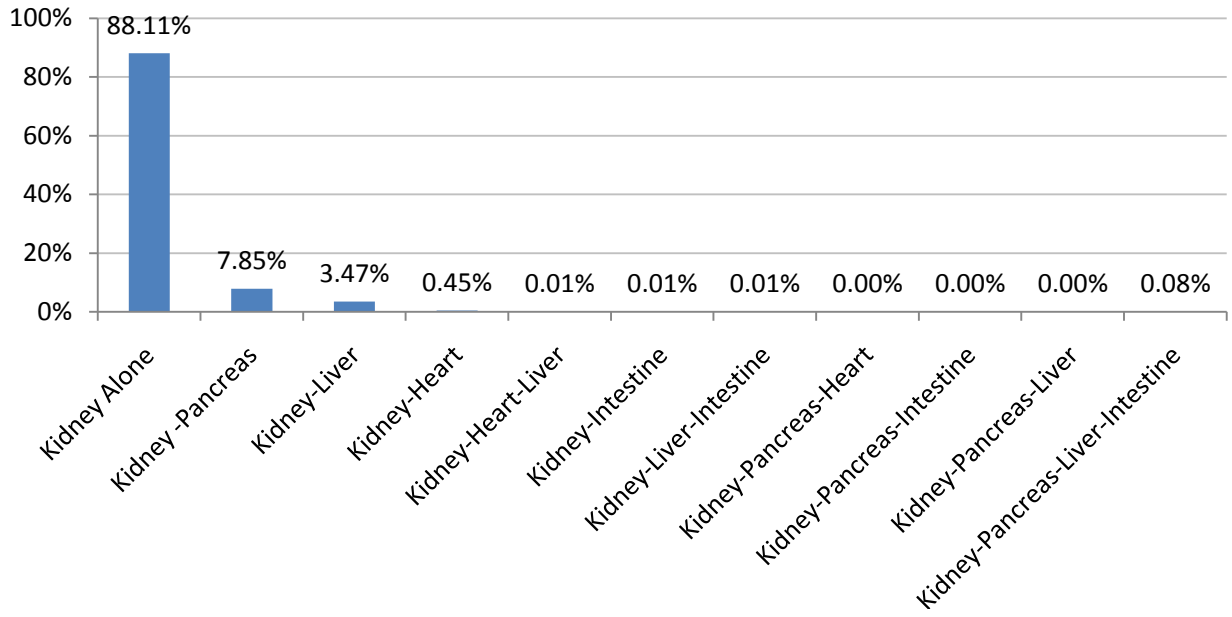


Figure 6: Proportion of renal/extra-renal multi-organ deceased donor kidney transplants 2005-2007

Of the 33,845 DD kidney transplants, approximately 88% were kidney-alone transplants and 12% renal/extra-renal transplants.

Table 2 shows the number of multi-organ renal/extra-renal transplants in 2008.

Table 2: Summary of Deceased Donor Multi-Organ Kidney Transplants from 2008

Multi-Organ Transplant	N	% of All DD Kidney
Pancreas/Kidney	863	7.56%
Liver/Kidney	444	3.89%
Heart/Kidney	55	0.48%
Liver/Intestine/Kidney/Pancreas	14	0.12%
Lung/Kidney	2	<0.02%
Intestine/Kidney	2	<0.02%
Liver/Heart/Kidney	1	<0.02%
Total Renal/Extra-Renal	1,381	12.1%
Total DD Kidney-alone	10,034	87.9%
Total DD Kidney	11,415	100%

In 2008, there were a total of 11,415 DD kidney transplants with approximately 88% being used for kidney-alone transplantation. Among the renal/extra renal transplants, SPK transplants accounted for 7.56% of all DD kidney transplants and liver-kidney transplants accounted for 3.89% of all DD kidney transplants.

What are the implications of the number of renal/extra-renal organ transplants on patients waiting for a kidney-alone transplant? It is very rare that both kidneys from a deceased donor would be transplanted into two adult multi-organ recipients. This statistic is of special interest to the pediatric transplant community. Figure 7 shows that for deceased donors under the age of 35, only 2.3% of the deceased donors resulted in both kidneys being unavailable for a pediatric kidney transplant recipient because they were transplanted into two adult multi-organ recipients after the institution of Share 35, which prioritized kidneys from donors less than 35 years old for pediatric candidates.

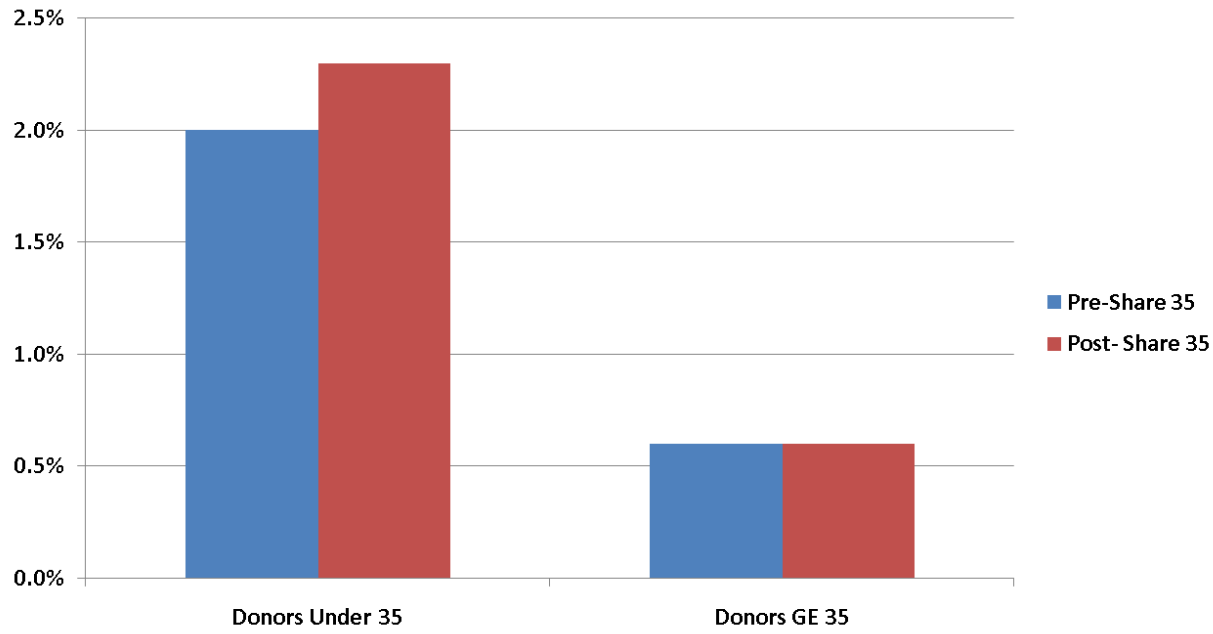


Figure 7: Proportion of donors that result in both kidneys being transplanted into renal/extra-renal transplant recipients according to donor age and stratified by "Share 35" UNOS policy
Pre- Share 35 dates for analysis: 12/27/2002 – 09/27/2005
Post- Share 35 dates for analysis: 09/28/2005 – 06/30/2008

What are the current pancreas allocation practices across the country?

In 2007, the Committee conducted a survey on pancreas allocation. Several questions on the survey related to local pancreas allocation practices. The Committee planned to use these responses to classify DSAs and to analyze data to see if results differ based on local allocation practice. In order to accurately classify DSAs, the Committee sent three follow-up questions to all OPO Executive Directors regarding their local pancreas allocation practices. The Committee decided to classify the OPO responses into three categories:

- Kidney follows the pancreas (KI follows PA)
- Pancreas follows the kidney (PA follows KI)
- Mixed

DSAs were classified into the above three categories based on their answers to the following questions:

1. Choose the allocation system that is most like your OPO's policy for SPK allocation as it relates to kidney-alone allocation:
    a. Kidney follows pancreas (e.g., SPKs are allocated first, then kidney-alone.)

b. Pancreas follows kidney (e.g., Kidney is allocated first. SPK candidates might receive a kidney if they reach a certain threshold on the kidney-alone list, such as within the top 20% of kidney candidates or in the top 12 candidates on the kidney-alone list).
c. Mixed (e.g., No formal policy. We allocate from all three lists on an ad hoc basis).

2. Choose the allocation system that is most like your OPO's policy for pancreas allocation:
   a. We prioritize SPK and allocate from the SPK list first.
   b. We prioritize solitary pancreas and allocate from the PA list first.
   c. We combine the SPK and PA lists into a single list and allocate from that.
   d. When both types of pancreas transplants are possible, we manually allocate to one from separate SPK and PA waiting lists based on certain criteria (e.g., waiting time).
3. Describe your OPO's pancreas allocation policy in your own words. In particular, we are interested in the order that your OPO allocates from your pancreas-alone, SPK, and kidney-alone lists. (e.g., in the absence of 0 mismatch pancreata and/or multiple 0 mismatch kidneys, paybacks, etc., we have a kidney follows pancreas system where we allocate first from the SPK list. If we do not place an SPK, we try to allocate the pancreas from the pancreas-alone list and the kidneys from the kidney-alone list.)

Results include deceased donor pancreas transplants that occurred during 2008 unless otherwise noted. These data include only pancreata allocated locally unless otherwise noted.

What types of allocation schemes are most common in the 58 DSAs?

Out of the 53 DSAs that allocate the pancreas locally, 43 DSAs were classified as kidney follows pancreas, 4 as pancreas follows kidney, and 6 as mixed, as shown in table 3. Of the DSAs where the kidney follows the pancreas, 28 give SPK absolute priority, 4 give PA absolute priority, and 8 have a combined SPK/PA list based on waiting time.

Table 3: Allocation Systems of the 53 DSAs that Allocate the Pancreas Locally

Allocation System		Number of DSAs
KI follows PA		43
PA follows KI		6
Mixed		4
Total		**53**
KI follows PA Sub-Categories		
	SPK has absolute priority	28
	Combined SPK and PA list	8
	PA has absolute priority	4
	Other	3
Total		**43**

Does the number of SPK, PAK, and PTA transplants differ by type of allocation system?
Figure 8 shows the percent of pancreas transplants by allocation system. KI follows PA systems represented the largest number of locally allocated pancreata transplanted in the US in 2008.

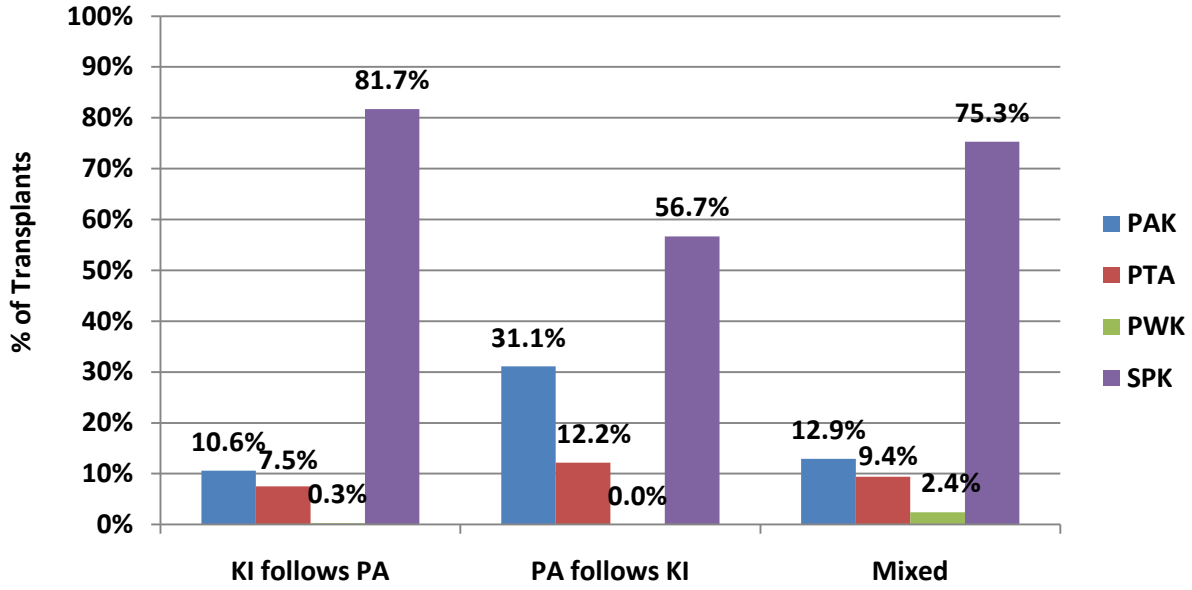


Figure 8: Locally Allocated Pancreas Transplants by Allocation System

Figure 9 shows SPK recipients in 2008 by age group demonstrating comparable distribution of SPK recipients by age among the allocation systems.

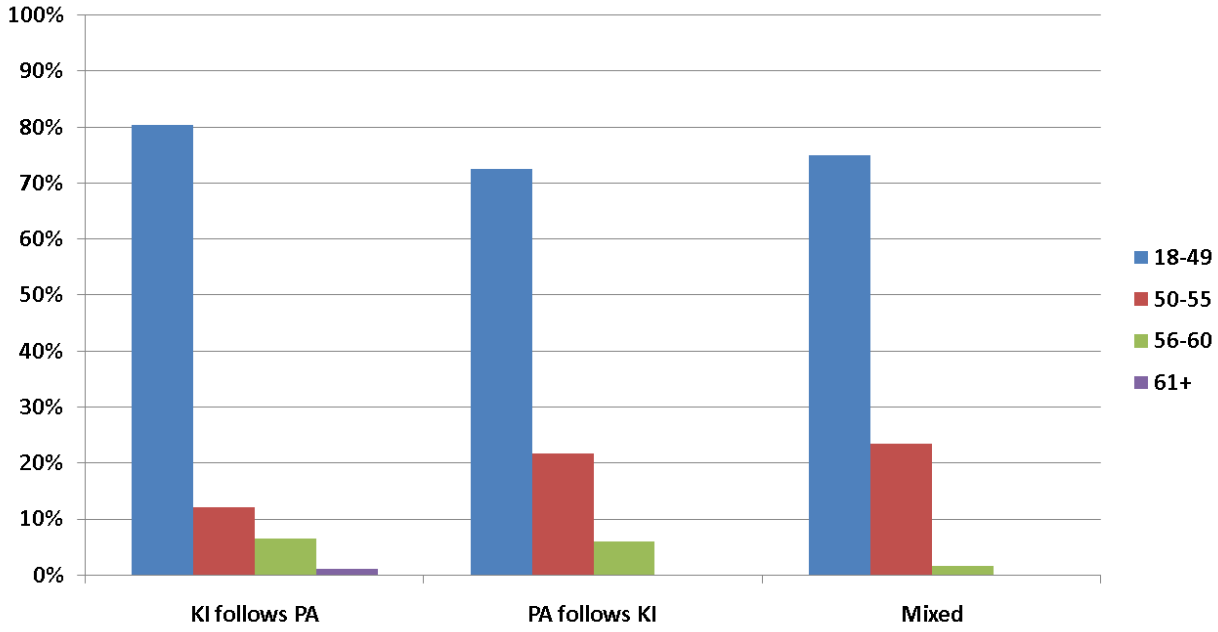


Figure 9: SPK Recipients by Age Group in 2008

Does the allocation system affect waiting list time for diabetic uremic candidates?

Waiting time differs dramatically according to the type of allocation system. Figure 10 shows the waiting times for SPK candidates by type of allocation system. When the kidney follows the pancreas, waiting time is lower for SPK candidates: 177 days in DSAs where the kidney follows the pancreas versus 645 days in DSAs where the pancreas follows the kidney. When considering only non-sensitized SPK candidates who are on dialysis, the waiting time is 144 days for SPK candidates in DSAs where the kidney follows the pancreas versus 486 days in DSAs where the pancreas follows the kidney.

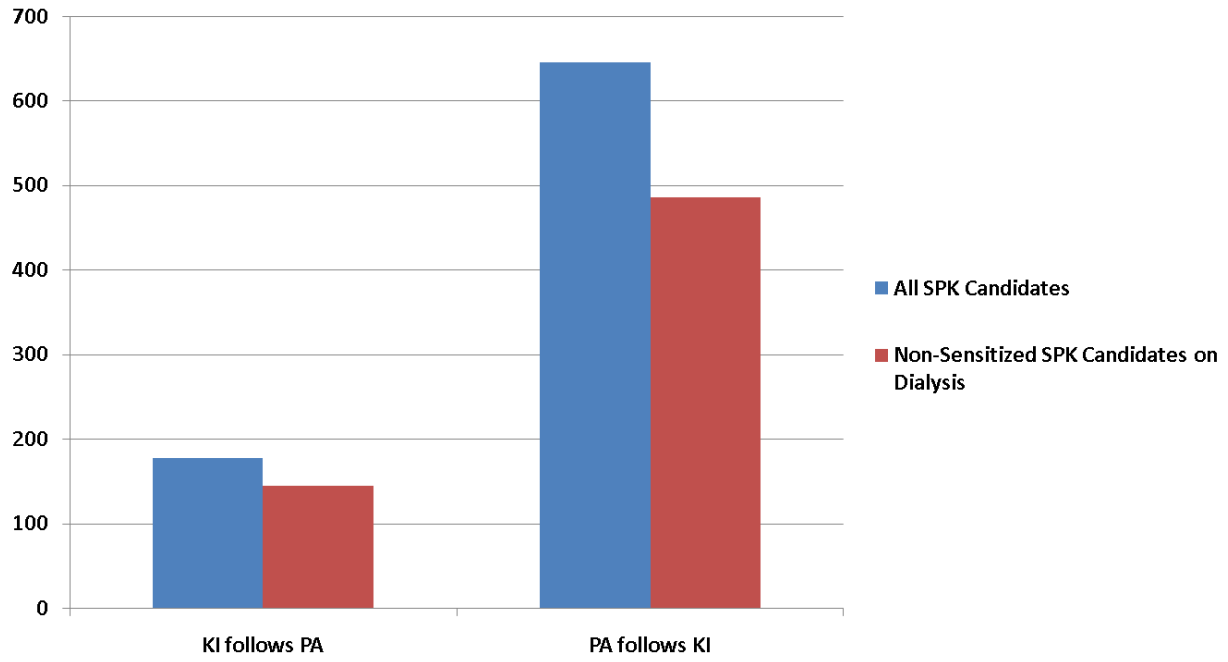


Figure 10: Days to Deceased Donor SPK Transplant (25th Percentile) According to Pancreas Allocation System

Does utilization of the kidney and the pancreas differ by type of allocation system?

