OPTN/UNOS Pancreas Transplantation Committee
Meeting Interim Report
Teleconference
January 22, 2014, 2:00 – 4:00 pm EST

Committee members participating:
Jonathan Fridell, MD
Jon Odorico, MD
Fuad Shihab, MD
Jacqueline Lappin, MD
Carlos del Coro MD
Chris Curran CTBS, CTOP
Gloria Hairston, BS
Joan Kelly RN, CCTC, BS
Karthik Ranganna, MD
Pedro R. Sandoval, MD
Xunrong Luo MD, PhD
Douglas Hale, MD

C**ommittee members unable to attend:**
David A. Axelrod MD, MBA
Heidi Yeh, MD
John Pirsch, MD
Muhammad Mujtaba, MD, FASN
Ramasamy Bakthavatsalam, MD
Silke Niederhaus, MD
Zoe Stewart, MD, PhD

UNOS staff participating:
Kristina Tyler, JD
Bob Carrico, PhD
Kerrie Cobb
Leah K. Slife
Kimberly H. Taylor

SRTR staff participating:
Raja Kandaswamy, MD, FACS
Ajay Israni MD, MS
Susan Leppke MPH

Meeting Minutes

1. **National Pancreas/Kidney-pancreas Offers Memo**

The Committee members previously received and reviewed the memo on National Pancreas/Kidney-Pancreas Offers (Exhibit A). Over the group email the Committee members informally showed support for Option 2 (defined in Exhibit A). Also, over group email, the Committee members asked for further clarification on the data tables presented in the memo

(Exhibit A), the impact on Facilitated Pancreas Allocation, and policy drafting repercussions for each Option.

UNOS staff compiled the Committee members email questions and presented the following information in response to the questions. The data shows that:

- A significant proportion of pancreata either alone or with a kidney are allocated directly from the OPO
- OPOs attempt to allocate approximately 22% of organs
- OPOs place approximately 22% of organs
- Organ Center (OC) goes further down the match list as compared to the OPO
- OC has higher percentage of center-level offers
- There are similar rates of acceptance from OPO placement versus OC placement (Note: Pancreatic donor quality is not reflected in the data. Keep in mind that theoretically the OC could be placing the lower quality pancreata)
    - Pancreas: OC - 3.9% have placement; OPO - 3.5% have placement
    - Kidney-Pancreas: OC - 4.7% have placement; OPO - 4.8% have placement

After reviewing the data explanations a member noted that the data tables show that the OPOs are equally efficient as the OC, if not more efficient, in terms of overall placement of national pancreas and kidney-pancreas offers.

A member noted that this topic doesn't directly address how this would affect expedited placement (aka facilitated pancreas allocation) but theoretically the expedited placement wouldn't changes regardless of the Committee's vote on the topic. This is because expedited placement would still occur, the only thing that could change is who is make the expedited placement offer, either the OPO or the OC.

The members discussed the proposed options for going forward:

- **OPTION 1:** Option 1 is for the OC **to retain** exclusive authority to make national pancreas and kidney-pancreas offers and the Pancreas Transplantation Committee will draft policy to correspond with current practice.

A member noted that semantics matter in Option 1 where "current practice" should refer to "System Notice" instead. This is because "current practice" is truly that the OC and OPOs are both making national pancreas and kidney-pancreas offers. Therefore Option 1 should read, "Option 1 is for the OC to retain exclusive authority to make national pancreas and kidney-pancreas offers and the Pancreas Transplantation Committee will draft policy to correspond with the May 21, 2007 System Notice".

A member explained that OPOs and Transplant Centers have screening criteria for certain organ offers. The member expressed a concern about Option 1 in that he questioned if the OC can incorporate an OPO's Transplant Center's specific screen criteria if the OC retains exclusive authority for making national pancreas and kidney-pancreas offers. The member was further concerned that if the OC cannot incorporate a center's screening criteria for organs then there may be a flood of unnecessary offers. Another member echoed this concern and explained that he supports the most efficient option and one that also helps the OPOs make offers.

