

OPTN/UNOS Pancreas Transplantation Committee
Meeting Summary
October, 8, 2015
Chicago, IL

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Discussions of the full committee on October, 8, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov/>.

Committee Projects

1. Pancreas Underutilization – Revisions to Facilitated Pancreas Allocation

The Proposal to Revise Facilitated Pancreas Allocation was out for public comment (until October 14) and the committee reviewed the proposal and public comment up to this point. In particular, the Committee focused on public comment concerns over the proposed qualifying criteria for programs to have access to facilitated pancreas allocation. During the development of the proposal, the committee conjectured that if the facilitated pancreas allocation list is comprised of programs with established records of importing and transplanting deceased donor pancreata, then the facilitated pancreas allocation system should increase pancreas utilization and transplantation. The criteria proposed in the public comment proposal would have required programs to perform at least 5 pancreas transplants using imported pancreata in one of the two previous years. This criteria will be used by UNOS staff annually to review the list of programs granted access to facilitated pancreas allocation. Public comment from both the regions and professional societies stated that this criteria was too restrictive. There was consensus in public comment that the criteria should be 5 pancreas transplants using imported pancreata within the two previous years. In response to this consensus in public comment, the Committee reviewed data on the effect of various criteria on the list of qualified programs, including the aforementioned criteria put forth by the community. Under the current voluntary system there are 31 programs with access to facilitated pancreas allocation, the original criteria would have allowed 23 programs, and the revised criteria based on consensus in public comment will yield 35 programs. Of these 35 programs, 21 do not currently receive facilitated pancreas offers. The committee agreed to wait for the public comment period to finish until it voted to change the criteria.

The other predominant theme in public comment was the concern expressed that the changes to facilitated pancreas allocation would affect normal pancreas allocation. The idea being that allowing access to facilitated pancreas allocation at 3 hours before donor recovery would infringe upon normal allocation practices. The committee addressed this concern in the public comment proposal by reviewing data on the length of time the OPO or Organ Center spent trying to place a pancreas. Overall, the average time from first offer to cross clamp was 19.3 hours (SD=10.7). For pancreas organs that were recovered the average was 21.1 (SD=10.7) and for those that were not recovered the average was 18.7 (SD=9.8). For all offers, 75% of the time more than 12.4 hours was spent trying to place the pancreas. This data reaffirmed to the committee that allowing the OPO or Organ Center to use facilitated pancreas allocation at 3 hours before donor recovery would still give adequate time for the standard allocation system to be the

primary method of organ placement. The Committee agreed to wait for the public comment period to finish until it addressed any concerns related to this.

2. Pancreas/Kidney Pancreas Post Implementation Clarifications

The Board of Directors approved the new pancreas allocation system in November of 2010. The changes to the pancreas allocation system were implemented on October 30, 2014. The Implementation Subcommittee is tasked with evaluating the proposal and developing any potential clarifications. The Subcommittee met in August 2015 to develop a data request based on the available 6-month Post-KAS data. The Subcommittee agreed with the plan to evaluate the proposal developed in 2010 by the Committee. The full Committee reviewed the data results during this meeting. In summary, the 6 month data showed very little change pre and post implementation of the new allocation system. The Committee concluded that the 1 year data available in early 2015 would be more valuable to draw conclusions and potentially develop clarifications.

Committee Projects Pending Implementation

1. Definition of Pancreas Graft Failure

In June 2015, the Board of Directors approved the Definition of Pancreas Graft Failure Proposal. This proposal establishes policy for when a pancreas graft has failed which will replace TIEDI help documentation to dictate exactly how professionals should document pancreas graft failure. The graft status section in the OPTN Pancreas and Kidney Pancreas Transplant Recipient Registration and Transplant Recipient Follow-Up Forms (“OPTN pancreas forms”) will be updated. Post-transplant c-peptide and HbA1c will be collected to help further understanding of pancreas graft function post-transplant in relation to standard markers of diabetes. Implementation is pending programming and OMB approval.