Figure 11 shows the ratio of transplants that are allocated locally to the total number of deceased donors, which is a measure of utilization. The ratio of pancreas transplantation to donors is nearly two times higher for the pancreas in DSAs where the kidney follows the pancreas, 0.13 versus 0.07, respectively. Pancreas utilization is far less than for kidney transplantation.

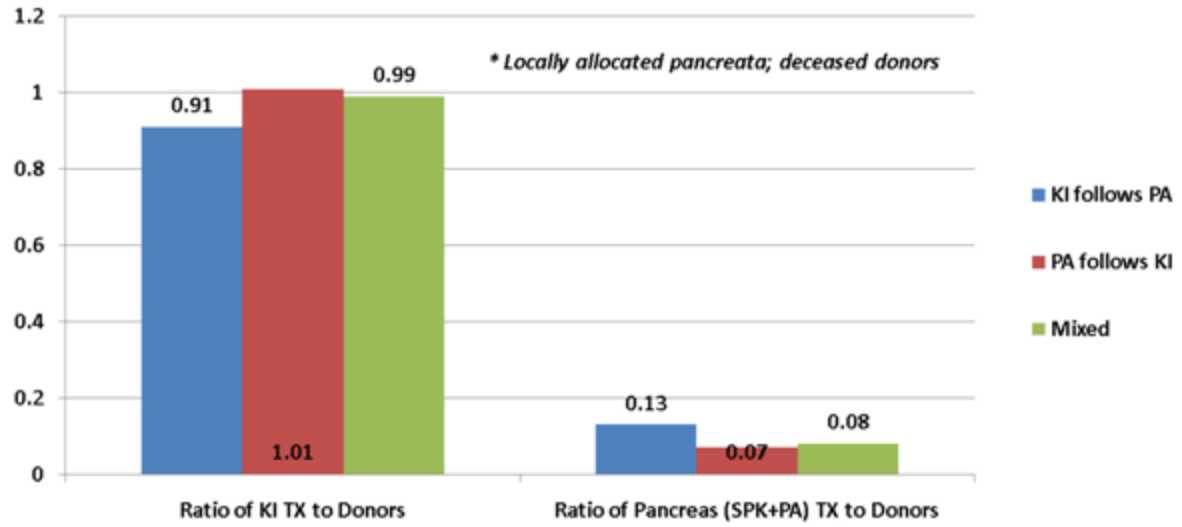


Figure 11: Ratio of local transplants to donors in 2007

Do SPK candidate waiting list outcomes differ by allocation system?

Figure 12 shows the competing risks for SPK candidates added to the waiting list from 2000 to 2005. Candidates in DSAs where KI follows PA were more likely to have been transplanted and less likely to be still waiting. At 36 months, the cumulative probability of being transplanted is 50.2% in DSAs where the kidney follows the pancreas but only 37.2% in DSAs where the pancreas follows the kidney. Also, there was a smaller cumulative rate of patients removed from the waiting list because of death or illness that precludes transplantation. The cumulative probability of death in DSAs where the pancreas follows the kidney is 15.5% versus 13.8% in DSAs where the kidney follows the pancreas.

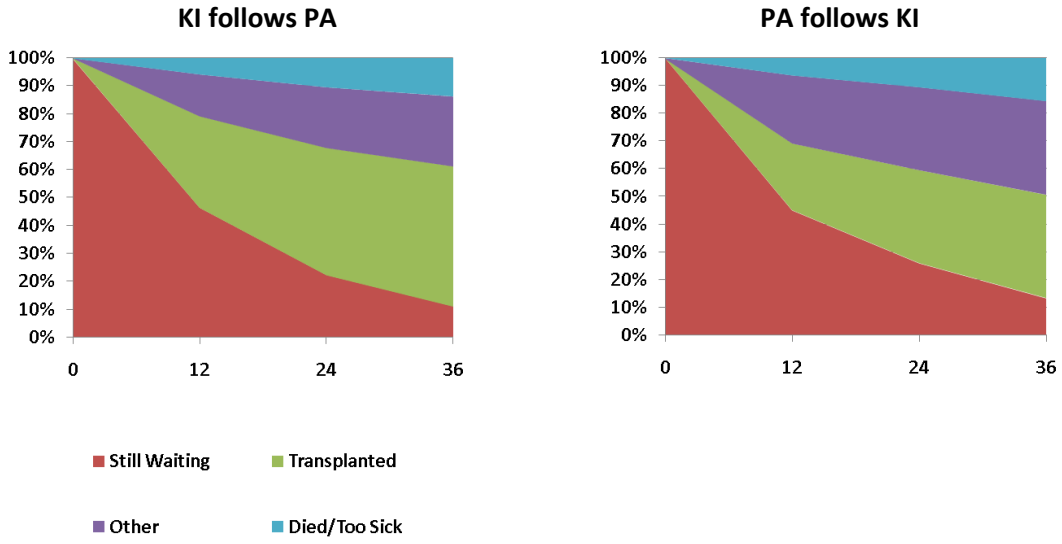


Figure 12: Competing Risks for SPK Candidates Added to the Waiting List Between 2000 and 2005 (Candidates who are on dialysis and are not highly sensitized)

Significant variation exists among DSAs on the priority given to SPK candidates. However, the majority of DSAs already employ an allocation system where the kidney follows the pancreas. The donor and recipient demographics were not notably different for SPK transplantation according to the type of the

allocation system. Having a system where the kidney follows the pancreas did not increase SPK transplantation in patients with type 2 diabetes, those not on dialysis, or in the proportion of young donor kidneys transplanted into older recipients (see **Exhibit B** for additional supporting evidence). In DSAs where the kidney follows the pancreas, SPK candidate waiting time to deceased donor transplant was significantly less than in DSAs where the PA follows the KI. Both overall rate of pancreas transplantation and proportion of SPK transplants were higher in systems where the kidney follows the pancreas.

Simulation Modeling

The Scientific Registry of Transplant Recipients has provided simulated allocation modeling of a pancreas allocation system where pancreas allocation is disentangled from kidney allocation and SPK and PA appear on a combined match run. The modeling used a group of candidates and donors from 2008 and assumed no variances. The model also assumed that all other renal/ extra-renal transplants were allocated before pancreas and kidney allocation began. There are five modeling runs:

- Current allocation scheme with no regional or national sharing of SPKs and no mandatory sharing of zero mismatch kidneys with a PRA under 20% (control run)
- Allocation Option #9: Local candidates allocated a pancreas from a waiting list that combines candidates for SPK and pancreas-alone transplants. SPK candidates who require a kidney transplant will be allocated a kidney independent of the kidney-alone match run providing they meet specific qualifying criteria. Deceased donor pancreata are allocated 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;
- Allocation Option #10: Similar to option 9 with respect to candidates being allocated a kidney independent of the kidney-alone match run providing they meet specific qualifying criteria. However, unlike option #9, the waiting list separates the SPK candidates and the PA candidates with the SPK candidates allocated organs that precede kidney paybacks and pediatric and adult kidney-alone (KI) recipients, and ahead of all PA candidates;
- Allocation Option #14: Single Kidney Contingency- When two kidneys are available, the allocation is similar to option 9 with a common waiting list of SPK and PA candidates. However, when only one SCD kidney from a donor <35 years of age is available, then the kidney is allocated first to high priority kidney-alone candidates. This high priority kidney group includes all candidates through the local pediatric classification. This group receives offers before candidates on the pancreas match run.
- Allocation Option #12: A combined list of SPK and PA candidates. High priority kidney candidates (all candidates through the local pediatric classification) receive offers for all kidneys before candidates on the pancreas match run. (See **Exhibit A** for the order of offers to pancreas and kidney candidates under a double kidney contingency.)

Simulation results can be found in table 4.

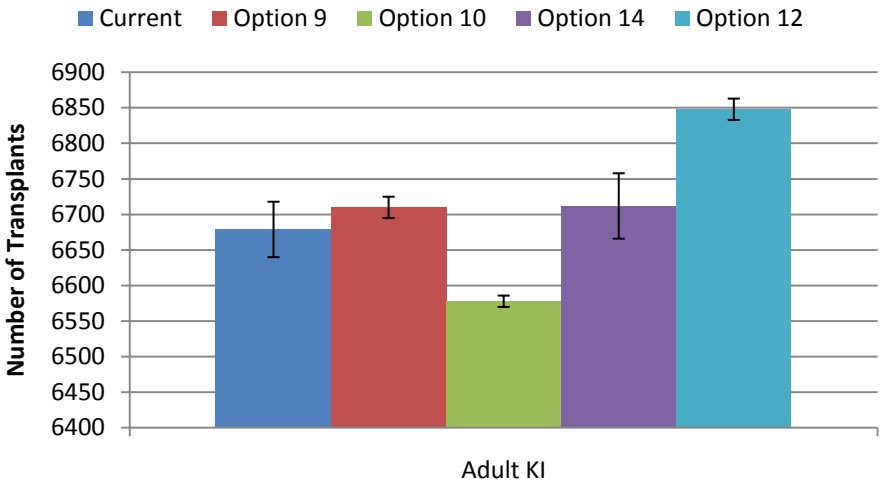
Table 4: Summary of KPSAM runs (Mean and Standard Deviation from 3 Iterations)

	Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
PA Alone	**339(18)**	**324(25)**	**224(3)**	**335(2)**	**385(13)**
SCD donor	323(18)	308(25)	209(2)	319(3)	367(16)
SCD donor < 35 years old	226(10)	214(15)	146(4)	229(3)	267(13)
Recipient age < 50	269(16)	258(14)	182(4)	260(2)	304(11)
Recipient age >= 50	71(5)	66(11)	42(4)	75(4)	81(6)
Recip Age >= 50, Don Age < 35	47(1)	46(12)	29(9)	53(2)	56(5)
Not Shared	158(9)	198(12)	125(6)	200(14)	184(12)
Shared	181(9)	126(15)	99(5)	135(13)	201(9)
SPK	**821(18)**	**816(24)**	**908(20)**	**797(19)**	**649(19)**
SCD donor	789(14)	781(26)	872(21)	762(20)	620(21)
SCD donor < 35 years old	633(12)	631(17)	693(18)	609(19)	488(16)
Recipient age < 50	655(13)	647(20)	717(9)	631(6)	516(16)
Recipient age >= 50	166(9)	169(4)	191(15)	166(14)	133(3)
Recip Age >= 50, Don Age < 35	133(14)	136(7)	148(15)	130(13)	104(3)
Not Shared	708(17)	682(8)	762(17)	676(14)	649(19)
Shared	113(10)	134(21)	146(4)	120(10)	1(0)
Adult KI at Listing	**9507(66)**	**9555(22)**	**9404(5)**	**9535(16)**	**9654(14)**
SCD donor	6679(39)	6710(15)	6578(8)	6712(46)	6848(15)
SCD donor < 35 years old	3182(17)	3203(23)	3112(21)	3192(58)	3309(7)
HLA 0 ABDR mm, SCD donor	510(15)	499(6)	491(13)	507(13)	536(5)
PRA >= 80%, SCD donor	1476(20)	1453(24)	1437(13)	1477(13)	1472(24)
0mm, PRA >=80%, SCD donor	210(5)	204(8)	203(5)	198(10)	214(17)
Pediatric KI at Listing	**556(11)**	**562(7)**	**575(7)**	**580(27)**	**613(12)**
SCD donor	488(13)	490(9)	511(6)	507(27)	544(14)
SCD donor < 35 years old	421(17)	417(14)	433(14)	438(33)	475(14)
HLA 0 ABDR mm, SCD donor	25(2)	29(6)	26(4)	24(2)	29(4)
PRA >= 80%, SCD donor	64(5)	61(4)	68(6)	66(2)	67(3)
0mm, PRA >=80%, SCD donor	6(3)	8(2)	6(3)	5(2)	7(1)

Between option 9 (combined waiting list of PA and SPK candidates) and the control run, there are no differences that are greater than the between run standard deviation. Between option 10 (waiting list with SPK priority over PA candidates) and the control run, there are more SPK transplants (821 to 908), fewer PA transplants (339 to 224), fewer adult KI transplants (9507 to 9404), and more pediatric KI transplants (556 to 575).

Examination of the same categories of transplants comparing option 9 and option 14 (single kidney contingency) showed no differences that are greater than the between run standard deviation. Option 12 (A combined list of SPK and PA candidates. High priority kidney candidates receive offers for all kidneys before candidates on the pancreas match run) resulted in significantly fewer SPK transplants than the control run and the other options.

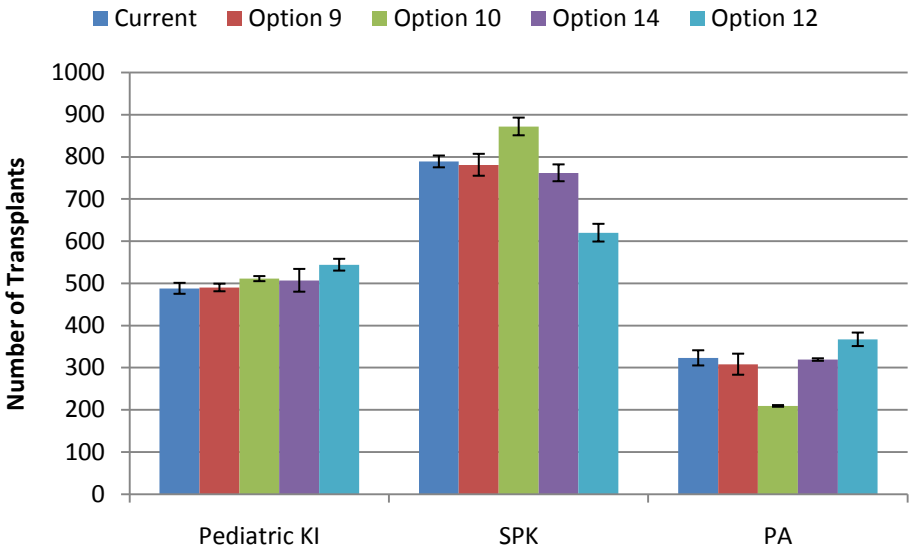
Figure 13 shows the simulation results for adult kidney candidates who receive kidney transplants from standard criteria (SCD) kidney donors.



Note: Error bars extend one standard deviation above and below the mean estimate.

Figure 13: Number of Adult KI Transplants from SCD Donors (Mean and Standard Deviation from 3 Iterations)

Figure 14 shows the simulation results for SPK, PA, and pediatric kidney candidates who receive kidney transplants from standard criteria (SCD) kidney donors.

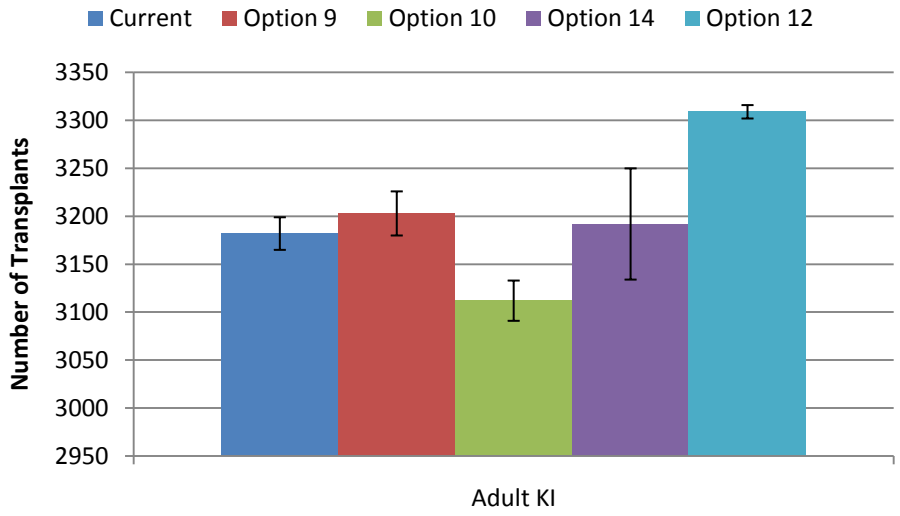


Note: Error bars extend one standard deviation above and below the mean estimate.