- **OPTION 2:** Option 2 is for the OC **to not retain** exclusive authority to make national pancreas or kidney-pancreas offers, where OPOs will have the ability to make national pancreas or kidney-pancreas offers. Notably, Option 2 allows the OC to retain the ability to make national pancreas of kidney-pancreas offers should an OPO seek assistance with these offers. This option will entail an educational effort to provide guidance to OPOs for making national pancreas or kidney-pancreas offers.

After reading Option 2 a member reminded the Committee that the original purpose of the May 21, 2007 System Notice was to serve as an immediate answer to a technology issue because, at the time, the OPOs were inundated with offers, and the OPOs' technology wasn't advanced enough to accommodate all the offers. The member further noted that he did not know if the original intention of the May 21, 2007 System Notice was for the OC to retain exclusive authority of national pancreas and kidney-pancreas offers indefinitely, or for the May 21, 2007 System Notice to serve as a temporary place-holder until OPOs' were capable of making the offers themselves.

- **OPTION 3:** Option 3 is to choose neither Option 1 nor 2 and propose a completely new option.

A member inquired about how national kidney offers work. An OPTN/UNOS representative explained that the OC has exclusive authority to make national kidney offers and the kidney policy contains policy language to reflect this.

From an OPO perspective, a member explained that for OPOs that have the technology and ability to make national pancreas and kidney-pancreas offers itself, the fact that the OPO currently has to contact the OC for the OC to make the offer, this causes a hindrance, delay, and time-consuming step in the organ placement process. The member further explained that when the OPO contacts the OC for a national kidney offer (for example), the OC re-evaluates the donor data to ensure its accuracy, double-checks the match-run for accuracy, asks the OPO questions, etc. And these steps have already been performed by the OPO previous to the OPO having to contact the OC. As such, there is a delay in the organ placement process.

An SRTR representative inquired how liver national offers occur. A member responded that the OPOs make the liver national offers (and the OC is not involved). The SRTR representative pointed out that the OC has restrictions on how many offers it can make, for an organ, at a time, whereas the OPOs do not have restrictions on how many offers it makes for an organ, prior to placing the organ. As a result, surgeons can unnecessarily be woken up in the middle of the night with an unrealistic offer because it will never come to fruition.

The SRTR representative suggested that if the Committee gives OPOs the option to make national pancreas and kidney-pancreas offers, the Committee should consider drafting guidelines for the OPOs regarding how to efficiently make the offers. A member supported the idea to "police" the OPOs to ensure they are engaged in acceptable practices for making national organ offers.

A member noted that the real inefficiency lies with national kidney offers.

An SRTR representative pointed out that when the OC is involved in the process, the OC serves as a third-party, where a transplant center may provide a provisional "yes" to the organ offer, but decline the offer at the last minute. However, where the OC is not involved, and the transplant center and OPO are in direct correspondence with each other, there is more of a commitment

from the transplant center when accepting an organ offer since the transplant center is in direct contact with the offering OPO. As a result, removing the OC from the process may result in less last-minute declines from transplant centers.

The Committee voted in support of Option 2 (0 in support of Option 1; 11 in support of Option 2; 0 in support of Option 3). The next step is for the Pancreas Committee to present the national pancreas and kidney-pancreas offers topic to the Executive Committee and recommend Option 2, in resolution of this topic, to the Executive Committee.

2. New Pancreas Allocation System

A member explained that the Board of Directors passed the new pancreas allocation system in November 2010. The proposal was entitled, "Proposal for an Efficient, Uniform Pancreas Allocation System". Part of the proposal contained a transition plan for kidney-pancreas candidates registered prior to the proposal being implemented (i.e. programmed). According to the Board of Director's approved Transition Plan, once the new pancreas allocation system is implemented existing kidney-pancreas candidates who have accrued kidney waiting time do not have to meet the pancreas portion of the kidney-pancreas qualifying criteria. Further, in 2010, it was acceptable to not draft corresponding policy language for transition plans. So the new pancreas allocation policy does not have corresponding policy language for the approved Transition Plan. As such, the member explained that the Committee needs to re-visit the previously approved Transition Plan, analyze the programming options currently available, and decide whether to keep the approved Transition Plan or create a new plan.