2. Require Serum Lipase for All Pancreas Donors

In November 2014, the Board of Directors approved the proposal to require the Collection of Serum Lipase for Pancreas Donors. This proposal requires serum lipase as a field in order to make electronic pancreas offers. The proposal also created a new field in DonorNet where OPOs report the upper limit of normal of the laboratory’s normal serum lipase reference range (i.e., maximum normal value or highest reference value.) Implementation is expected during the third quarter 2016.

Implemented Committee Projects

1. Pancreas Allocation System

The Board of Directors approved the new pancreas allocation system in November of 2010. The changes to the pancreas allocation system were implemented on October 30, 2014. The Implementation Subcommittee has reviewed 6 month data and will review 1 year data in early 2016.

Review of Public Comment Proposals

1. Simultaneous Liver Kidney Allocation

The committee fully supports the medical eligibility criteria and believes that it will reduce the number of kidneys being transplanted to individuals who do not need a kidney with a liver.

The committee suggested that the safety net might disincentivize living donation. The committee member stated that if a candidate would likely receive a deceased donor kidney shortly after liver transplant through the safety net, then it could potentially dissuade living donation following the liver transplant. Although, the committee acknowledges that living donor kidney after a liver transplant has been an infrequently used alternative.

The committee raised several concerns and expressed confusion pertaining to the idea of mandating regional sharing of kidneys with SLK candidates. The Kidney Committee Chair explained to the committee that the allocation of the kidney was still up to the OPO's discretion. However, several committee members were confused on how the policy would interact with mandatory Share 35 allocation. It was the consensus of the committee that this proposal would suggest to OPOs that the kidney would follow the liver regionally, thus prioritizing SLK over other multi-organ allocations, specifically simultaneous pancreas-kidney transplants (SPK). Additionally, the committee suggests that the entire multi-organ allocation order project be addressed holistically, rather than the SLK piece move forward initially and the rest being worked on later.

The committee is concerned that this proposal may lead to a further decline in volume of pancreas transplants. A deceased donor pancreas is most likely to get transplanted if it is placed as a SPK transplant. If a regional SLK were to be prioritized above the SPK, the pancreas may never get transplanted. The committee is not convinced that the marginal benefit of a SLK over a liver-alone, for a similar meld score patient, warrants prioritization above the SPK list, particularly at the regional level. It is important to note that candidates are required to qualify for kidney-alone waiting time as part of qualifying for SPK waiting time, thus meeting criteria that is more restrictive compared to the eligibility criteria for SLK in this proposal. This fact concerns the committee, as they conjectured that SPK candidates have the highest mortality on the wait list of all kidney candidates.

2. Establish Pediatric Training and Experience

A question was raised regarding the difference in outcomes between centers meeting the volume criteria and centers not meeting the volume criteria. It was stated that 5 year outcomes may not be the best measure, especially with the fact that patients may be traveling greater distances after the implementation of this proposal which leads to issues with follow-up. Additionally, a committee member brought up the hypothetical situation of a pediatric patient at an adult hospital who was very ill, not being required to be transported to a pediatric hospital for a transplant due to safety issues with transportation. It was agreed that this situation was unlikely and that programming for such a situation was not possible.

3. Addressing the Term "Foreign Equivalent" in OPTN/UNOS Bylaws

It was suggested by the Committee that if key personnel requirements are in place to promote donor safety and transplant outcomes, then these same requirements should apply to other staff.

4. Changes to Transplant Program Key Personnel Procurement Requirements

The Committee reviewed this proposal and had no significant concerns.

5. Proposal to Revise OPTN/UNOS Data Release Policies

There was concern over how individuals with easily identifiable data would be protected with this proposal. The DAC liaison responded that this has been an existing issue and there is a required data use agreement for the data requestor that requires them to not identify individuals.

Other Significant Items

1. Future Projects

The committee identified two new projects that would be a priority for the committee moving forward:

- Investigate restrictions by blood type for kidney-pancreas allocation.
- Revisit the Pancreas After project from 2013, demonstrating improved outcomes for PAK.

Upcoming Meetings

- October 20th, 2015 (Teleconference)
- December 9th, 2015 (Teleconference)