Figure 14: Number of Other Transplants from SCD Donors (Mean and Standard Deviation from 3 Iterations)

For all options except option 12, there are no significant differences between runs in the numbers of transplants from SCD kidney donors for SPK, PA, adult KI, and pediatric KI candidates. Option 12 resulted in far fewer transplants from SCD donors for SPK candidates and more transplants from SCD kidney donors for PA, adult KI, and pediatric KI candidates.

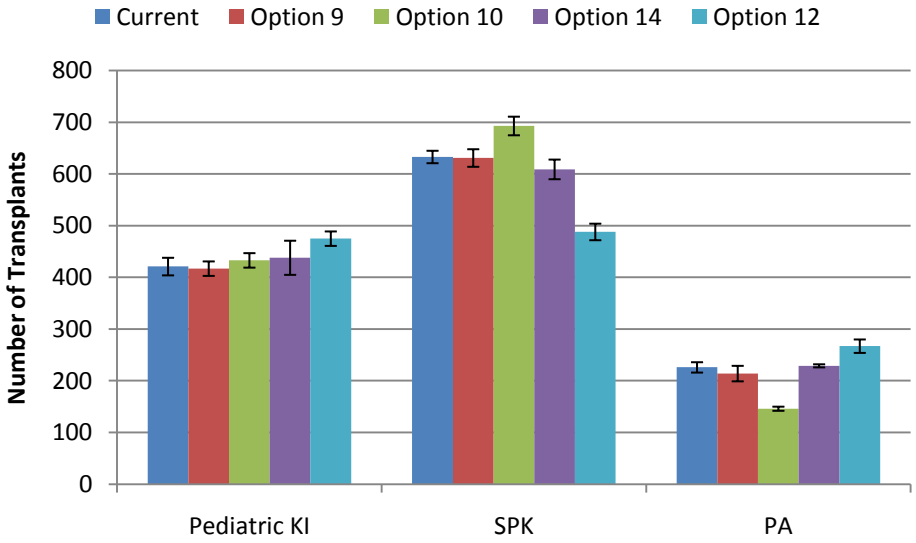
Figure 15 shows the simulation results for adult kidney candidates who receive kidney transplants from standard criteria (SCD) kidney donors who are under the age of 35.



Note: Error bars extend one standard deviation above and below the mean estimate.

Figure 15: Number of Adult KI Transplants from SCD Donors Under Age 35 (Mean and Standard Deviation from 3 Iterations)

Figure 16 shows the simulation results for SPK, PA, and pediatric kidney candidates who receive kidney transplants from standard criteria (SCD) kidney donors who are under the age of 35.



Note: Error bars extend one standard deviation above and below the mean estimate.

Figure 16: Number of Other Transplants from SCD Donors Under Age 35 (Mean and Standard Deviation from 3 Iterations)

For all options except option 12, there are no significant differences between runs in the numbers of transplants for SCD kidney donors under the age of 35 for SPK, PA, adult KI, and pediatric KI candidates. Option 12 resulted in far fewer transplants from donors under the age of 35 for SPK candidates and more transplants from SCD kidney donors under the age of 35 for PA, adult KI, and pediatric KI candidates.

The Committee did not note any differences between the options for minority SPK, PA, or kidney-alone candidates. Option 9 is estimated to result in 91 additional SCD donor transplants for African American recipients compared to the current system; this increase is more than 4 times the standard deviation of the Option 9 runs (20) and is unlikely to be caused by random variation. More detailed simulation results can be found in **Exhibit C.**

The Committee ruled out option 12 because of the disproportionate change in access to organs for SPK transplant candidates. The Committee chose not to pursue option 10 because that allocation method had the potential to have a detrimental impact on access to renal allografts for adult and pediatric renal candidates. Also, option 10 would not eliminate the disincentive for SPK candidates to pursue a living donor kidney followed by a PAK.

The Committee debated whether to pursue option 9 or option 14 because the results were similar for all groups. The Committee opted for a system that combined SPK and PA candidates on a single match run that is entirely disentangled from the kidney match run because it did not think the simulation results between option 9 and option 14 were different enough to warrant the additional costs and administrative burden for the OPTN and the OPOs.

What is the evidence for the SPK qualifying criteria?

The SPK qualifying criteria more uniformly define the types of diabetic, uremic candidates who are currently listed for SPK and receive a high net benefit from the transplant. One metric to measure net benefit is life years from transplant (LYFT). LYFT is defined as the difference between a candidate's median projected lifespan post-transplant minus his projected median waitlist survival without a transplant. Figure 5 (displayed earlier in this section) shows the LYFT for the diabetic candidates listed for an SPK transplant. The LYFT analyses include all diabetic SPK transplants regardless of type of diabetes. These diabetic SPK candidates have a higher LYFT than the diabetic and non-diabetic KI candidates. The figures below shows waiting list mortality and post transplant survival for SPK candidates by type of diabetes. Figure 4 (displayed earlier in this section) shows that the waiting list mortality for SPK candidates is worse than the mortality for pancreas after kidney and pancreas transplant alone candidates regardless of type of diabetes.

Figure 17 shows that patient survival post transplant is similar for SPK candidates classified as having type 1 and type 2 diabetes.

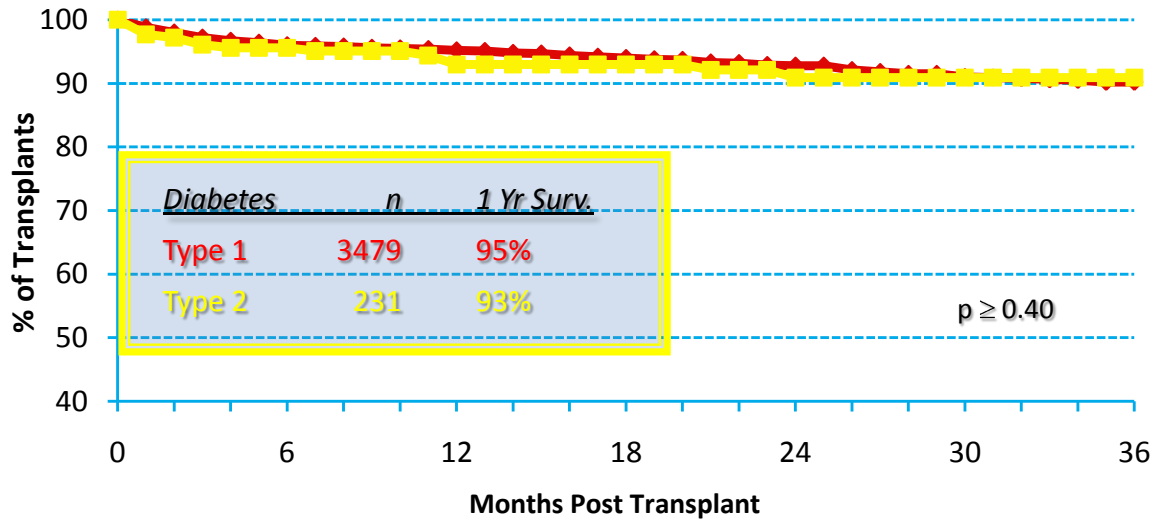


Figure 17: SPK Patient Survival by Diabetes Type
Deceased Donor Primary Pancreas Transplants in the US 1/1/1999 – 5/15/2003[1]

Figure 18 shows that pancreas graft function is similar for SPK candidates classified as having type 1 and type 2 diabetes.

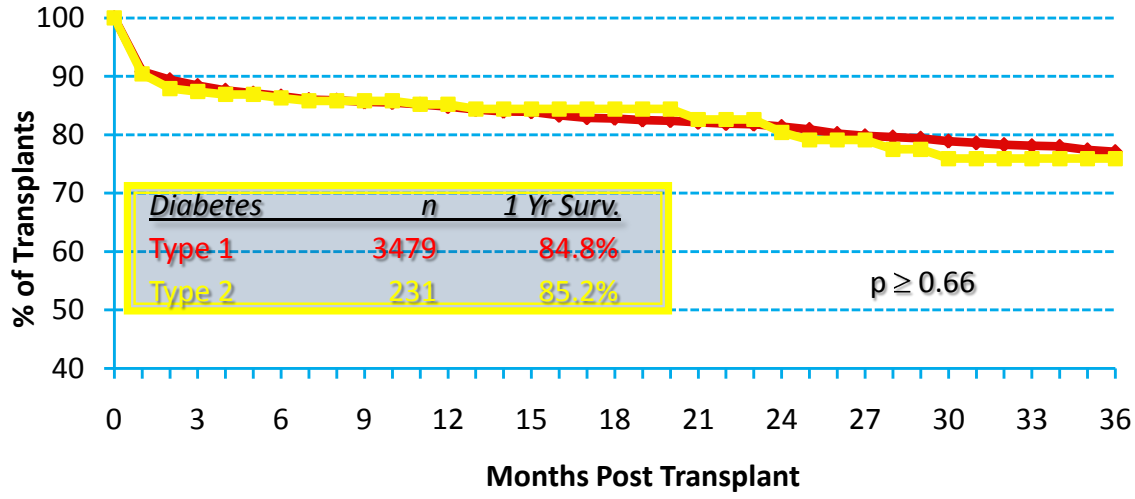


Figure 18: SPK Pancreas Graft Function by Diabetes Type
Deceased Donor Primary Pancreas Transplants in the US 1/1/1999 – 5/15/2003[2]

[1] Figure and data provided by the International Pancreas Transplant Registry.
[2] Figure and data provided by the International Pancreas Transplant Registry.

The Committee seeks to maintain the ability for the candidates who have historically received and had a high net benefit from an SPK transplant to receive an SPK transplant. To determine the characteristics of this group, the Committee contacted the transplant programs that list candidates for SPK transplant that are classified as having type 2 diabetes. This group includes non-obese candidates who are on insulin and have symptoms consistent with type 1 diabetes but who may have a c-peptide value greater than 2 ng/mL.

BMI value

The BMI value of 30kg/m^2 is from the standard definition of obesity of a BMI over 30 kg/m^2.[1] Many groups use a BMI of 30 kg/m^2 as the definition of obesity. An expert panel convened by the National Heart, Lung, and Blood Institute (NHLBI) in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), both part of NIH, identified obesity as a BMI of 30 kg/m^2 or greater. The Centers of Disease Control and Prevention and the World Health Organization (WHO) define "obesity" as a BMI equal to or more than 30 kg/m^2.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal meets several of the HHS Program Goals and strategic plan goals: best use of donated organs, equitable access, maximum capacity, and operational effectiveness.

Best Use of Donated Organs

This proposal seeks to make the best use of donated organs by allocating kidneys and pancreata to candidates who have some of the highest net benefit from the organs--SPK candidates. Please see the LYFT analyses outlined in the supporting evidence section for further details. Improved access to SPK will result in greater use of marginal grafts that have been demonstrated to have improved outcomes when used in the context of SPK transplant compared to PA alone. Thus, in a system in which candidates can receive both organs, use of marginal allografts should increase.

Equitable Access

This proposal will reduce the geographic disparities in access and waiting time for SPK and pancreas-alone candidates by eliminating variation across DSAs and by disentangling pancreas allocation from kidney allocation. With a combined SPK and PA list, all candidates for a pancreas transplant have the opportunity to receive offers for high quality pancreata. By disentangling pancreas allocation from kidney allocation, SPK candidates will no longer be subject to disparities that result from issues in kidney allocation within the DSA, such as variable allocation practices in the DSA and payback debt.

Maximum Capacity

This proposal will help achieve maximum capacity because it aims to increase the use of pancreata and improve the opportunity for pancreas candidates to receive a transplant. This goal would be accomplished by combining SPK and PA candidates onto a single match run list. On a single list, candidates for both categories of pancreas transplants would have an equal opportunity to receive offers of high quality organs. A single list for all pancreas candidates would be operationally efficient for OPOs. It would also retain some high quality kidneys for the kidney allocation system in the situations in which a pancreas graft is allocated for pancreas-alone transplantation. A common list would not discourage a SPK candidate from seeking a living kidney donation.

[1] Division of Nutrition, Physical Activity and Obesity, National Center for Chronic Disease Prevention and Health Promotion.

Operational Effectiveness

This proposal will improve operational effectiveness for both OPOs and the OPTN. OPOs will only need to consult one match run when allocating pancreata, as opposed to three match runs in the current paradigm. It will be easier for OPO staff to train coordinators on how to allocate pancreata, and this allocation will take less time. Also, OPO staff will no longer have to arbitrate disputes over the kidney between pancreas and kidney programs because the policy will no longer be ambiguous on the order of allocation. The OPTN will only have to maintain one pancreas match run instead of two. Furthermore, disentangling pancreas allocation from kidney allocation will make the pancreas allocation system easier to maintain. If the systems are entangled, then any change to kidney allocation could also result in changes to the pancreas allocation system. Importantly, this process could result in a faster and more efficient method of allocating organs. It would also be less costly to implement and maintain.

Plan for Evaluating the Proposal:

For each goal, the Committee will review the related policy performance metrics listed below:

- establish a uniform, national system to govern the allocation of pancreas allografts
    - Number of variances to national policy
- reduce geographic inequities of access and waiting time
    - Median waiting time or time to 25% of list being transplanted before and after policy change locally, regionally, and nationally for SPK and PA candidates
    - Waiting list mortality for SPK candidates before and after policy change locally, regionally, and nationally
- increase utilization of the pancreas allografts
    - Utilization rate of the pancreas, both in total and for SPK and PA separately
    - Utilization of the pancreas by pancreas donor risk index strata before and after policy change
    - Discard rate for the pancreas locally, regionally, and nationally before and after the policy change
- maximize capacity of pancreas transplantation by eliminating the disincentive for living donor kidney transplantation followed by pancreas-after-kidney transplantation;
    - Number and proportion of PAK transplants before and after policy change
- standardize the pancreas allocation process to increase access to organs and reduce waiting times for both SPK and PA candidates without significantly adversely affecting access and waiting times for pediatric and adult KI recipients
    - Number and proportion of deceased donor pediatric KI transplants before and after policy change locally, regionally, and nationally
    - Number and proportion of deceased donor adult KI transplants before and after policy change locally, regionally, and nationally
    - Relative number of SPK transplants compared to relative number of adult and pediatric KI transplants before and after policy change
    - Fate of kidneys from deceased donors under the age of 35 before and after the policy change
    - Median waiting time or time to 25% of list being transplanted before and after policy change locally, regionally, and nationally for pediatric KI candidates
    - Median waiting time or time to 25% of list being transplanted before and after policy change locally, regionally, and nationally for adult KI candidates
    - Number and proportion of pediatric transplants from living donors before and after policy change

- develop appropriate qualifying criteria for candidates waiting for an SPK transplant
    - Number of annual additions to the SPK waiting list before and after policy change locally, regionally, and nationally
    - Proportion of SPK candidates who meet SPK qualifying criteria
    - Number and proportion of SPK candidates who qualify for an SPK transplant at listing but no longer meet qualifying criteria at the time of transplant
    - Outcomes for SPK candidates who meet SPK qualifying criteria
    - Outcomes for SPK candidates who do not meet SPK qualifying criteria
    - Outcomes for SPK recipients who meet SPK qualifying criteria
- promote appropriate utilization of SPK transplantation if/when a new kidney allocation system is developed
    - Utilization rate of the pancreas in SPK transplants
    - Number of SPK transplants before and after policy change
- enhance operational efficiency, reduce computer programming requirements, and decrease OPO and OPTN administrative costs for pancreas allocation by disentangling it from the kidney allocation system
    - Cost to implement policy change
    - Average number of offers per pancreas before and after policy change
    - Number and proportion of local, regional, and national pancreas placements before and after policy change

The Committee will review these data 6 months after implementation and every subsequent 6 months for three years after implementation. The Committee will monitor the impact on pediatric KI transplantation in particular and will recommend policy modifications if they identify a significant negative impact on pediatric KI transplantation.

Additional Data Collection:

If approved, this proposal would result in two additional fields and dates for these values being collected in UNet^{SM} to capture the c-peptide value and insulin status for SPK candidates. The c-peptide value and insulin status are two of the metrics needed to determine if a candidate meets SPK qualifying criteria. Therefore, this additional data collection meets the data collection principle of developing transplant, donation, and allocation policy. The SPK qualifying criteria are an essential part of the revisions to pancreas allocation policy.

Expected Implementation Plan:

If approved, transplant centers and OPOs would both need to alter their practices.

Transplant Centers. Pancreas transplant programs will need to evaluate all existing and new SPK candidates to determine if they meet the SPK qualifying criteria. Programs will need to enter any data necessary to determine SPK qualifying criteria in UNet^{SM}. Programs should also examine whether their candidates are listed for SPK, pancreas-alone, or both and whether these listings still meet the needs of their candidates, particularly in light of the improved access for candidates receiving a living donor kidney followed by a pancreas-alone transplant.