In order to decide whether to keep the approved Transition Plan or create a new one the Committee reviewed the following implementation options. (As background, the new pancreas allocation system creates four new qualifying fields for pancreas candidates. Upon implementation the four new pancreas qualifying fields must be met in order for the kidney-pancreas candidate to accrue waiting time.)

- Implementation Option 1: A kidney-pancreas candidate's waiting time will revert to zero until the pancreas qualifying criteria are met. Option 1 allows existing kidney-pancreas candidate's waiting time to go to zero upon implementation until the pancreas qualifying criteria are met. Once the pancreas qualifying criteria are met then the kidney-pancreas candidate will gain all its waiting time back.
    - Option 1 Details:
        - Communicate to centers that they must enter pancreas portion of kidney-pancreas candidates' qualifying criteria prior to implementation
        - If pancreas portion of kidney-pancreas candidates' qualifying criteria are not met then waiting time returns to zero until qualifying criteria are met
        - Changes approved Transition Plan
        - No change to policy language
- Implementation Option 2: A kidney-pancreas candidate's waiting time will stop until the pancreas qualifying criteria are met. Option 2 is the implementation option where an existing kidney-pancreas candidate's waiting time will stop upon implementation and until the pancreas qualifying criteria are met. When the pancreas qualifying criteria are met then the kidney-pancreas candidate's waiting time will continue to accrue and the kidney-pancreas candidate will gain all the waiting time back.

- Option 2 Details:
  - Communicate to centers that they must enter pancreas portion of kidney-pancreas candidates' qualifying criteria prior to implementation
  - If pancreas portion of kidney-pancreas candidates' qualifying criteria are not met then waiting time remains as it was on the date of implementation until pancreas qualifying criteria are met
  - Changes approved Transition Plan
  - Draft new policy language that will be located in *Policy 11.4.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old:* "A candidate who is registered for a kidney-pancreas and has accrued kidney waiting time prior to this policy will continue to accrue waiting time only when the candidate meets the pancreas portion of the kidney-pancreas waiting time criteria in *Policy 11.4.B* below. When the kidney-pancreas candidate meets the pancreas portion of the kidney-pancreas waiting time criteria, the candidate's waiting time will be adjusted to include all previously accrued kidney waiting time."

- Implementation Option 3: A kidney-pancreas candidate's waiting time will continue to accrue regardless of pancreas qualifying criteria being met (this option is the most similar to intent of approved Transition Plan). Option 3 mostly corresponds with the intent of the approved transition plan, where a kidney-pancreas candidate's waiting time will continue to accrue regardless of the pancreas qualifying criteria being met. In other words, if a center does not have to enter the pancreas qualifying criteria for the kidney-pancreas candidate, into the system, prior to implementation, for the kidney-pancreas candidate to continue to accrue waiting time after implementation. The kidney-pancreas candidate will continue to accrue waiting time without the pancreas qualifying criteria being met.

  - Option 3 Details:
    - Corresponds with approved Transition Plan
    - Centers are expecting this plan
    - Draft new policy language that will be located in *Policy 11.4.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old:* "A candidate who is registered for a kidney-pancreas prior to this policy and has accrued kidney waiting time prior to this policy, does not have to meet the pancreas portion of the kidney-pancreas waiting time criteria in Policy 11.4.B below."

The members reviewed and discussed the following example of how the implementation options would affect an existing kidney-pancreas candidate's waiting time upon implementation of the pancreas allocation system.

Implementation Options Example

Options	Organ type	WT, in days, at implementation	30 days after implementation (PA qualifying criteria are NOT met)	60 days after implementation (PA qualifying criteria are met)
1	KP	0 days	0	260
	KI	200 days	230	260
2	KP	200	200	260
	KI	200	230	260
3	KP	200	230	260
	KI	200	230	260

This example shows the corresponding wait time for the implementation options listed above.