OPOs. OPOs will be required to allocate organs from the combined SPK/PA match run before allocating organs from the kidney match run. OPOs will need to understand how SPK qualifying criteria work and

only allow the kidney to follow the pancreas when a candidate is receiving an offer for an SPK. The kidney cannot be allocated to a candidate based on his or her pancreas-alone listing.

This proposal will require programming in UNet[SM]. Information on how UNOS will monitor compliance can be found in the monitoring and evaluation section below.

Communication and Education Plan:

Such a large scale change to pancreas allocation policy will require extensive education and communication about the changes and how to operate under the new policy. The tables below outline proposed communication and education activities.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice (summary of all policy changes approved by the board in a PDF format)	Transplant Coordinators, Transplant Surgeons, Transplant Physicians, Transplant Center Program Directors, Transplant Administrators, OPO Staff	Electronic – Included in the monthly e-newsletter sent on the 3rd Monday of each month	30 days after the board approves the change.
Notice to pancreas programs explaining the changes and giving an avenue for questions	Pancreas Program Staff, OPO Staff	Electronic - Included in the monthly e-newsletter sent on the 3rd Monday of each month	Within 3 months of Board approval
Notice to groups that have a PA or SPK AAS to reapply to retain AAS	OPOs and transplant centers that participate in a PA or SPK AAS	Electronic	Within 3 months of Board approval
Presentation at regional meetings on the changes	Transplant Coordinators, Transplant Surgeons, Transplant Physicians, Transplant Center Program Directors, Transplant Administrators, OPO Staff	In-person presentation	Regional meeting cycle before implementation
System Notice	UNet[SM] users	Through UNet[SM]	8 weeks, 4 weeks, and 2 weeks before implementation, upon implementation

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe and Frequency**
Training for OPOs on new policy	OPO transplant coordinators, Directors of Procurement	Electronic Learning Module and/or Live Meeting Webinars	Month before implementation, After implementation as needed
Training for transplant centers on new policy	Pancreas program transplant program clinical coordinators, data coordinators, other program staff	Electronic Learning Module and/or Live Meeting Webinars	Month before implementation, After implementation as needed

Monitoring and Evaluation:

The Department of Evaluation and Quality (DEQ) will monitor the new elements of pancreas allocation policy as follows:

Monitoring of Policy 3.8.1.4 (Kidney-Pancreas Qualifying Criteria)
Through the site survey process, DEQ will review and verify completion and documentation of required tests for eligibility including the date performed.

Monitoring of Policy 3.8.3.1 (Order of Allocation to Pancreas, Kidney-Pancreas, and Kidney Candidates)
Routine allocation analysis will include monitoring for compliance with policy. This monitoring includes routine analysis of match runs in which the relevant organs have been allocated and transplanted.

Monitoring of Policy 3.8.4.3 (Waiting Time)
DEQ will continue to monitor for "Time of Waiting" as described in Policy 3.8.1.4 (Kidney-Pancreas Qualifying Criteria).

Policy Proposal:

For the convenience of the reader, the proposed policy language for Policy 3.8 (Pancreas Allocation Policy) is below, followed by the current policy language in its entirety. Because of the major substantive and formatting changes, only new content in the proposed policy language is underlined. Changes in location within Policy 3.8 are ***not*** denoted by underlines and strikethroughs. A crosswalk between the proposed policy and the current policy is located in **Exhibit D**. For policy not located in section 3.8 (Pancreas Allocation Policy), proposed policy language is underlined (example) and deleted policy language is stricken through (~~example~~).

Proposed Policy Language for Policy 3.8 (Pancreas Allocation Policy)

Policy 3.8 Pancreas Allocation Policy

Purpose: The following policies describe the process for listing pancreas, kidney-pancreas candidates, and pancreas islet and for allocating organs to pancreas, kidney-pancreas, and pancreas islet candidates.

Key Terms:

Body Mass Index (BMI) - A measure of body size, calculated as weight in kilograms divided by height in meters squared.

Calculated Panel Reactive Antibody (CPRA) - The percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. The CPRA is derived from HLA antigen/allele group and haplotype frequencies for the different racial/ethnic groups in proportion to their representation in the national deceased donor population.

C-Peptide- A byproduct of insulin production, usually by the pancreas. The level of C-peptide is a gauge of how much insulin is being produced in the body.

Creatinine Clearance (CrCl)- A measure used to determine kidney function, the CrCl indicates the volume of serum or plasma that would be cleared of creatinine by one minute's excretion of urine.

Glomerular Filtration Rate (GFR) - A measure used to determine kidney function, the GFR indicates the kidney's ability to filter and remove waste products.

3.8.1 Pancreas and Kidney-Pancreas Listing and Qualifying Criteria

3.8.1.1 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.

3.8.1.2 Previous Kidney Donor Antigens Considered "Self" Antigens in Pancreas Match Runs. Upon listing a candidate for pancreas after kidney transplantation, the transplant program has the option of entering the candidate's prior kidney donor's antigens, which will then be considered "self" antigens in pancreas match runs. In the event a candidate's prior kidney donor's antigens are entered, the match system for pancreas allocation will take into account the candidate's antigens and all of the kidney donor's mismatched antigens that are entered into UNet^{SM}, ~~Mismatches~~ Antigens that are common to a candidate's prior kidney donor and a subsequent pancreas donor are considered as matches and the candidate will appear on the match-run print out for all pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.

3.8.1.3 Combined Kidney-Pancreas Waiting List Criteria. Each candidate registered on the Kidney-Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.

3.8.1.4 Kidney-Pancreas Qualifying Criteria. In order to be eligible to accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate must:

- Qualify for a solitary kidney transplant according to the criteria used for a kidney candidate to accrue waiting time specified in Policy 3.5.11.1 (Time of Waiting); **and**
- Meet *one* of the following criteria:
  1. On insulin and c-peptide less than or equal to 2 ng/mL; or
  2. On insulin and c-peptide greater than 2 ng/mL and BMI less than or equal to 30 kg/m^2

Candidates who do not meet these criteria will not be eligible for waiting time for a kidney-pancreas offer on a match run.

Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria on the dates submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the OPTN contractor.

3.8.1.4.1 Exceptions. Candidates listed for an SPK transplant on or before their 18th birthday do not have to meet SPK qualifying criteria.

3.8.2 Required Information

3.8.2.1 Inclusion of HLA Data. ~~Recipient~~ Candidate HLA (at least 1 A, 1 B, and 1 DR antigen) information must be included when listing a potential pancreas or combined kidney-pancreas candidate on the Waiting List.

3.8.2.2 Essential Information for Pancreas Offers. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

1. Donor name and Donor I.D. number, age, sex, race and weight;
2. Date of admission for the current hospitalization;
3. Diagnosis;
4. Blood type;
5. Current history of abdominal injuries and operations including pancreatic trauma;
6. Pertinent past medical or social history including pancreatitis;
7. Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
8. Indications of sepsis;
9. Pre-or post-transfusion serologies as indicated in Policies 2.2.3.1 and 2.2.3.5~~2.2.7.1~~ (pre-transfusion preferred):
10. Current medication and transfusion history;
11. Blood glucose;
12. Amylase;
13. Insulin protocol;
14. Alcohol use (if known);
15. Familial history of diabetes; and
16. HLAA, B, Bw4, Bw6, and DR antigens.

3.8.2.3 Prospective Crossmatching. A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the

prospective crossmatch may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.

3.8.3 Allocation Sequence

3.8.3.1 Order of Allocation to Pancreas, Kidney-Pancreas, and Kidney Candidates. The Host OPO must offer organs from the combined pancreas/kidney-pancreas match run through the local pancreas and kidney-pancreas candidates as described in Policy 3.8.3.2 (Allocation Sequence) before offering organs to any isolated kidney candidates.

3.8.3.2 Allocation Sequence. Pancreata, kidney-pancreas combinations, and pancreas islets from donors 50 years of age or less who have a BMI less than or equal to 30 kg/m^2 shall be allocated according to the following sequence:

1. Local zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
2. Local pancreas and kidney-pancreas candidates with a CPRA ≥80%;
3. Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
4. National zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
5. Local pancreas and kidney-pancreas candidates;
6. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally) with a CPRA ≥ 80%;
7. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally);
8. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally) with a CPRA ≥ 80%;
9. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally);
10. Local pancreas islet candidates;
11. Regional pancreas islet candidates;
12. National pancreas islet candidates.

Pancreata, kidney-pancreas combinations, and pancreas islets from donors greater than 50 years of age or from donors who have a BMI greater than to 30 kg/m^2 shall be allocated according to the following sequence:

1. Local zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
2. Local pancreas and kidney-pancreas candidates with a CPRA ≥80%;
3. Regional zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
4. National zero mismatch pancreas and kidney-pancreas candidates with a CPRA ≥ 80%;
5. Local pancreas and kidney-pancreas candidates;
6. Local pancreas islet candidates;
7. Regional pancreas islet candidates;
8. National pancreas islet candidates;
9. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally) with a CPRA ≥ 80%;
10. Regional pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally);
11. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas regionally) with a CPRA ≥ 80%;
12. National pancreas candidates and kidney-pancreas candidates (if the Host OPO chooses to offer the kidney-pancreas nationally).

In the event that a kidney is not available at the time of the organ offer, the OPO may offer the pancreas to pancreas-alone candidates only.

3.8.3.3 Facilitated Pancreas Allocation. In the event that the Organ Center has attempted, but has been unable, to place the pancreas for a period of at least five (5) hours, or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of candidates has by that time been exhausted, the pancreas shall be offered through the Organ Center for pancreas-alone candidates listed with those transplant centers that have recorded in writing their desire, to participate in the system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to candidates who have not previously received an offer for that pancreas. The pancreas shall be offered to pancreas-alone candidates listed at transplant centers participating in the facilitated pancreas option according to the sequence in Policy 3.8.3.2 (Allocation Sequence).~~, in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below.~~

Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- ~~Isolated pancreas candidates with unacceptable HLA antigens listed in UNet^{SM} sufficient to yield CPRA ≥ 80%)[1]; and~~
- ~~Combined kidney-pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.~~

Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO and (b) ~~agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to Policy 3.8.1.7 in the event there is a candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, and (c)~~ documents this agreement and its desire to participate in the system in writing.

3.8.3.4 Organ Offer Limits. All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNet^{SM} or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients[1] according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.3.2~~3.8.1~~, as applicable (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO continues to offer kidney/pancreas combinations for zero antigen mismatched potential recipients beyond the 10th potential recipient, a kidney payback will

[1] For the purposes of Policy 3.8.3.3, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

be generated pursuant to Policy 3.5.5 (Payback Requirements). If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNet[SM], the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNet[SM]. No obligation to pay back the pancreas will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.8.3.5 Regional or National Allocation to Alternate Recipients. For a pancreas that is shared regionally or nationally, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points at that center to seek alternate candidates on the OPO's waiting list to receive the pancreas in the event that the pancreas cannot be used by that candidate. Selection of alternate candidates must be according to the pancreas allocation policy.

3.8.4 Determinants for Scoring

3.8.4.1 CPRA. To receive priority in the allocation of isolated pancreata or kidney-pancreas combinations based upon CPRA, candidate unacceptable HLA antigens sufficient to yield an 80% or greater probability of incompatibility with deceased donors (i.e., Calculated Panel Reactive Antibody (CPRA) ≥ 80%)[1] ~~sufficient to yield CPRA ≥ 80%)~~ must be entered into UNet[SM] ~~as described in Policies 3.8.1.1 – 3.8.1.4~~. Pancreata from donors with antigens included among the unacceptable antigens for a candidate will not be offered for that candidate.

3.8.4.2 Zero antigen mismatches. To receive priority in the allocation of pancreata or kidney-pancreas combinations based on a zero mismatch between the candidate and the donor, the candidate must meet the following definition:

A zero antigen mismatch is defined as occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens. A zero antigen mismatch is also defined as a match occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B, and DR antigens when at least one antigen is identified at each locus.

Phenotypic identity means that the donor and candidate each has the same antigens identified at each pair of A, B, and DR HLA loci. Candidates with only one antigen identified at an HLA locus (A, B, or DR) are presumed "homozygous" at that locus (i.e. homologous chromosomes are presumed to code for identical antigens at that locus). For example, a donor or candidate typed as A2, A- (blank) would be considered A2, A2.

A zero antigen mismatch would also include cases where both antigens are identified at a locus in the candidate but the donor is typed as being homozygous for one of the candidate's antigens at that locus. For example, there would be a zero antigen mismatch if the recipient were typed as A1, A31, B8, B14, DR3, DR4 and the donor were typed as A1.A- (blank), B8, B14. DR3, DR-(blank). If the donor is homozygous at any A, B, or

[1] For purposes of Policy 3.8, requirements for identifying and listing unacceptable antigens, as well as the definition of and parameters for calculating CPRA, are the same as those listed in Policy 3.5.11.3 (Sensitized Wait List Candidates) for assigning priority in the allocation of deceased donor kidneys.

DR locus, the match can be said to be a zero antigen mismatch, as long as none of the identified A, B, or DR donor antigens are different from those of the recipient.

3.8.4.3 Waiting Time. Within each classification in Policy 3.8.3.2 (Allocation Sequence), candidates will be ranked based on waiting.

Waiting time for pancreas and pancreas islet candidates begins on the date the candidate was listed for the organ.

Once an adult kidney-pancreas candidate is eligible for waiting time, waiting time for adult kidney-pancreas candidates begins on the date the candidate met the criteria specified in Policy 3.5.11.1 (Time of Waiting) regardless of listing date (i.e., the date the candidate began dialysis or the date the candidate had a GFR or CrCl less than or equal to 20 mL/min).

If a candidate who is listed for an SPK transplant on or before his or her 18th birthday qualifies for an SPK, then the candidate's waiting time begins on the earlier date of:

- the date the candidate met the criteria specified in Policy 3.5.11.1 (Time of Waiting) regardless of listing date (i.e., the date the candidate began dialysis or the date the candidate had a GFR or CrCl less than or equal to 20 mL/min); or
- the date of listing.

If a candidate is listed for an SPK transplant on or before his or her 18th birthday does not qualify for an SPK, then waiting time begins at the date of listing.

Candidates shall continue to accrue waiting time while registered on the waiting list as inactive.

3.8.5 Waiting Time Adjustments

3.8.5.1 Waiting Time Adjustments. Waiting time accrued by an isolated pancreas transplant candidate while registered on the waiting list shall not be assigned to the listing for a combined kidney-pancreas transplant or an isolated kidney transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).

Waiting time accrued by a combined kidney-pancreas transplant candidate while registered on the waiting list shall not be assigned to the listing for an isolated pancreas transplant or an isolated kidney transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).

Waiting time accrued by an isolated kidney transplant candidate while registered on the waiting list shall not be assigned to the listing for a combined kidney-pancreas transplant or an isolated pancreas transplant except as outlined in Policy 3.2.1.8 (Waiting Time Modification).

Waiting time accrued by a combined kidney-pancreas candidate who has received a kidney-alone transplant may be assigned to a pancreas-alone and/or islet alone listing for that candidate.

3.8.5.2 Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Cell Candidates

1. Waiting time accrued by an isolated whole pancreas transplant candidate while registered on the waiting list shall be transferred to the listing for pancreatic islet cell transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with

other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the whole pancreas and pancreatic islet waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

2. Waiting time accrued by a pancreatic islet cell transplant candidate while registered on the waiting list shall be transferred to the listing for whole pancreas transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the pancreatic islet and whole pancreas waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

3.8.5.3 Waiting Time Reinstatement for Pancreas Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor pancreas, the candidate may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as pancreas graft failure requiring the removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center of:

- A completed Pancreas Waiting Time Reinstatement Form, and
- A pancreatectomy operative report

OR

- A completed Pancreas Waiting Time Reinstatement Form, and
- A statement of intent from the transplant center to perform a pancreatectomy, and
- A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.

The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.

3.8.6 Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased. If a pancreas transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all pancreas waiting lists and shall notify within 24 hours of the event. If the pancreas recipient is again added to a pancreas waiting list, waiting time shall begin as of the date and time the candidate is relisted. If the recipient is waiting for a combined kidney-pancreas transplant and receives only an isolated pancreas transplant, the recipient's accrued waiting time while listed for the combined organ transplant shall automatically be transferred to the isolated Kidney Waiting List.

3.8.7 Islet Allocation Protocol

3.8.7.1 Criteria for Active Status. A candidate is not eligible for active status if the candidate:

- Is insulin independent and
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNet^{SM}.

If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

- That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, and
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNet^{SM} within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change.

If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months.

The transplant center must present any documentation required by this policy to the OPTN upon request.

3.8.7.2 Accrual of Waiting Time. A candidate is eligible to accrue waiting time:

- while listed in an active or inactive status; and
- until the candidate has received a maximum of three islet infusions.

Waiting time will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.

One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate waiting the longest would receive 1 point (75/75 x 1 = 1). A person with the 60th longest time of waiting would be assigned 0.2 points (75-60)/75 x 1 = 0.2). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local or regional waiting list.

3.8.7.3 Medical Suitability. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. After islet processing is completed, the transplant center will determine if the islet

preparation is medically suitable for the candidate. Medical suitability is defined as meeting the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom the center accepted the islets. If the islets are medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.