Under Implementation Option 1, the kidney-pancreas candidate's waiting time goes to zero, upon implementation, if the kidney-pancreas candidate has not met the pancreas qualifying criteria at implementation. The kidney-pancreas candidate's waiting time will remain at zero until the pancreas qualifying criteria are met. When the kidney-pancreas candidate's pancreas qualifying criteria are met the kidney-pancreas candidate regains all the waiting time.

Under Implementation Option 2, the kidney-pancreas candidate will stop accruing waiting time, at implementation, if the kidney-pancreas candidate has not met the pancreas qualifying criteria. The kidney-pancreas candidate's waiting time will remain the same until the kidney-pancreas candidate meets the pancreas qualifying criteria, at which time the kidney-pancreas candidate will regain all the waiting time.

Under Implementation Option 3, the kidney-pancreas candidate will continue to accrue waiting time, at implementation, even if the kidney-pancreas candidate's pancreas qualifying criteria are not met. Option 3 is the option most similar to the intent of the approved Transition Plan.

The Committee members discussed kidney and kidney-pancreas waiting time scenarios where there could be potential gaming of the system.

A member asked how frequently kidney-pancreas candidates' fail to meet the pancreas qualifying criteria when the candidates meet only the kidney qualifying criteria? An SRTR representative explained that approximately 4% of the existing kidney-pancreas candidates will be effected by not meeting pancreas qualifying criteria at the time the transition takes place. The SRTR representative explained that the Transition Plan will only effect a small minority of candidates who have to meet the pancreas qualifying criteria.

The SRTR representative pointed out that Implementation Option 2 levels the playing field for existing kidney-pancreas candidates and newly listed kidney-pancreas candidates. This is because Implementation Option 2 requires a kidney-pancreas candidate listed after the pancreas allocation system implementation to meet both kidney and pancreas qualifying criteria and kidney-pancreas candidates listed prior to implementation essentially have to meet both kidney and pancreas qualifying criteria as well. As such, both categories of kidney-pancreas candidates meeting both kidney and pancreas qualifying criteria in order to accrue waiting time after implementation. In contrast with Implementation Option 3 the existing kidney-pancreas candidates will not have to meet the pancreas portion of the of the kidney-pancreas qualifying criteria in order to continue accruing waiting time after implementation. Further, there may be a rush to list Type 2 diabetics prior to new pancreas allocation system implementation, if the Committee chooses Implementation Option 3, because the Type 2 diabetics will not have to meet the pancreas qualifying criteria in order to accrue kidney-pancreas waiting time after implementation.

A member pointed out that if there is no penalty or incentive to enter a candidate's pancreas qualifying criteria then a center may never actually enter the candidate's information into the system. On the other hand, reducing a candidates waiting time to zero, as in Implementation Option 1, is harsh for a candidate, especially if the center just fails to enter a candidate's information. In conclusion, the member noted that Implementation Option 1 is too punitive and Implementation Option 3 is too liberal.

Another member pointed out that with Implementation Options 1 and 2 the kidney-pancreas candidate's waiting time will always catch up once the candidate's pancreas qualifying criteria are met. OPTN/UNOS staff reminded the Committee that while the member's previous statement is true the kidney-pancreas candidate may be lower on the match run list, and potentially miss an offer, during the interim time period where their pancreas qualifying criteria are not met. Further, the OPTN/UNOS staff suggested that the policy language for the transition clause may contain an end date to provide centers an incentive to enter the information within a set time period.

A member pointed out that Implementation Option 3 allows an overweight, Type 2 diabetic to game the system by currently qualifying for a kidney-pancreas and accruing waiting time, and upon implementation, never entering pancreas qualifying criteria, but continuing to accrue kidney-pancreas waiting time, even though the candidate doesn't qualify for a kidney-pancreas under the new pancreas allocation system.

A member pointed out that Implementation Option 3 is not a bad plan from the point of view of being fair to all existing kidney-pancreas candidates and the Committee would not want to disadvantage existing kidney-pancreas candidates.

OPTN/UNOS staff pointed out that Implementation Option 3 is the option that mostly coincides with the Board approved Transition Plan. Staff pointed out Implementation Option 3 is the Transition Plan that centers expect to occur with the implementation of the pancreas allocation system. As such, if the Committee supports a different Implementation Option then the Committee should be aware that we will need to make an extra effort to highlight and communicate the change to centers.

A member explained that an important question to keep in mind is, "What are we going to do with the existing kidney-pancreas candidate who doesn't qualify for a kidney-pancreas after implementation?" The members do not support removing the candidate from the list in this

scenario. OPTN/UNOS staff pointed out that if an existing kidney-pancreas candidate doesn't qualify for a kidney-pancreas after implementation of the new pancreas allocation system then the candidate will remain on the list, but won't continue to accrue waiting time.

A member pointed out that the Committee should try to remain close to what the Committee initially said they would do and Implementation Options 2 and 3 seem are relatively consistent with the initial discussions on this topic. An SRTR representative pointed out that the Committee should keep in mind that match run list will be a combined list with pancreas and kidney-pancreas candidates, as such, that makes the list more competitive.

A member noted that he is not worried about centers overloading the list with kidney-pancreas candidates with Type 2 diabetics immediately prior to implementation because if pancreas surgeons are smart they will not set themselves up to fail with high risk, obese, patients who don't qualify, where there could be poor outcomes.

The Committee members had a split vote between Implementation Option 2 and Implementation Option 3 (0 in support of Implementation Option 1; 6 in support of Implementation Option 2; and 6 in support of Implementation Option 3). As such, the Committee will reconvene to hold a re-vote. In the interim the OPTN/UNOS staff will inquire about the feasibility of creating a monitoring report for existing kidney-pancreas candidates.

3. Bylaws Review Subcommittee Update

A Bylaws Review Subcommittee member gave a quick update on the Subcommittee's progress to date. The Bylaws Review Subcommittee has been performing a review of several areas of improvement in the Pancreas and Islet Bylaws. Specifically, the Subcommittee made language changes to the following areas of the Bylaws:

Administrative Change: Changed the language that references the Appendix D membership requirements to make it clear that all Appendix D requirements apply to pancreas and islet programs.

Primary Pancreas Transplant Surgeon Requirements: Made changes to G.2.B.2 – primary surgeon requirements under the clinical experience pathway. New language provides leeway for the time period to fulfill the 10 pancreas procurements. The new language permits the surgeon to fulfill the 10 pancreas procurements as primary surgeon or first assistant either cumulatively during fellowship or subsequent to fellowship. Prior to making the language changes to G.2.B.2 the Subcommittee also considered drafting a new pathway under the primary surgeon requirements. The new pathway would have been a combination pathway that allowed the surgeon to fulfill the transplant and procurement requirements using experience from the fellowship and clinical time periods. However, after several discussions about the combination pathway the Subcommittee decided that the main problem was the time period the permitted for the surgeon to fulfill the 10 pancreas procurement requirement under the clinical experience pathway. As such, the Subcommittee opted to expand this time period in order to make it more obtainable.

Primary Pancreas Physician Requirements: Similar to the Primary Pancreas Transplant Surgeon requirements, the Subcommittee discussed creating a combination pathway for the primary pancreas physician. The combination pathway would have been a third pathway in order to become qualified as a primary pancreas physician. The combination pathway would

have been in addition to the Fellowship and Clinical Experience Pathway. However, after several discussions the Subcommittee decided that the issue lay in the first requirement under the Clinical Experience Pathway. The first requirement under the Clinical Experience Pathway requires the physician to be involved in the primary care of 15 or more newly transplants pancreas recipients. The Subcommittee expanded the time period the physician has to complete this requirement by allowing the 2 to 5 year period to overlap with the physician's fellowship.