3.8.7.4 Process for Re-Allocating Islets. If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and
- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.

The transplant center must maintain this documentation and submit it upon request.

Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,
- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers,
- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run,
- Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

3.8.7.5 Removal from the Pancreas Islet Waiting List. The transplant center must remove the candidate from the waiting list within 24 hours of the candidate receiving his/her third islet infusion.

Current Policy Language for Policy 3.8 (Pancreas Allocation Policy)

3.8 PANCREAS ALLOCATION. The following policies shall apply to the allocation of pancreata.

3.8.1 Pancreas Organ Allocation. For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor, unless there is a candidate on the Waiting List who meets the requirements of Policy 3.5.4 or Policy 3.8.1.7 and for whom there is a zero antigen mismatch with the donor. Within the Waiting List for isolated pancreas, candidates shall be prioritized as set forth in Policy 3.8.1.1 below. Within the Waiting Lists for kidney-pancreas combination and combined solid organ-islet transplant, length of time waiting shall be considered for the selection of organ recipients. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero antigen mismatch between the candidate and donor and the candidate is highly sensitized as defined in Policy 3.5.4 If the pancreas is not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch candidate or pursuant to Policy 3.5.4 the pancreas, if procured from a donor less than or equal to 50 years old and with body mass index (BMI) less than or equal to 30 kg/m^2, shall be allocated regionally and then nationally, or for candidates listed for facilitated pancreas placement as described in Policy 3.8.1.3, in the following sequence. Pancreata procured from donors greater than 50 years old or with body mass index (BMI) greater than 30 kg/m^2 that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch candidate or pursuant to Policy 3.5.4, shall be allocated according to Policy 3.8.1.5 below:

3.8.1.1 Local Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- Isolated pancreas candidates with unacceptable HLA antigens listed in UNet^{SM} sufficient to yield an 80% or greater probability of incompatibility with deceased donors (i.e., Calculated Panel Reactive Antibody (CPRA) $\geq$ 80%)[1]; and
- All other isolated pancreas candidates.

3.8.1.2 Regional Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- Isolated pancreas candidates with unacceptable HLA antigens listed in UNet^{SM} sufficient to yield CPRA $\geq$ 80%)[1];
- All other isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.

[1] For purposes of Policy 3.8, requirements for identifying and listing unacceptable antigens, as well as the definition of and parameters for calculating CPRA, are the same as those listed in Policy 3.5.11.3 (Sensitized Wait List Candidates) for assigning priority in the allocation of deceased donor kidneys.

3.8.1.3 National Whole Pancreas Allocation. Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- **Iso**lated pancreas candidates with unacceptable HLA antigens listed in UNet^{SM} sufficient to yield CPRA $\geq$ 80%)[1];
- All other isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.

3.8.1.4 Facilitated Pancreas Allocation. In the event that the Organ Center has attempted, but has been unable**,** to place the pancreas for a period of at least five (5) hours**,** or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of candidates has by that time been exhausted, the pancreas shall be offered through the Organ Center for candidates listed with those transplant centers that have recorded in writing their desire, to participate in the system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to candidates who have not previously received an offer for that pancreas. The pancreas shall be offered, in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- Isolated pancreas candidates with unacceptable HLA antigens listed in UNet^{SM} sufficient to yield CPRA $\geq$ 80%)[1]; and
- Combined kidney-pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.

  Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO (b) agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to Policy 3.8.1.7 in the event there is a candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, and (c) documents this agreement and its desire to participate in the system in writing.

3.8.1.5 Islet Transplantation. If the donor is less than or equal to 50 years old and has body mass index (BMI) less than or equal to 30 kg/m^2 and suitable recipient is not identified by the allocation criteria specified in Policies 3.8.1, 3.8.1.1, 3.8.1.2, 3.8.1.3, or 3.8.1.4, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

If the donor is greater than 50 years old or has BMI greater than 30 kg/m^2, and a suitable recipient is not identified at the local level of organ allocation by the criteria specified in Policy 3.8.1, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host

OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation, and then regionally followed by nationally for whole organ transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

3.8.1.6 Islet Allocation Protocol. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. After islet processing is completed, the transplant center will determine if the islet preparation is medically suitable for the candidate. Medical suitability is defined as meeting the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom the center accepted the islets. If the islets are medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.

If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and
- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.

The transplant center must maintain this documentation and submit it upon request.
Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,
- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers,
- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run,
- Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

Waiting Time
A candidate is eligible to accrue waiting time:

- while listed in an active or inactive status; and
- until the candidate has received a maximum of three islet infusions.

Waiting time will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list,

whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.

One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate waiting the longest would receive 1 point (75/75 x 1 = 1). A person with the 60th longest time of waiting would be assigned 0.2 points (75-60)/75 x 1 = 0.2). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local or regional waiting list.

Active and Inactive Status
A candidate is **not** eligible for active status if the candidate:

- Is insulin independent **and**
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNet^{SM}.

If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

  - That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, **and**
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNet^{SM} within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change. If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months. The transplant center must present any documentation required by this policy to the OPTN upon request.

Removal from the Waiting List
The transplant center must remove the candidate from the waiting list within 24

hours of the candidate receiving his/her third islet infusion.

3.8.1.7 **Mandatory Sharing of Zero Antigen Mismatch Pancreata.** In the event there is a candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the pancreas from that donor shall be offered, first, to the appropriate Member for any highly sensitized candidate waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.4 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then be offered to the appropriate Member for any highly sensitized candidate (i.e. candidate with, unacceptable HLA antigens listed in UNet^{SM} sufficient to yield CPRA $\geq$ 80%)[1]) waiting for an isolated pancreas transplant with a zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting, unless there is a candidate listed on the Host OPO's local candidate waiting list for combined kidney/pancreas or isolated pancreas transplantation who is mismatched with the donor and also has unacceptable HLA antigens listed in UNet^{SM} sufficient to yield CPRA $\geq$ 80%. In this event, for local allocation, the pancreas shall be offered for the mismatched candidate(s) with unacceptable HLA antigens listed in UNet^{SM} sufficient to yield CPRA $\geq$ 80% (based upon length of time waiting if more than one candidate meets these criteria) before being offered for highly sensitized zero antigen mismatched isolated pancreas transplant candidates regionally and nationally.

3.8.1.7.1 Organ Offer Limit. All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNet^{SM} or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients[1] according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO continues to offer kidney/pancreas combinations for zero antigen mismatched potential recipients beyond the 10th potential recipient, a kidney payback will be generated pursuant to Policy 3.5.5 (Payback Requirements). If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNet^{SM}, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback

[1] For the purposes of Policy 3.8.1.7.1, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNet[SM]. No obligation to payback the pancreas will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.8.2 Waiting Time Adjustment. Waiting time accrued by a transplant candidate for one or more organs shall be transferred as follows if it is determined that the candidate requires another organ or organ combination:

(i) Waiting time accrued by a kidney transplant candidate while registered on the Waiting List shall be assigned also to the listing for a combined kidney-pancreas transplant if it is determined that the candidate requires a combined kidney-pancreas transplant.

(ii) Waiting time accrued by a kidney transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the candidate requires a pancreas transplant.

(iii) Waiting time accrued by a kidney-pancreas transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the candidate is suitable for a pancreas alone transplant.

(iv) Waiting time accrued by a kidney-pancreas transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated kidney transplant if it is determined that the candidate is suitable for a kidney alone transplant.

(v) Waiting time accrued by an isolated pancreas transplant candidate while registered on the Waiting List shall not be assigned to the listing for a combined kidney-pancreas transplant.

(vi) Waiting time accrued by an isolated pancreas transplant candidate while registered on the Waiting List shall not be assigned to the listing for an isolated kidney transplant.

3.8.2.1 Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Cell Candidates

(i) Waiting time accrued by an isolated whole pancreas transplant candidate while registered on the waiting list shall be transferred to the listing for pancreatic islet cell transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the whole pancreas and pancreatic islet waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

(ii) Waiting time accrued by a pancreatic islet cell transplant candidate while registered on the waiting list shall be transferred to the listing for whole pancreas transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer

between the pancreatic islet and whole pancreas waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

3.8.3 **Inclusion of HLA Data.** Recipient HLA information must be included when listing a potential pancreas or combined kidney-pancreas candidate on the Waiting List.

3.8.4 **Reporting Candidates' Unacceptable Antigens.** To receive priority in the allocation of isolated pancreata based upon CPRA, candidate unacceptable antigens sufficient to yield CPRA $\geq$ 80%) must be entered into UNet^{SM} as described in Policies 3.8.1.1 – 3.8.1.4. Pancreata from donors with antigens included among the unacceptable antigens for a candidate will not be offered for that candidate.

3.8.5 **Regional or National Allocation to Alternate Recipients.** For a pancreas that is shared regionally or nationally, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points at that center to seek alternate candidates on the OPO's waiting list to receive the pancreas in the event that the pancreas cannot be used by that candidate. Selection of alternate candidates must be according to the pancreas allocation policy.

3.8.6 **Minimum Information for Pancreas Offers.**

3.8.6.1 Essential Information Category. The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

(i) Donor name and Donor I.D. number, age, sex, race and weight;
(ii) Date of admission for the current hospitalization;
(iii) Diagnosis;
(iv) Blood type;
(v) Current history of abdominal injuries and operations including pancreatic trauma;
(vi) Pertinent past medical or social history including pancreatitis;
(vii) Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
(viii) Indications of sepsis;
(ix) Pre-or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred):
(x) Current medication and transfusion history;
(xi) Blood glucose;
(xii) Amylase;
(xiii) Insulin protocol;
(xiv) Alcohol use (if known);
(xv) Familial history of diabetes; and
(xvi) HLAA, B, Bw4, Bw6, and DR antigens.

3.8.7 **Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased**. If a pancreas transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all pancreas waiting lists and shall notify within 24 hours of the event. If the pancreas recipient is again added to a pancreas waiting list, waiting time shall begin as of the date and time the candidate is relisted. If the recipient is waiting for a combined kidney-pancreas transplant and receives only an isolated pancreas transplant, the recipient's accrued waiting time while listed for the combined organ transplant shall automatically be transferred to the isolated Kidney Waiting List.

3.8.8 **<u>Waiting Time Reinstatement for Pancreas Recipients</u>**. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor pancreas, the candidate may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as pancreas graft failure requiring the removal of the organ within the first two weeks of transplant.
Waiting time will be reinstated upon receipt by the Organ Center

- A completed Pancreas Waiting Time Reinstatement Form, and
- A pancreatectomy operative report

OR

- A completed Pancreas Waiting Time Reinstatement Form, and
- A statement of intent from the transplant center to perform a pancreatectomy, and
- A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.

The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.

3.8.9 **<u>Prospective Crossmatching</u>**. A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.

Other Affected Policy Language: Policy 3.2 (Waiting List)

3.2.1 **Renal ~~and Renal-Pancreas Combination~~ Candidate Listing**. In order to list a potential recipient of a kidney ~~or a kidney-pancreas combination~~ transplant on the Waiting List, the potential recipient's complete HLA antigen information (at least 1 A, 1 B, and 1 DR antigen) must be included at the time of listing the potential recipient. This requirement shall not apply to potential recipients listed for combined kidney-nonrenal transplantation, with the exception of kidney-pancreas transplantation as specified in Policy 3.8.2. (Inclusion of HLA Data). The entry of the complete HLA antigen information for candidates on the Waiting List shall require the use of current World Health Organization (WHO) Nomenclature. (This requirement that WHO nomenclature be used shall be implemented with the implementation of the New Data Collection Forms.)

3.2.1.8 **Waiting Time Modification.** Transplant candidates on the Waiting List may have waiting time accrued under a previous Waiting List registration reinstated under the following circumstances:

i. The candidate was incorrectly removed from the Waiting List, as a result of errors and/or miscommunication between clinical/clerical personnel. The reinstated waiting time shall include time accrued under the previous registration, in addition to the time interval during which the candidate was removed from the Waiting List.

ii. The candidate was removed from the Waiting List for medical reasons other than having received a transplant and subsequently was relisted for the same organ with the same diagnosis. The reinstated waiting time only shall include time accrued under the previous registration and not the time interval during which the candidate was removed from the Waiting List.

Upon receipt by the Organ Center of a completed Waiting Time Modification Form (with all required information) and verification of the information through review of the candidate's history, Organ Center staff may reinstate the candidate's waiting time.

All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ-specific Committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific Committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval. Modification requests for isolated kidney and combined kidney/pancreas waiting time shall indicate and substantiate with supporting documentation that the candidate met waiting time criteria as defined in Policy 3.5.11.1 (Time of Waiting), ~~or~~ Policy 3.5.12.1 (Time of Waiting), or Policy 3.8.4.3 (Waiting Time) as of the ~~listing~~ date requested. Under the circumstances described in this paragraph, waiting time modifications will be made, in the case of requests for modifying kidney or pancreas waiting time, after consideration and approval by the Kidney Transplantation Committee (for kidney and kidney/pancreas candidates) or~~&~~ Pancreas Transplantation Committee (for kidney/pancreas and pancreas candidates), or, in the case of pediatric (*i.e.*, less than 18 years old) kidney candidates, with approval from the Chair

of the Kidney ~~& Pancreas~~ Transplantation Committee to proceed to a subCommittee of the full Committee followed by consideration and unanimous approval by this subCommittee. Pediatric candidate cases addressed by a subCommittee of the Kidney ~~& Pancreas~~ Transplantation Committee will subsequently be referred to the full Committee for consideration of final action as determined appropriate by the Committee and in the case of requests for modifying waiting time for organs other than kidney, kidney-pancreas, and pancreas (except as provided in Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates)) only upon approval by the Board of Directors, or by the Executive Committee subject to ratification by the Board of Directors. Requests for modifying kidney or pancreas waiting time, along with decisions of the Kidney Transplantation Committee ~~&~~ ~~Pancreas Transplantation Committee~~ or subCommittee in the case of pediatric candidates and Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

3.2.4 **Match System Access**. OPOs are required to use the Match System (UNet^{SM}) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9, and ~~3.8.5~~3.8.2.2) and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. The OPO shall be responsible for two separate determinations 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure utilizing the ABO source documents for on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNet^{SM}.

Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run.

If the transplant center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type, such as in the event of a directed donation or to prevent organ wastage, the transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting a candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
    - ABO;
    - Serologies;
    - Donor HLA and candidate's unacceptable antigens;
    - Height; and
    - Weight.

For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the transplant at

his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

3.2.4.1 Removal of Kidney Transplant Candidates from Kidney Waiting Lists When Transplanted or Deceased. If a kidney, ~~kidney/pancreas or kidney/islet~~ transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the recipient is again added to a Waiting List for that transplanted organ, waiting time shall begin as of the date and time the candidate is relisted. ~~If the recipient is waiting for a combined kidney/pancreas or kidney/islet transplant and receives only an isolated kidney transplant, the recipient's accrued kidney waiting time shall automatically be transferred to the isolated pancreas or islet, as applicable, Waiting List.~~

~~**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.~~

~~**3.2.8 Previous Kidney Donor Antigens Considered "Self" Antigens in Pancreas Match Runs.** Upon listing a candidate for pancreas after kidney transplantation, the transplant program has the option of entering the candidate's prior kidney donor's antigens, which will then be considered "self" antigens in pancreas match runs. In the event a candidate's prior kidney donor's antigens are entered, the match system for pancreas allocation will take into account the candidate's antigens and all of the kidney donor's mismatched antigens that are entered into UNet℠. Mismatches that are common to a candidate's prior kidney donor and a subsequent pancreas donor are considered as matches and the candidate will appear on the match run print out for all pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.~~

~~**3.2.9 Combined Kidney Pancreas Waiting List Criteria.** Each candidate registered on the Kidney Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.~~

3.2.~~10~~7 Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises. Waiting time accrued by a candidate for a transplant of a life-saving organ while waiting on the Waiting List may also be accrued for a second organ, when it is determined that the candidate requires a multiple-organ transplant. For purposes of this policy, a life-saving organ shall be defined as the heart, lung or liver. Kidney, pancreas or intestine may qualify as life-saving organs if routine alternative therapies are not possible and demonstrable and after all transplant centers and programs within those centers, the other transplant programs within the OPO and the OPO itself agree to the waiting time adjustment.

Other Affected Policy Language: Policy 3.3 (Acceptance Criteria)

3.3.5 **Transplant Recipient Backup for Organ Offers.** OPOs are encouraged to make backup offers for all organs. A backup offer shall be considered equivalent to an actual organ offer and the backup center shall have one hour to respond after receiving the minimum data required for an organ offer pursuant to Policies 3.5.9, 3.6.9, 3.7.12 and/or ~~3.8.5~~3.8.2.2. Refusal to consider or respond to a backup offer will be considered as a refusal to accept the organ. The backup center may later refuse to accept the organ based on medical or logistical criteria. The backup center should be notified promptly of any change in donor status or organ disposition.

Other Affected Policy Language: Policy 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation)

3.4.2 **Time Limit For Acceptance**. A transplant center, or its designee, must access donor information within UNet^{SM} within one hour of receiving the initial organ offer notification. If UNet^{SM} is not accessed within one hour by the transplant center or its designee, the offer will be considered refused. Once the appropriate donor information is provided as described in Policies 3.5.9, 3.6.9, 3.7.12, and ~~3.8.5~~3.8.2.2, a transplant center shall be allowed one hour from the time of accessing the donor information, except as otherwise provided in Policies 3.5.3.5 (Time Limit) and ~~3.8.1.6.1 (Time Limit)~~ 3.8.3.4 (Organ Offer Limit), in which to communicate its acceptance or refusal of the organ. After one hour elapses, or shorter period as defined under Policies 3.3.5 and ~~3.8.1.6.1~~3.8.3.4, without a response, the offer will be considered refused and the offering entity may offer the organ to the transplant center(s) for the patient(s) listed next in priority on the match list.

Other Affected Policy Language: Policy 3.5 (Kidney Allocation Policy)

3.5.3.4 Kidney/Non-Renal Exception. ~~When kidneys are procured for the purpose of simultaneous kidney and non-renal organ transplantation, only one of the kidneys procured must be shared as a zero antigen mismatch.~~ In the event the kidney/non-renal organ transplant is not performed, the kidney retained for that transplant must be immediately offered for zero antigen mismatched candidates. ~~This exception does not apply to kidney islet combined transplants or kidney-pancreas combined transplants for zero antigen mismatched highly sensitized candidates as defined in Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates).~~

3.5.3.5 Organ Offer Limit. Kidneys to be shared as zero antigen mismatches, either alone or with pancreata, must be offered to the appropriate recipient transplant centers through UNet^{SM} or through the Organ Center within 8 hours after organ procurement for standard donors and within 4 hours after organ procurement for expanded criteria donors (organ procurement is defined as cross clamping of the donor aorta). For standard criteria donor (SCD) kidneys, offers must be made for at least 10 zero antigen mismatched potential recipients.[1] If there are less than 10 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. For expanded criteria donor (ECD) kidneys, offers must be made for at least the first 5 zero antigen mismatched potential recipients. If there are less than 5 zero antigen mismatched potential recipients on the match list, then offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.~~1~~3.2 (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO chooses to continue offering the kidney (s) for zero antigen mismatched potential recipients beyond the 10th potential recipient for a SCD or 5th potential recipient for an ECD, no obligation to pay back the kidney pursuant to Policy 3.5.5 (Payback Requirements) will be generated, even if the kidney is accepted for a zero antigen mismatched potential recipient. If the Host OPO chooses to share the zero antigen mismatch through UNet^{SM}, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the organ(s) recovery, defined as cross clamping of the donor aorta, to report the sharing. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNet^{SM}. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

3.5.4 **Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates.** Please refer to Policy 3.8.3 (Allocation Sequence). ~~An offer of a donor kidney to a highly sensitized candidate for whom there is a zero antigen mismatch with~~

[1] For the purposes of Policy 3.5.3.5, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

~~the donor, who is also a candidate for a combined kidney-pancreas transplant, must be accompanied by an offer of the pancreas from the donor. For purposes of this policy, "highly sensitized" is defined as panel reactive antibody (PRA) level of 80% or greater regardless of preliminary crossmatch results.~~

~~**3.5.4.1** Sharing. When kidneys are procured with the option of simultaneous kidney and pancreas transplantation, if there is any highly sensitized candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the kidney and pancreas from that donor shall be offered to the appropriate Member for the candidate with the zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting.~~

3.5.5 Payback Requirements. Except as otherwise provided in Policy 3.5.3.5 (Sharing of Zero Antigen Mismatched Kidneys - Time Limit), ~~3.8.1.6.1 (Sharing of Zero Antigen Mismatch Pancreata - Time Limit),~~ 3.8.3.4 (Organ Offer Limit), 3.5.5.2 (Exception for Prior Living Organ Donors), and 3.5.11.5.1 (Pediatric Kidney Transplant Candidates Priority for Kidneys from Donors Aged Less than 35 Years), when a kidney is shared pursuant to: (i) the zero antigen mismatch sharing policy, (ii) a voluntary arrangement for sharing the kidney with an organ other than a kidney from the same donor for transplantation into the same recipient, or (iii) a voluntary arrangement for sharing the kidney for a candidate with a PRA of 80% or greater and a negative preliminary crossmatch with the donor, the OPO receiving the kidney must offer through the Organ Center a kidney from the next suitable standard donor that does not meet the criteria for a Donation after Cardiac Death donor[1], six years old and older up to and including age 59, of the same ABO blood type as the donor from whom the shared kidney was procured at such time as the OPO has accumulated obligations to offer two kidneys (of the same ABO blood type) through the Organ Center, unless the kidney was a payback kidney. Kidneys from donors meeting the following exclusions: (i) donor is defined as an ECD, (ii) donor meets criteria for a Donation after Cardiac Death donor, or (iii) donor is less than six years old and 60 years old or older may be offered for payback at the discretion of the Host OPO in satisfaction of payback debts pursuant to standard accounting and other protocols for payback offers and acceptance. The Organ Center shall offer payback kidneys to OPOs waiting for at least two payback kidneys of the same blood type in the sequential order in which the debts were incurred with the first offer to the OPO with the longest single outstanding debt.

[1]For purposes of Policy 3.5 (Allocation of Deceased Kidneys), Donation after Cardiac Death donors shall be defined as follows: (1) A controlled Donation after Cardiac Death donor is a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room; (2) An uncontrolled Donation after Cardiac Death donor is a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.

3.5.5.1 Kidney/Non-Renal Organ Sharing.

3.5.5.1.1 Deferment of the Kidney/Non-Renal Exception. OPOs that have accumulated six or more payback obligations within the blood type of a locally procured donor shall not be permitted to defer the obligation to offer the kidneys from this donor in satisfaction of payback debts by retaining a kidney for transplant with a non-renal organ locally, except for ~~kidneys allocated for a kidney pancreas transplant pursuant to Policy 3.5.4, or~~ a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, ~~or~~ liver, or pancreas. The kidney/non-renal exception shall be deferred until

the OPO has reduced its payback obligation to less than six.

3.5.5.1.2 Deferment of Voluntary Arrangements. OPOs that have accumulated six or more payback obligations within the same blood type shall not be offered, and, if offered, shall not accept kidneys shared with a non-renal organ from a donor of the same blood type as the accumulated payback obligations, except for ~~kidneys allocated for a kidney pancreas transplant pursuant to Policy 3.5.4, or~~ a kidney/non-renal organ transplant where the non-renal organ is a heart, lung, ~~or~~ liver, or pancreas. The offer/acceptance of kidneys voluntarily shared with non-renal organs shall be deferred until the OPO has reduced its payback obligation to less than six.

3.5.11.1 Time of Waiting. Except for candidates who are less than 18 years old, the "time of waiting" begins as of the time an active candidate listed for an isolated kidney ~~or combined kidney/pancreas~~ transplant meets the minimum criteria set forth below and this information (along with the date the criteria are met) is recorded on UNet^{SM}; provided, however, that "time of waiting" under this policy shall not precede the date of the candidate's listing. Programs must be able to verify with appropriate supporting documentation that the candidate met the criteria as of the date submitted; this documentation will be subject to audit by the OPTN contractor either through on site audits or otherwise upon request for submission to the OPTN contractor. Programs shall enter information required by the Waiting Time Qualification Form on UNet^{SM} , including whether the candidate met the following criteria.

- measured (actual urinary collection) or calculated or creatine clearance or GFR (Cockcroft-Gault or other reliable formula) less than or equal to 20 ml/min; or
- initiation of chronic maintenance dialysis (defined as dialysis that is regularly furnished to an End-Stage Renal Disease (ESRD) candidate in a hospital based, independent (non-hospital based), or home setting).

"Time of waiting" for candidates listed for an isolated kidney ~~or combined kidney/pancreas~~ transplant who are less than 18 years old begins when the candidate is placed on the Waiting List. While not required for purposes of initiating waiting time, programs shall report whether or not pediatric candidates are on dialysis, and if on dialysis, a dialysis start date. Candidates, regardless of age, shall continue to accrue waiting time while registered on the Waiting List as inactive.

Other Affected Policy Language: Policy 3.9 (Allocation System For Organs Not Specifically Addressed)

3.9.3 **Organ Allocation to Multiple Organ Transplant Candidates**. Candidates for a multiple organ transplant where one of the required organs is a heart, lung, or liver shall be registered on the individual Waiting list for each organ. When the candidate is eligible to receive a heart, lung or liver pursuant to Policies 3.6 (Allocation of Livers) and 3.7 (Allocation of Thoracic Organs) or an approved variance to these policies, the second required organ shall be allocated to the multiple organ candidate from the same donor if the donor is located with the same local organ distribution unit where the multiple organ candidate is registered. If the multiple organ candidate is on a waiting list outside the local organ distribution unit where the donor is located, voluntary sharing of the second organ is recommended. When the second organ is shared, the same organ of an identical blood type shall be paid back to the Host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney in which case the organ shall be paid back pursuant to Policy 3.5~~.4.~~5 (Payback Requirements). This policy shall not apply to the allocation of heart-lung combinations. Heart-lung combinations shall be allocated in accordance with Policy 3.7.7 (Allocation of Thoracic Organs to Heart-Lung Candidates) and all other applicable provisions of Policy 3.7, or an approved variance to these policies. For candidates awaiting a combined liver-intestine transplant, please refer to Policy 3.11.4 or Policy 3.6.4.8. For candidates awaiting a combined kidney-pancreas transplant, please refer to Policy 3.8.3 (Allocation Sequence).

Candidates who:

- have been listed for multiple organs, and
- are eligible to receive a heart, lung or liver pursuant to Policies 3.6 (Allocation of Livers) and 3.7 (Allocation of Thoracic Organs) or an approved variance to these policies, must appear on the heart, lung, or liver match run.

Candidates who:

- have been listed for multiple organs, and
- have been named as the recipient of a directed organ(s) donation by the person(s) who authorized the donation, must appear on at least one of the deceased donor's match runs for at least one organ type.

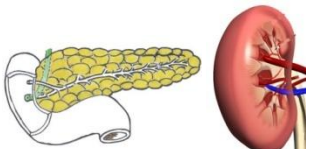
Exhibit A

How Kidneys will be Allocated under This Proposal (Option 9)

Terms

SPK- Simultaneous pancreas-kidney candidate
PA- Pancreas-alone candidate
0 ABDR Mismatch- Candidates who have a zero mismatch with the donor on the A, B, and DR loci
High CPRA- Candidates who have a CPRA of 80% or greater

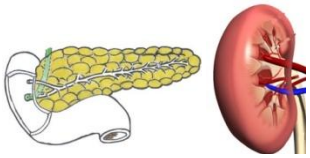
In most cases, all kidney-extra renal offers other than the kidney-pancreas offers will be made before SPK offers. If there is only one kidney available at the time of the pancreas match run, that kidney will follow the path of Kidney 1.



Pancreas Kidney 1

Pancreas Match Run
(Donors ≤ 50 years with a BMI ≤ 30 kg/m^2)

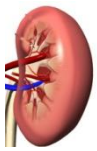
0 ABDR Mismatch High CPRA OPO SPK/PA
High CPRA OPO SPK/PA
0 ABDR Mismatch High CPRA Regional SPK/PA
0 ABDR Mismatch High CPRA National SPK/PA
OPO SPK/PA



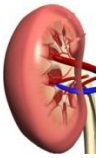
Pancreas Kidney 1

High CPRA Regional SPK/PA*
Regional SPK/PA*
High CPRA National SPK/PA*
National SPK/PA*
OPO PA Islets
Regional PA Islets
National PA Islets

**SPK offered only if the kidney is available and at the discretion of the OPO*



Kidney 2



Kidney 1

If a PA candidate accepts the pancreas, Kidney 1 will go to the kidney match run.

At this point, the OPO may choose whether to continue to offer the kidney with the pancreas or to offer the kidney to candidates on the kidney match run. If a PA candidate accepts the pancreas, Kidney 1 will go to the kidney match run.

Kidney Match Run
(Standard Criteria Donors ≤ 35 years)

0 ABDR Mismatch: OPO KI – ABO Identical
0 ABDR Mismatch: Payback KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: National KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA – ABO Identical

0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA – ABO Identical
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: National KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: OPO KI, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: OPO KI - ABO Compatible
0 ABDR Mismatch: Payback KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA - ABO Compatible

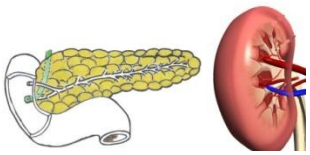
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, 21%-79% CPRA - ABO Compatible
OPO KI, Prior Living Organ Donors
OPO KI, Highest Scoring High CPRA
OPO KI, Pediatric
UNOS KI Payback Debts
UNOS KI Payback Credits
OPO KI
Regional KI, Highest Scoring High CPRA
Regional KI, Pediatric
Regional KI
National KI, Highest Scoring High CPRA
National KI, Pediatric
National KI

How the Single Kidney Contingency Allocation Could Work (Option 14)

Terms

SPK- Simultaneous pancreas-kidney candidate
PA- Pancreas-alone candidate
0 ABDR Mismatch- Candidates who have a zero mismatch with the donor on the A, B, and DR loci
High CPRA- Candidates who have a CPRA of 80% or greater

Only a single kidney is available from a standard criteria donor age <35 years (e.g., one kidney was allocated to a kidney-extra renal candidate other than SPK). There is only one kidney available at the time of the pancreas match run. That kidney will follow the path of Kidney 2.



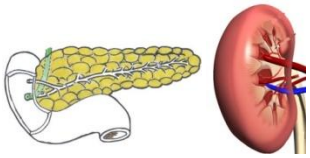
Pancreas Kidney 2

Pancreas Match Run
(Donors ≤ 50 years with a BMI ≤ 30 kg/m^2)

0 ABDR Mismatch High CPRA OPO SPK/PA
High CPRA OPO SPK/PA
0 ABDR Mismatch High CPRA Regional SPK/PA
0 ABDR Mismatch High CPRA National SPK/PA

Kidney 2

If a PA candidate accepts the pancreas, Kidney 2 will go to the kidney match run.



Pancreas Kidney 2

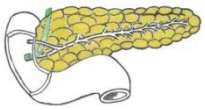
Kidney 2 goes to the kidney match run through the local pediatric classification.

The OPO waits to make further pancreas offers until it knows whether Kidney 2 will be available.

Kidney Match Run
(Standard Criteria Donors ≤ 35 years)

0 ABDR Mismatch: OPO KI – ABO Identical
0 ABDR Mismatch: Payback KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: National KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA – ABO Identical

Exhibit A

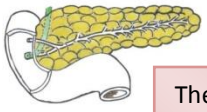


Pancreas

The OPO waits to make further pancreas offers until it knows whether Kidney 2 will be available.

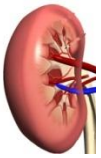
0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA – ABO Identical
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: National KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: OPO KI, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: OPO KI - ABO Compatible
0 ABDR Mismatch: Payback KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA - ABO Compatible

Exhibit A



Pancreas

The OPO waits to make further pancreas offers until it knows whether Kidney 2 will be available.

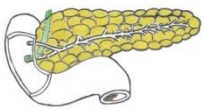


Kidney 2

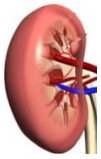
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, 21%-79% CPRA - ABO Compatible
OPO KI, Prior Living Organ Donors
OPO KI, Highest Scoring High CPRA
OPO KI, Pediatric

OPO SPK/PA

After the local pediatric KI classification, Kidney 2 is offered to the OPO SPK/PA classification on the pancreas match run if it is still available. If the kidney is not available, the OPO will offer the pancreas to PA candidates only



Pancreas



Kidney 2

UNOS KI Payback Debts
UNOS KI Payback Credits
OPO KI
Regional KI, Highest Scoring High CPRA
Regional KI, Pediatric
Regional KI
National KI, Highest Scoring High CPRA
National KI, Pediatric
National KI

At this point, the OPO may choose whether to continue to offer the kidney with the pancreas or to offer the kidney to candidates on the kidney match run. If a PA candidate accepts the pancreas, Kidney 2 will go to the kidney match run.

High CPRA Regional SPK/PA*
Regional SPK/PA*
High CPRA National SPK/PA*
National SPK/PA*
OPO PA Islets
Regional PA Islets
National PA Islets

**SPK offered only if the kidney is available and at the discretion of the OPO*

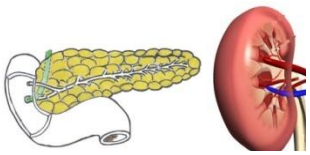
Exhibit A

How the Double Kidney Contingency Allocation Could Work (Option 12)

Terms

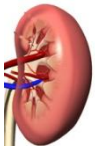
SPK- Simultaneous pancreas-kidney candidate
PA- Pancreas-alone candidate
0 ABDR Mismatch- Candidates who have a zero mismatch with the donor on the A, B, and DR loci
High CPRA- Candidates who have a CPRA of 80% or greater

Both kidneys are available from a standard criteria donor age <35 years. If there is only one kidney available at the time of the pancreas match run,that kidney will follow the path of Kidney 1.