Alternate Pathway for Predominately Pediatric Programs: The Subcommittee decided the pancreas requirements shouldn't apply to multivisceral en bloc transplants under the Alternate Pathways for Predominately Pediatric Programs. (See Primary Pancreas Transplant Surgeon Requirement and Primary Pancreas Transplant Physician Requirements; G.2.C.5 and G.3.C.5.) The Subcommittee decided that for multivisceral en bloc transplants the transplant surgeon or physician does not need to be a pancreas transplant surgeon or physician to perform a multivisceral transplant. As such, the members decided to include the following sentence for the multivisceral requirement: "If a hospital is going to include the pancreas as part of a multivisceral en bloc then the pancreas requirements don't apply."

Requirements for Designated Pancreatic Islet Transplant Programs: The Subcommittee removed ambiguous language from G.5 Primary Pancreatic Islet Transplant Surgeon Requirements and G.6 Primary Pancreatic Islet Transplant Physician Requirements. The Subcommittee changed "the primary pancreatic islet transplant surgeon" to "a primary transplant surgeon". Under G.4.C Expert Medical Personnel the Subcommittee changed language to require the program to have on site the listed experts (as opposed to recommending the program have adequate access to). And the Subcommittee created an additional requirement that the primary physician and surgeon have both islet transplant experience and post-islet transplant patient management experience.

A member explained that a representative from the CIT's Steering Committee contacted him regarding the Steering Committee weighing in on the islet section of the Bylaws. Several members supported the idea that CIT's Steering Committee provide their input on the islet section of the Bylaws. The member said he would forward the email to the Bylaws Subcommittee Chairs after the teleconference.

Path Forward

Due to the tied vote, the Committee will reconvene to re-vote on the Transition Plan for existing kidney-pancreas candidates.

The member said he would forward the email chain, regarding CIT providing input on the islet section of the Bylaws, to the Bylaws Subcommittee Chairs.

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Brian Shepard
Interim Executive Director & CEO

MEMORANDUM

TO: Pancreas Transplantation Committee

FROM: Kristina Tyler, JD, Liaison to Pancreas Transplantation Committee

RE: National Pancreas Offers and National Kidney-Pancreas Offers

DATE: January 2, 2014

Background

At the OPTN/UNOS Executive Committee meeting on May 18, 2007, the Executive Committee gave the Organ Center (OC) exclusive responsibility for making national kidney, kidney-pancreas, and pancreas offers. This is documented in the May 21, 2007 System Notice (System Notice). The System Notice states:

> Effective Wednesday, May 23, 2007, all kidney, kidney-pancreas, and pancreas offers that extend beyond regional placement will be made exclusively by the UNOS Organ Center. This decision was approved by the Executive Committee as a temporary process change until more specific screening criteria can be programmed and the system can be modified to allow OPOs to access and use Organ Center screening resources. Those OPOs that make electronic organ offers beyond their DSA will turn over organ placement to the Organ Center upon reaching national-level candidates on the match.

Since May 21, 2007, the OC has retained sole authority to make national kidney-pancreas and pancreas offers. However, this System Notice is outdated since OPOs currently have the technology and ability to make national kidney-pancreas and pancreas offers themselves. Additionally, there is no policy that prevents OPOs from making national pancreas offers or kidney-pancreas offers directly, without going through the OC.

Since the Executive Committee made the initial decision for the OC to exclusively make national pancreas offers and national kidney-pancreas offers, the Pancreas Transplantation Committee will present a recommendation to the Executive Committee as to whether the System Notice should remain in effect for national pancreas and kidney-pancreas offers. As such, the Committee needs to determine the appropriate path forward. The paragraphs below outline the area of improvement, questions to answer, data to consider, information to assist you in your recommendation, and proposed options.

Area of Improvement

Currently, there is no policy language describing the OC's authority to *exclusively* make national pancreas or kidney-pancreas offers, although current practice is for OPOs to defer to the OC for national pancreas or kidney-pancreas offers. To be consistent, , if the Executive Committee wants the OC to continue to retain exclusive authority to make national pancreas and kidney-pancreas offers, then there needs to be policy language to support the requirement.