Pancreas

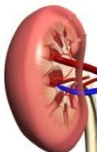
Kidney 1



Kidney 2

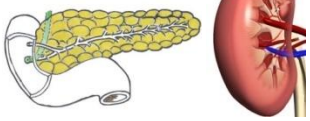
Pancreas Match Run
(Donors ≤ 50 years with a BMI ≤ 30 kg/m^2)

0 ABDR Mismatch High CPRA OPO SPK/PA
High CPRA OPO SPK/PA
0 ABDR Mismatch High CPRA Regional SPK/PA
0 ABDR Mismatch High CPRA National SPK/PA



Kidney 1

If a PA candidate accepts the pancreas, Kidney 1 will go to the kidney match run.



Pancreas

Kidney 1

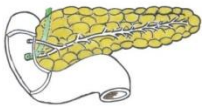
Kidney 1 goes to the kidney match run through the local pediatric classification.

Kidney Match Run
(Standard Criteria Donors ≤ 35 years)

0 ABDR Mismatch: OPO KI – ABO Identical
0 ABDR Mismatch: Payback KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: National KI, 80%-100% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA – ABO Identical

The OPO waits to make further pancreas offers until it knows whether Kidney 1 will be available.

Exhibit A

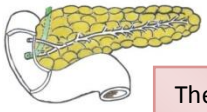


Pancreas

The OPO waits to make further pancreas offers until it knows whether Kidney 1 will be available.

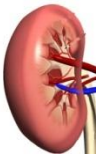
0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA – ABO Identical
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA – ABO Identical
0 ABDR Mismatch: Payback KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: Regional KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: National KI, 21%-79% CPRA – ABO Identical
0 ABDR Mismatch: OPO KI, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, 80%-100% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Payback KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: Regional KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: National KI, 21%-79% CPRA, B Candidates/O Donors
0 ABDR Mismatch: OPO KI - ABO Compatible
0 ABDR Mismatch: Payback KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, 80%-100% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, Pediatric 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, Pediatric 0%-20% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, Pediatric 0%-20% CPRA - ABO Compatible

Exhibit A



Pancreas

The OPO waits to make further pancreas offers until it knows whether Kidney 1 will be available.

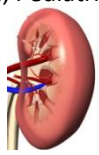


Kidney 1

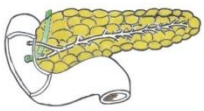
0 ABDR Mismatch: National KI, Pediatric 0%-20% CPRA - ABO Compatible
0 ABDR Mismatch: Payback KI, 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: Regional KI, 21%-79% CPRA - ABO Compatible
0 ABDR Mismatch: National KI, 21%-79% CPRA - ABO Compatible
OPO KI, Prior Living Organ Donors
OPO KI, Highest Scoring High CPRA
OPO KI, Pediatric

OPO SPK/PA

After the local pediatric KI classification, Kidney 1 is offered to the OPO SPK/PA classification on the pancreas match run if it is still available. If the kidney is not available, the OPO will offer the pancreas to PA candidates only



Kidney 2



Pancreas

Kidney 1

At this point, the OPO may choose whether to continue to offer the kidney with the pancreas or to offer the kidney to candidates on the kidney match run. If a PA candidate accepts the pancreas, Kidney 1 will go to the kidney match run.

UNOS KI Payback Debts
UNOS KI Payback Credits
OPO KI
Regional KI, Highest Scoring High CPRA
Regional KI, Pediatric
Regional KI
National KI, Highest Scoring High CPRA
National KI, Pediatric
National KI

High CPRA Regional SPK/PA*
Regional SPK/PA*
High CPRA National SPK/PA*
National SPK/PA*
OPO PA Islets
Regional PA Islets
National PA Islets

**SPK offered only if the kidney is available and at the discretion of the OPO*

Additional Supporting Evidence

There is no uniform national system for allocating pancreata (PA) in the context of simultaneous pancreas kidney (SPK) transplantation. Local donation services areas (DSAs) can set their own policy to allocate combined kidney and pancreas transplants with kidney or pancreas priority. Our goals were to determine the variability of organ allocation practices for SPK transplantation and the impact on recipient demographics and access to transplantation.

METHODS:
All 53 (DSAs) engaged in local allocation of PA for transplantation were surveyed by the OPTN regarding current PA allocation practices. DSAs were classified into 3 groups:

1. Kidney (KI) follows PA (i.e., KI is allocated to SPK recipient first, then to KI alone recipient);
2. PA follows KI (i.e., KI is allocated to KI recipient list; if candidate is appropriate for SPK, then PA allocated with KI to recipient);
3. Mixed (i.e., No formal policy or partial priority).

Results were based on OPTN data as of 1/2009 and included all locally allocated US adult pancreas transplants performed in 2008. 43 DSAs were classified as KI follows PA; 4 as PA follows KI; and 6 as mixed. Of the 43 DSAs where KI follows PA, 28 gave SPK absolute priority over PA, 4 gave solitary PA absolute priority over SPK, 8 have a combined SPK/PA list based on waiting time, and 3 were unclassified.

RESULTS:
The demographics of allocation for SPK transplantation were compared according to the three pancreas allocation systems.

Table 5: Donor and recipient demographics of SPK transplantation according to KI follows PA or PA follows KI allocation

Demographic	KI follows PA	PA follows KI
Median age recipients	41 years	43 years
Deceased donors (DD) >40yrs age	10.0%	15.7%
DD <35 yrs to SPK recipients >50 yrs	14.6%	25.0%

The donor and recipient demographics were not significantly different for SPK transplantation according to the type (KI follows PA or PA follows KI) of the allocation system.

Is there risk of "gaming" the system?
What is the likelihood that an SPK candidate would be allocated both organs but receive a kidney only transplant? Approximately 900 kidney and pancreata were allocated to SPK candidates annually. 16 candidates who were on the SPK list in 2006 received a kidney-only transplant. This situation occurred at one transplant center three times and at another transplant center two times during this period. The 11 other cases were single cases at 11 different transplant centers. These data indicated that transplant centers are not listing candidates for an SPK when they only intend on transplanting the kidney. In general, these patients do not receive the pancreas for technical reasons (e.g. advanced atherosclerotic diseases or anatomic abnormality in the donor).

If a national policy is in place where the kidney follows the pancreas, what is the likelihood that older type 2 diabetics will get an SPK transplant?

Figure 19 shows the proportion of SPK transplants in candidates with type 2 diabetes by allocation system in 2008. In 2006, there were a total of 318 SPK recipients that were older than 45 years old, and *only 38* patients had type 2 diabetes. The data indicated that relatively few SPK transplants occur in older (age >45 years) patients with type 2 diabetes.

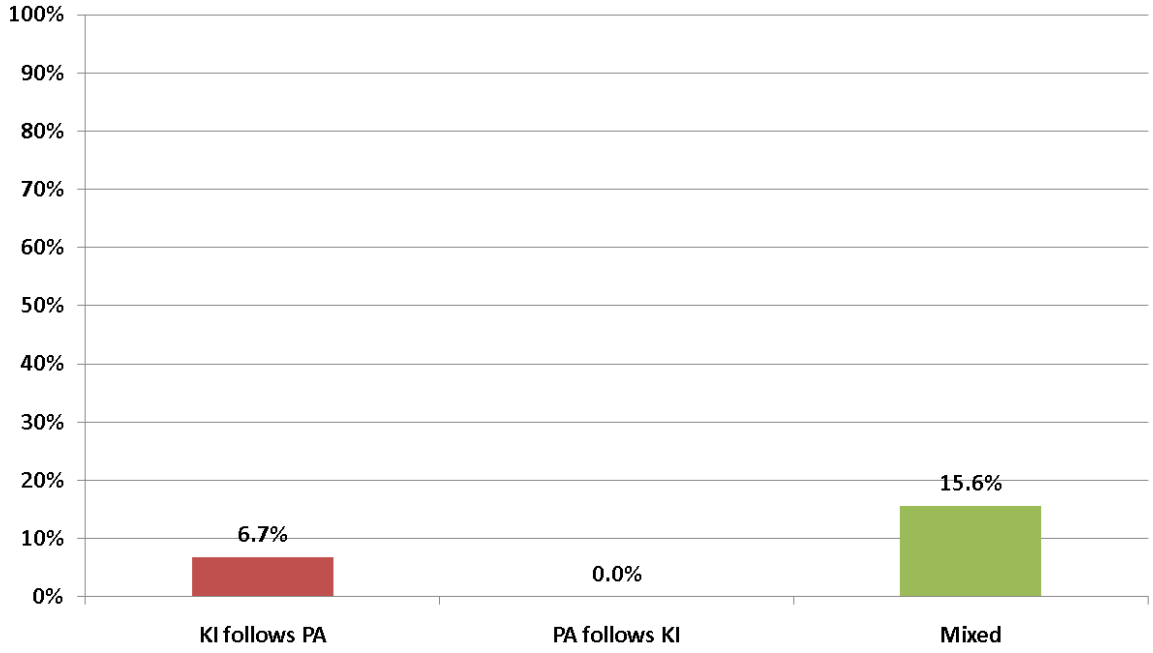


Figure 19: SPK Transplants in Candidates with Type 2 Diabetes

Are SPK candidates with relatively good renal function receiving a kidney?

In 2006-2008, there were 41 SPK transplants in recipients who were not yet on dialysis and did not have a creatinine clearance less than or equal to 20. That represented approximately 2% of SPK transplant recipients over that 2 year time period. For kidney-alone transplantation, there were 187 kidney transplants in recipients who were not yet on dialysis and did not have a creatinine clearance less than or equal to 20, which represented approximately 1% of kidney transplant recipients over that 2 year time period. The data indicated that relatively few SPK transplants occurred in recipients that did not meet the medical qualifying criteria for renal transplantation. Under the new allocation system, these patients would not qualify to accrue waiting time SPK transplantation.

Conclusions:

The donor and recipient demographics were not significantly different for SPK transplantation according to the type (KI follows PA or PA follows KI) of the allocation system. KI follows PA allocation did NOT result in a meaningful number of KI transplants in SPK candidates offered both organs; did NOT increase SPK transplantation in patients with type 2 DM; did NOT result in an increase in kidney transplants in SPK candidates not on dialysis; and did NOT result in an increase in the number of young donor kidneys transplanted into older diabetic recipients.

There is a lack of evidence that any "gaming" is now occurring in the current era in which there is even more liberal SPK allocation opportunities where local allocation of pancreas follows kidney systems dominate AND SPK priority is the rule, not a combined waiting list for SPK and PA candidates.

These data provide insights about how to develop and model a new and consistent national allocation system for pancreas transplantation recipients that increases access and decreases waiting time for transplantation. The Pancreas Committee proposes a unified national allocation system with a combined waiting list of SPK and PA candidates, in which local pancreas allocation occurs such that the pancreas follows the kidney if an SPK candidate is allocated the organs.

Additional Simulation Results

Table 6: KPSAM Results for SCD KI alone Transplants (Mean and Standard Deviation from 3 Iterations)

		Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
Variable	**Level**					
All SCD KI Alone		7166(39)	7200(7)	7090(14)	7219(22)	7392(30)
Recipient Race	African American	2392(6)	2483(20)	2374(24)	2455(9)	2478(30)
	Hispanic	1109(18)	1125(29)	1105(13)	1101(12)	1169(14)
	Caucasian	3144(9)	3093(28)	3093(6)	3157(22)	3221(32)
	Other/Missing Race/Ethnicity	521(30)	500(15)	518(20)	506(5)	524(22)
Recipient Sex	Female	3060(9)	3038(28)	3006(54)	3030(37)	3154(27)
	Male	4106(48)	4163(32)	4084(64)	4188(35)	4238(21)
Recipient Age	<18	420(16)	427(16)	442(5)	446(25)	478(11)
	18-34	982(11)	992(9)	988(25)	974(22)	997(15)
	35-49	2092(19)	2089(46)	2052(30)	2099(20)	2149(20)
	50-64	2780(49)	2787(56)	2719(39)	2794(37)	2852(49)
	65+	892(25)	906(17)	888(43)	906(11)	916(10)
ABO Type	A	2611(26)	2620(11)	2581(28)	2603(21)	2697(22)
	AB	378(8)	362(14)	370(12)	368(8)	375(14)
	B	926(10)	934(4)	925(20)	938(13)	962(8)
	O	3251(16)	3284(8)	3214(18)	3309(6)	3357(34)
	Shared-payback	254(15)	259(17)	260(3)	247(7)	269(14)
Shared/Payback	Shared-nonpayback	1085(4)	1087(27)	1064(22)	1111(37)	1164(30)
	Not Shared	5827(53)	5854(43)	5766(9)	5861(43)	5959(63)
Regionally Shared		509(5)	526(31)	511(9)	535(29)	584(25)
Nationally Shared		830(18)	820(19)	813(13)	823(17)	849(13)
Peak PRA	<10%	3847(79)	3910(36)	3808(13)	3894(24)	4004(32)
	10-80%	1699(21)	1691(26)	1686(16)	1695(19)	1763(32)
	>80%	1539(21)	1514(25)	1505(12)	1543(15)	1539(25)
	Missing	81(5)	85(2)	92(10)	87(19)	87(7)
Pediatric At Listing		488(13)	490(9)	511(6)	507(27)	544(14)
Adult At Listing		6679(39)	6710(15)	6578(8)	6712(46)	6848(15)
HLA mismatch	0 ABDR	535(14)	528(12)	517(12)	531(11)	565(8)
	0 A	979(16)	978(21)	951(16)	977(5)	1026(16)
	1 A	2691(56)	2644(34)	2672(71)	2692(13)	2749(28)
	2 A	3497(20)	3579(25)	3467(71)	3549(29)	3617(10)
	0 B	701(26)	694(14)	678(12)	681(21)	746(4)

Exhibit C

Variable	Level	Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
	1 B	1815(6)	1794(37)	1799(36)	1803(46)	1866(54)
	2 B	4650(50)	4712(20)	4612(29)	4735(55)	4780(54)
	0 DR	1327(13)	1307(13)	1300(24)	1346(22)	1385(13)
	1 DR	3327(25)	3354(51)	3273(33)	3323(9)	3392(47)
	2 DR	2512(65)	2539(49)	2517(31)	2550(10)	2615(30)
Pediatric Recipient Donor Age < 35		421(17)	417(14)	433(14)	438(33)	475(14)
Pediatric Recipient Donor Age >= 35		66(8)	73(6)	78(11)	68(14)	69(13)
Adult Recipient Donor Age < 35		3182(17)	3203(23)	3112(21)	3192(58)	3309(7)
Adult Recipient Donor Age >= 35		3496(30)	3507(13)	3466(17)	3520(24)	3539(22)
Pediatric Recipient 0mm		25(2)	29(6)	26(4)	24(2)	29(4)
Pediatric Recipient 0mm PRA >= 80%		6(3)	8(2)	6(3)	5(2)	7(1)
Pediatric Recipient PRA >= 80%		64(5)	61(4)	68(6)	66(2)	67(3)
Adult Recipient 0mm		510(15)	499(6)	491(13)	507(13)	536(5)
Adult Recipient 0mm PRA >= 80%		210(5)	204(8)	203(5)	198(10)	214(17)
Adult Recipient PRA >= 80%		1476(20)	1453(24)	1437(13)	1477(13)	1472(24)

Table 7: KPSAM Results for ECD KI alone Transplants (Mean and Standard Deviation from 3 Iterations)

		Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
Variable	**Level**					
All ECD KI Alone		1686(16)	1688(21)	1676(3)	1673(34)	1661(10)
Recipient Race	African American	562(21)	558(11)	581(13)	565(13)	574(26)
	Hispanic	231(11)	236(10)	225(11)	234(10)	222(11)
	Caucasian	772(27)	774(19)	749(19)	755(24)	752(18)
	Other/Missing Race/Ethnicity	120(2)	120(6)	121(4)	119(12)	113(6)
Recipient Sex	Female	601(18)	618(18)	602(17)	592(10)	601(12)
	Male	1085(18)	1070(18)	1074(15)	1081(27)	1060(2)
Recipient Age	<18	0(0)	0(0)	0(0)	0(0)	0(0)
	18-34	37(5)	41(2)	42(5)	35(4)	36(6)
	35-49	253(16)	262(27)	264(10)	257(26)	230(26)
	50-64	843(18)	834(8)	837(21)	835(18)	842(29)
	65+	552(27)	551(21)	534(19)	547(17)	553(11)
ABO Type	A	546(3)	559(5)	543(8)	531(33)	550(16)
	AB	68(12)	60(3)	55(7)	61(12)	58(3)
	B	172(7)	162(15)	177(11)	170(5)	160(5)
	O	900(3)	907(10)	900(10)	911(14)	892(10)
Shared/Payback	Shared-payback	52(7)	48(11)	55(5)	51(6)	46(13)
	Shared-nonpayback	317(8)	315(12)	327(13)	295(15)	322(13)
	Not Shared	1317(12)	1325(20)	1294(15)	1327(36)	1293(20)
Regionally Shared		233(6)	234(15)	243(6)	215(23)	234(4)
Nationally Shared		135(13)	130(13)	139(14)	131(5)	134(16)
Peak PRA	<10%	1117(18)	1123(22)	1108(13)	1103(27)	1094(24)
	10-80%	419(12)	412(18)	414(26)	408(11)	414(14)
	>80%	127(11)	133(13)	132(14)	138(6)	131(6)
	Missing	23(2)	20(2)	22(4)	23(4)	22(1)
Pediatric At Listing		0(0)	2(0)	1(0)	0(0)	2(0)
Adult At Listing		1686(16)	1688(21)	1676(2)	1673(34)	1660(11)
HLA mismatch	0 ABDR	54(4)	49(5)	50(3)	53(5)	53(2)
	0 A	164(18)	163(9)	156(8)	164(7)	165(6)
	1 A	655(6)	633(30)	661(13)	632(28)	646(11)
	2 A	866(8)	893(5)	859(6)	877(49)	850(1)
	0 B	88(16)	83(11)	91(6)	93(8)	91(8)
	1 B	446(18)	456(12)	459(12)	449(27)	433(6)
	2 B	1152(19)	1149(25)	1125(14)	1132(29)	1136(14)