Considerations

Should the OC retain the authority to exclusively make national pancreas or kidney-pancreas offers? If the OC retains authority to exclusively make national pancreas and kidney-pancreas offers, the Pancreas Transplantation Committee will need to draft policy making it a requirement.

Support for Current Practice and the Executive Committee's Decision

Facilitated pancreas allocation must be done by the OC, and Facilitated Pancreas Allocation and national pancreas offers closely coincide in practice. It could be inefficient for the OC to cease national pancreas offers while retaining the facilitated pancreas process.

The OC also currently makes national kidney offers. For consistency purposes (as well as to make placement less complex for OPOs) pancreas allocation typically mirrors kidney allocation wherever possible.

Current Kidney policy 3.5.7.3 grants the OC authority to exclusively make national kidney offers. Policy 3.5.7.3 states that, "With the exception of 0-ABDR mismatched kidneys and kidneys shared nationally for 100% CPRA candidates, if a kidney is not placed in the donor hospital's DSA, then the host OPO must contact the OPTN Contractor to assist with national placement." (Note that in the Policy Rewrite, policy 8.7.C National Kidney Offers, grants the OC the authority to exclusively make national kidney offers. Policy 8.7.C states that, "With the exception of zero mismatched kidneys and kidneys shared nationally for 100% CPRA candidates, if a kidney is not placed in the donor hospital's DSA, then the host OPO must contact the Organ Center to assist with national placement." Policy 8.7.C is currently approved by the Board of Directors but not implemented since it is part of the kidney allocation system, it will become effective when the kidney allocation system is programmed and implemented some time in 2014.)

Support for Eliminating the Requirement

The 2007 System Notice clearly states that the OC's exclusive authority to make national pancreas and kidney-pancreas offers was meant to be a "temporary process change" until programming and system changes allow OPOs to make national pancreas and kidney-pancreas offers itself. Therefore, it appears the Executive Committee's intent was for OC to only temporarily oversee the national pancreas and kidney-pancreas offers. As such, there is a strong argument that due to advancements in DonorNet since 2007, OPOs have the ability to make national pancreas or kidney-pancreas offers. Current technology may make the 2007 System Notice regarding the OC's exclusive authority to oversee national pancreas or kidney-pancreas offers a moot point. If the OC does not retain the authority to exclusively make national pancreas or kidney-pancreas offers then there is consistency between current pancreas and kidney-pancreas policy and the 2007 System Notice's intent.

Other Considerations

Regarding national kidney-pancreas offers, it is feasible for the OC to isolate kidney and pancreas offers, so the OC may continue to make national kidney or pancreas offers without retaining exclusive authority over national kidney-pancreas offers. However, for consistency with the new pancreas allocation system, the national kidney-pancreas offers should coincide with national pancreas offers in practice and policy.

Regarding other organ offers, policy does not have a comparable practice that entails national liver, heart, lung, or intestine offers. There is no comparable practice of using the OC for all national offers for other organs.

The OC is staffed and trained to make national pancreas and kidney-pancreas offers. Removing the national pancreas and kidney-pancreas offer requirement from the OC could adversely impact the organ placement level.

Data

The four tables below present data pertinent to national pancreas and kidney-pancreas offers and acceptances. The data show the number of distinct center level offers by source offer and number of matches by source of the offer from the time period 01/01/2012 through 06/30/2013. The tables are based on OPTN data as of November 8, 2013. The data for each table are subject to change based on future data submission or correction.

The table below shows the number of distinct center level offers, by source of offer, for national offers on pancreas match runs from 01/01/2012 through 06/30/2013.

United Network for Organ Sharing
National Offers on Pancreas Match Runs from 01/01/2012 - 06/30/2013
Number of Distinct Center Level Offers by Source of Offer - Organ Center(OC) vs. Recovering OPO (OPO)

	Match Had an Acceptance					
	No		Yes		All	
	Number of National Distinct Center Level Offers		Number of National Distinct Center Level Offers		Number of National Distinct Center Level Offers	
	N	%	N	%	N	%
National Electronic Offers Sent By:						
Organ Center	31,377	82.9	1,586	80.6	32,963	82.8
Recovering OPO	5,816	15.4	351	17.8	6,167	15.5
Both the OC and the OPO	92	0.2	4	0.2	96	0.2
No Electronic Offers were Made	557	1.5	26	1.3	583	1.5

The table below shows the number of matches, by source of offer, for national offers on pancreas match runs from 01/01/2012 – 06/30/2013.

United Network for Organ Sharing
National Offers on Pancreas Match Runs from 01/01/2012 - 06/30/2013
Number of Matches by Source of Offer - Organ Center(OC) vs. Recovering OPO (OPO)

	Match Had an Acceptance					
	No		Yes		All	
	Number of Matches with National Offers		Number of Matches with National Offers		Number of Matches with National Offers	
	N	%	N	%	N	%
National Electronic Offers Sent By:						
Organ Center	2,302	68.2	93	69.9	2,395	68.2
Recovering OPO	776	23.0	28	21.1	804	22.9
Both the OC and the OPO	278	8.2	9	6.8	287	8.2
No Electronic Offers were Made	21	0.6	3	2.3	24	0.7

The table below shows the number of distinct center level offers, by source of offer, for national offers on the kidney-pancreas match runs from 01/01/2012 – 06/30/2013.

United Network for Organ Sharing
National Offers on Kidney-Pancreas Match Runs from 01/01/2012 - 06/30/2013
Number of Distinct Center Level Offers by Source of Offer - Organ Center(OC) vs. Recovering OPO (OPO)

	Match Had an Acceptance				All	
	No		Yes			
	Number of National Distinct Center Level Offers		Number of National Distinct Center Level Offers		Number of National Distinct Center Level Offers	
	N	%	N	%	N	%
National Electronic Offers Sent By:						
Organ Center	20,218	83.4	1,263	85.7	21,481	83.6
Recovering OPO	3,583	14.8	193	13.1	3,776	14.7
Both the OC and the OPO	127	0.5	3	0.2	130	0.5
No Electronic Offers were Made	308	1.3	15	1.0	323	1.3

The table below shows number of matches, by source of offer, for national offers on the kidney-pancreas match runs from 01/01/2012 – 06/30/2013.

United Network for Organ Sharing
National Offers on Kidney-Pancreas Match Runs from 01/01/2012 - 06/30/2013
Number of Matches by Source of Offer - Organ Center(OC) vs. Recovering OPO (OPO)

	Match Had an Acceptance				All	
	No		Yes			
	Number of Matches with National Offers		Number of Matches with National Offers		Number of Matches with National Offers	
	N	%	N	%	N	%
National Electronic Offers Sent By:						
Organ Center	1,005	56.3	50	62.5	1,055	56.6
Recovering OPO	412	23.1	21	26.3	433	23.2
Both the OC and the OPO	365	20.5	8	10.0	373	20.0
No Electronic Offers were Made	2	0.1	1	1.3	3	0.2

Proposed Options

OPTION 1: Option 1 is for the OC **to retain** exclusive authority to make national pancreas and kidney-pancreas offers and for the Pancreas Transplantation Committee to draft policy to correspond with current practice.

OPTION 2: Option 2 is for the OC **to not retain** exclusive authority to make national pancreas or kidney-pancreas offers, and for OPOs to have the ability to make national pancreas or kidney-pancreas offers. Option 2 allows the OC to retain the ability to make national pancreas of kidney-pancreas offers should an OPO request assistance with these offers. This option may require education to provide guidance to OPOs for making national pancreas or kidney-pancreas offers.

OPTION 3: Option 3 is to choose neither Option 1 nor Option 2, and instead propose a completely new option.

Sincerely,

Kristina Tyler, JD
Liaison to Pancreas Transplantation Committee

cc:
Roger Brown, Assistant Director, Organ Center
Jason Livingston, JD, Director, Assistant General Counsel, Liaison to Executive Committee
James Alcorn, JD, Director of Policy
Gena Boyle, MS, Policy Manager, Liaison to Kidney Transplantation Committee