Exhibit C

		Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
Variable	**Level**					
	0 DR	201(15)	202(10)	197(8)	205(6)	194(6)
	1 DR	766(16)	756(28)	747(10)	761(29)	736(13)
	2 DR	718(18)	731(36)	732(12)	708(28)	731(19)
Adult Recipient 0mm		54(4)	49(5)	50(3)	53(5)	53(2)
Adult Recipient 0mm PRA >= 80%		16(4)	14(3)	15(2)	20(6)	20(3)
Adult Recipient PRA >= 80%		127(11)	132(13)	132(14)	138(6)	130(6)

Table 8: KPSAM Results for SPK Transplants (Mean and Standard Deviation from 3 Iterations)

		Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
Variable	**Level**	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
All SPK		821(18)	816(24)	908(20)	797(19)	649(19)
Recipient Race	African American	141(2)	142(10)	152(8)	138(2)	117(1)
	Hispanic	98(6)	100(6)	110(6)	94(2)	73(8)
	Caucasian	557(15)	552(4)	620(9)	544(14)	444(14)
	Other/Missing Race/Ethnicity	24(3)	23(8)	26(5)	20(4)	16(2)
Recipient Sex	Female	317(6)	319(23)	354(10)	314(7)	255(10)
	Male	504(13)	497(2)	555(13)	482(20)	395(12)
Recipient Age	<18	0(0)	0(0)	0(0)	0(0)	0(0)
	18-34	180(4)	178(7)	197(5)	173(7)	144(17)
	35-49	476(9)	470(19)	520(10)	458(13)	372(5)
	50-64	163(8)	166(5)	189(14)	163(14)	131(3)
	65+	3(1)	3(2)	2(1)	3(0)	2(1)
ABO Type	A	270(8)	267(10)	296(14)	269(14)	218(14)
	AB	37(1)	37(6)	39(3)	36(3)	27(1)
	B	61(2)	61(2)	74(2)	64(6)	50(5)
	O	452(8)	451(10)	499(14)	427(4)	355(9)
Shared/Payback	Shared-payback	0(0)	0(0)	0(0)	0(0)	0(0)
	Shared-nonpayback	113(10)	134(21)	146(4)	120(10)	1(0)
	Not Shared	708(17)	682(8)	762(17)	676(14)	649(19)
Regionally Shared		88(9)	94(9)	101(7)	81(11)	1(0)
Nationally Shared		25(3)	40(15)	45(6)	40(2)	0(0)
Peak PRA	<10%	602(10)	585(15)	673(7)	585(5)	479(14)
	10-80%	149(22)	149(15)	153(13)	139(11)	108(5)
	>80%	64(5)	75(3)	72(4)	64(6)	57(3)
	Missing	7(2)	7(1)	10(3)	8(1)	5(1)
HLA mismatch	0 ABDR	11(4)	9(3)	12(3)	10(1)	2(1)
	0 A	73(5)	72(6)	81(6)	73(9)	49(6)
	1 A	352(17)	355(10)	383(19)	346(3)	277(6)
	2 A	396(11)	389(12)	444(21)	378(27)	324(19)
	0 B	27(4)	23(6)	29(5)	25(3)	10(3)
	1 B	216(4)	232(14)	255(14)	221(9)	173(12)
	2 B	579(17)	561(35)	625(24)	551(13)	467(9)
	0 DR	60(5)	63(4)	66(7)	67(1)	41(7)
	1 DR	347(7)	339(16)	372(13)	337(19)	269(12)

Exhibit C

		Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
Variable	**Level**	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
	2 DR	414(9)	415(9)	470(3)	393(11)	339(7)
Donor age < 35		656(16)	658(15)	719(18)	634(18)	509(13)
Donor Age >= 35		165(3)	158(11)	189(2)	163(2)	140(7)
Recipient Age < 50		655(13)	647(20)	717(9)	631(6)	516(16)
Recipient Age >= 50		166(9)	169(4)	191(15)	166(14)	133(3)
Recipient Age >= 50, Donor age <35		133(14)	136(7)	148(15)	130(13)	104(3)
0mm, PRA >= 80%		7(2)	5(2)	5(2)	3(1)	1(0)

Table 9: KPSAM Results for PA Transplants (Mean and Standard Deviation from 3 Iterations)

		Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
Variable	**Level**					
All PA		339(18)	324(25)	224(3)	335(2)	385(13)
Recipient Race	African American	32(1)	31(2)	21(6)	31(3)	35(2)
	Hispanic	25(5)	21(4)	12(1)	23(2)	25(3)
	Caucasian	280(12)	271(24)	189(8)	279(5)	323(16)
	Other/Missing Race/Ethnicity	2(1)	1(0)	2(1)	2(1)	2(1)
Recipient Sex	Female	170(9)	165(14)	119(2)	168(4)	199(8)
	Male	169(10)	159(11)	105(2)	167(2)	186(5)
Recipient Age	<18	0(0)	0(0)	0(0)	0(0)	0(0)
	18-34	78(3)	66(4)	52(4)	76(8)	83(7)
	35-49	191(17)	192(11)	130(2)	184(10)	222(5)
	50-64	71(5)	66(11)	41(5)	75(4)	80(5)
	65+	0(0)	1(0)	1(0)	1(0)	1(0)
ABO Type	A	130(4)	127(8)	84(4)	122(3)	139(6)
	AB	5(2)	6(1)	6(2)	6(1)	6(1)
	B	24(1)	24(5)	23(3)	22(3)	25(4)
	O	180(13)	167(13)	112(2)	185(3)	215(4)
Shared/Payback	Shared-payback	0(0)	0(0)	0(0)	0(0)	0(0)
	Shared-nonpayback	181(9)	126(15)	99(5)	135(13)	201(9)
	Not Shared	158(9)	198(12)	125(6)	200(14)	184(12)
Regionally Shared		74(6)	82(6)	82(9)	76(11)	83(0)
Nationally Shared		107(6)	44(10)	18(5)	60(6)	118(9)
Peak PRA	<10%	213(7)	192(16)	138(6)	209(3)	234(7)
	10-80%	76(7)	78(4)	53(3)	72(2)	90(8)
	>80%	41(2)	46(6)	27(1)	44(4)	47(5)
	Missing	9(3)	8(2)	6(1)	10(3)	14(2)
HLA mismatch	0 ABDR	2(0)	4(1)	1(0)	3(2)	7(3)
	0 A	32(3)	31(0)	21(4)	34(2)	41(7)
	1 A	168(15)	159(15)	101(6)	156(11)	195(10)
	2 A	139(6)	134(12)	103(5)	145(10)	149(10)
	0 B	16(3)	19(4)	9(2)	16(6)	26(4)
	1 B	115(2)	101(4)	72(6)	111(9)	129(3)
	2 B	209(17)	204(20)	142(8)	208(6)	230(13)
	0 DR	29(5)	28(3)	16(2)	23(7)	35(7)
	1 DR	166(12)	158(15)	110(2)	162(10)	194(13)

Exhibit C

Variable	Level	Current	Option 9: Combined list of SPK/PA candidates	Option 10: SPK priority over PA	Option 14: Combined list 1 KI 0mm adult & pediatric priority over SPK	Option 12: Combined list Both KI 0mm adult & pediatric priority over SPK
	2 DR	145(4)	138(11)	98(3)	149(13)	156(13)
Donor age < 35		236(9)	223(16)	153(7)	240(4)	278(10)
Donor Age >= 35		103(9)	101(9)	71(6)	95(3)	107(6)
Recipient Age < 50		269(16)	258(14)	182(4)	260(2)	304(11)
Recipient Age >= 50		71(5)	66(11)	42(4)	75(4)	81(6)
Recipient Age >= 50, Donor age <35		47(1)	46(12)	29(9)	53(2)	56(5)
0mm, PRA >= 80%		2(1)	3(1)	0(0)	2(2)	3(3)

Exhibit D

Policy Crosswalk

Current Policy Location	Proposed Policy Location	Changes
N/A	Policy 3.8 Introduction	New language; States the purpose of the policy
N/A	Policy 3.8 Key Terms	New language; Defines key terms used in the policy
N/A	Policy 3.8.1.4 Listing and Qualifying Criteria: SPK Qualifying Criteria	New language; Provides SPK qualifying criteria
N/A	Policy 3.8.3.1 Allocation Sequence: Order of Allocation to Pancreas, Kidney-Pancreas and Kidney Candidates	New language; SPK candidates receive offers for organs before all KI candidates
Policy 3.8.1 (Pancreas Organ Allocation **Policy 3.8.1.1 (Local Whole Pancreas Allocation)** **Policy 3.8.1.2 (Regional Whole Pancreas Allocation)** **Policy 3.8.1.3 (National Whole Pancreas Allocation)**	Policy 3.8.3.2 Allocation Sequence: Allocation Sequence	• SPK and PA candidates are combined onto a single match run • 0 MM SPK candidates no longer have priority over 0 MM PA candidates • The order of classifications mirrors the existing order of PA classifications
Policy 3.8.1.4 (Facilitated Pancreas Allocation)	Policy 3.8.3.3 Allocation Sequence: Facilitated Pancreas Allocation	No substantive changes; Language refined for clarity
Policy 3.8.1.5 (Islet Transplantation)	Policy 3.8.3.2 Allocation Sequence: Allocation Sequence	No substantive changes; New format (included with other classifications in Policy 3.8.3.2)
Policy 3.8.1.6 (Islet Allocation Protocol)	Policy 3.8.7 Islet Allocation Protocol: Criteria for Active Status; Accrual of Waiting Time; Medical Suitability; Process for Re-Allocating Islets; Removal from the Waiting List	No substantive changes, New format (sections re-ordered)

Policy 3.8.1.7 (Mandatory Sharing of Zero Antigen Mismatch Pancreata)	Policy 3.8.3.2 Allocation Sequence: Allocation Sequence	• 0 MM SPK candidates no longer have priority over 0 MM PA candidates • 0 MM SPK and PA Candidates have priority over other SPK and PA candidates (included in Policy 3.8.3.2 (Allocation Sequence)
Policy 3.8.1.7.1 (Organ Offer Limit)	Policy 3.8.3.4 Allocation Sequence: Organ Offer Limits	No substantive changes; Policy numbers updated
Policy 3.8.2 (Waiting Time Adjustment)	Policy 3.8.5.1 Waiting Time Adjustments: Adjustments	Waiting time can no longer be automatically transferred between KI, SPK, and PA registrations
Policy 3.8.2.1 (Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Candidates)	Policy 3.8.5.2 Waiting Time Adjustments: Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Candidates	No substantive changes
Policy 3.8.3 (Inclusion of HLA Data)	Policy 3.8.2.1 Required Information: Inclusion of HLA Data	No substantive changes; Adds clarification formerly found in Policy 3.2.1 (Renal and Renal-Pancreas Combination Candidate Listing)
Policy 3.8.4 (Reporting Candidates' Unacceptable Antigens)	Policy 3.8.4.1 Determinants for Scoring: CPRA	No substantive changes; Language updated based on new format and location
N/A	Policy 3.8.4.2 Determinants for Scoring: Level of Mismatch	New language; Mirrors language in kidney allocation policy
N/A	Policy 3.8.4.3 Determinants for Scoring: Waiting Time	New language; • States that candidates are ranked based on waiting time within each classification • Defines when waiting time begins for SPK and PA candidates
Policy 3.8.5 (Regional or National Allocation to Alternate Recipients)	Policy 3.8.3.5 Allocation Sequence: Alternate Recipients	No substantive changes

Policy 3.8.6 (Minimum Information for Pancreas Offers) Policy 3.8.6.1 (Essential Information Category)	Policy 3.8.2.2 Required Information: Minimum Information for Pancreas Offers	No substantive changes; Policy numbers updated
Policy 3.8.7 (Removal of Pancreas Transplant Candidates from Pancreas Waiting List When Transplanted or Deceased)	Policy 3.8.5 Removal from the List	No substantive changes
Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients)	Policy 3.8.5.3 Waiting Time Adjustments: Waiting Time Reinstatement for Pancreas Recipients	No substantive changes
Policy 3.8.9 (Prospective Crossmatching)	Policy 3.8.2.3 Required Information: Prospective Crossmatching	No substantive changes
Policy 3.2.1 (Renal and Renal-Pancreas Combination Candidate Listing)	Policy 3.2.1 (Renal Candidate Listing)	• Removes reference to kidney-pancreas candidates • Information is included in Policy 3.8.2.1 (Inclusion of HLA Data)
Policy 3.2.1.8 (Waiting Time Modification)	Policy 3.2.1.8 (Waiting Time Modification)	• Changes Kidney & Pancreas Transplantation Committee to Kidney Transplantation Committee and Pancreas Transplantation Committee as appropriate to reflect the separation of the Committees • Adds a reference to where kidney-pancreas waiting time information is located
Policy 3.2.4 (Match System Access)	Policy 3.2.4 (Match System Access)	Pancreas policy reference updated

Policy 3.2.4.1 (Removal of Kidney Transplant Candidates from Kidney Waiting Lists When Transplanted or Deceased)	Policy 3.2.4.1 (Removal of Kidney Transplant Candidates from Kidney Waiting Lists When Transplanted or Deceased)	• Removes references to kidney/pancreas and kidney islet candidates • Information can be found in Policy 3.8.5 (Removal from the List) • Removes automatic transfer of waiting time when a candidate only receives a kidney based on changes to pancreas waiting time policy- Policy 3.8.4.3 (Waiting Time). The transfer is still allowed. New language is in Policy 3.8.4.3.
Policy 3.2.7 (Pancreas Waiting List Criteria)	Policy 3.8.1.1 Listing and Qualifying Criteria: Pancreas Waiting List Criteria	No substantive changes; New location
Policy 3.2.8 (Previous Kidney Donor Antigens Considered "Self" Antigens in Pancreas Match Runs)	Policy 3.8.1.2 Listing and Qualifying Criteria: Previous Kidney Donor Antigens Considered "Self" Antigens in Pancreas Match Runs	No substantive changes; New location; Clarified language
Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria)	Policy 3.8.1.3 Listing and Qualifying Criteria: Combined Kidney-Pancreas Waiting List Criteria	No substantive changes; New location
Policy 3.2.10 (Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises)	Policy 3.2.7 (Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises)	Changes numbering based on other policy changes
Policy 3.3.5 (Transplant Recipient Backup for Organ Offers)	Policy 3.3.5 (Transplant Recipient Backup for Organ Offers)	Pancreas policy reference updated
Policy 3.4.2 (Time Limit for Acceptance)	Policy 3.4.2 (Time Limit for Acceptance)	Pancreas policy reference updated
Policy 3.5.3.4 (Kidney/ Non-Renal Exception)	Policy 3.5.3.4 (Kidney/ Non-Renal Exception)	No longer requires a zero mismatch KI offer to be made before an SPK offer when only one kidney is available

Exhibit D

Policy 3.5.3.5 (Organ Offer Limit)	Policy 3.5.3.5 (Organ Offer Limit)	Pancreas policy reference updated
Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates) **Policy 3.5.4.1 (Sharing)**	Policy 3.5.4 (Sharing of Zero Antigen Mismatched Kidneys to Combined Kidney-Pancreas Candidates) Policy 3.5.4.1 (Sharing)	• 0 MM SPK candidates no longer have priority over 0 MM PA candidates • Consolidates SPK information in pancreas allocation policy
Policy 3.5.5 (Payback Requirements)	Policy 3.5.5 (Payback Requirements)	Pancreas policy reference updated
Policy 3.5.5.1.1 (Deferment of the Kidney/Non-Renal Exception) **Policy 3.5.5.1.2 (Deferment of Voluntary Arrangements)**	Policy 3.5.5.1.1 (Deferment of the Kidney/Non-Renal Exception) Policy 3.5.5.1.2 (Deferment of Voluntary Arrangements)	• Disentangles SPKs from paybacks • Allows an OPO to defer a payback obligation in order to do an SPK transplant, similar to other renal/ extra-renal transplants
Policy 3.5.11.1 (Time of Waiting)	Policy 3.5.11.1 (Time of Waiting)	Removes SPK waiting time criteria (now located in Policy 3.8.4.3)
Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates)	Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates)	Directs readers to policies on combined kidney-pancreas transplants