OPTN Pancreas Transplantation Committee
Meeting Summary
April 7, 2025
Conference Call

Dolamu Olaitan, MD, Chair
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Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Cisco Webex teleconference on 04/07/2025 to discuss the following agenda items:

1. Public Comment Feedback Review and Discussion
2. New Project Discussion
3. Offer Filters Presentation
4. Match Run Dashboard

The following is a summary of the Committee's discussions.

1. Public Comment Feedback Review and Discussion

The Committee reviewed and discussed the Winter 2025 public comment analysis and considered whether to incorporate the recommendations made.

Summary of presentation:

The top themes from the Winter 2025 public comment update are as follows:

Medical Urgency Criteria:

- Broad support for using objective measures like the Hypo-AQ IA sub-score and CGM data.
    - There were recommendations of caution for using CGM data as concerns of access were brought up.
- Suggestions to include the Clarke score due to its familiarity and widespread use.
- Caution around incorporating diabetic ketoacidosis (DKA) as a criterion; support for developing educational materials to ensure consistent evaluation by review boards.
- Standardized assessment tools for severe hypoglycemic events and DKA were recommended

Patient Access Concerns:

- Worry that multi-organ transplant (MOT) policies might disadvantage pancreas-alone candidates.
- ASTS raised concerns that MOT allocation might limit access for pediatric, kidney-alone, and pancreas-alone patients.
- Comments also address concerns that pancreas-after-kidney (PAK) or those with a failed pancreas graft after simultaneous pancreas-kidney (SPK) transplants might not have access to the medical urgency status since they do not present with impaired awareness of hypoglycemia.

Continuous Distribution:

- Feedback indicated support for continuous distribution, commentors voiced their concern around proximity efficiency, highlighting the need to ensure it receives adequate as an attribute

Summary of discussion:

- The Committee will consider including the Clarke score as a clinical criteria for medical urgency.
- Diabetic ketoacidosis (DKA) will need to be reviewed as a clinical criteria due to its subjectivity
- The Committee will consider drafting example narratives to guide transplant programs in applying for medical urgency for their candidates.
- The Committee identified areas for post-implementation monitoring:
    - Pancreas-after-kidney (PAK) and simultaneous pancreas-kidney (SPK) transplant groups to ensure no increase in mortality or unintended consequences
- The Committee will review match run analysis data to consider whether changes in attribute weights are warranted for proximity efficiency attribute

The Chair queried whether adding the Clarke score in as a clinical criteria could be done without sending the items back out for public comment. It was affirmed that sense this feedback came from public comment and is a logical outgrowth of the Committee's work, it would not need to be sent back out for public comment until a final proposal was released. A member asked whether it would be operationally difficult for programs to switch to using the Hypo A-Q IA subscoring system, as opposed to the Clarke score, as it provides better data. They advised that adding too many options might confuse the centers and impact data gathering and analysis. Another member agreed that the Hypo A-Q IA scoring system provides objectivity, noted that precedent from estimated glomerular filtration rate (eGFR) policy allows multiple formulas, as long as the formula is not race based. They highlighted that flexibility might ease the policy implementation. The Chair acknowledged the concern and noted that there is a need for defined thresholds for the proposed Pancreas Review Board that would approve medical urgency requests. The Clarke and Hypo A-Q IA scores have defined thresholds, but other tools may not. A member voiced their concern around the subjectivity of the Clarke score, favoring the more objective Hypo A-Q IA subscore. They called out that not all patients have access to continuous glucose monitors (CGMs).

Another member added their concern about leaving the scoring too open-ended could cause inconsistencies in requests and the application of the medical urgency status. A member offered their insight that though they use the Clarke score, since the broader adoption of CGMs, it is less accurate and less used. They advised that they use clinical history of severe hypoglycemic events as an indicator of concern. Other members shared their support of using the CGM data as an objective metric for impaired awareness of hypoglycemia. One member noted that clinician discretion and patient-centered scoring should be a priority for the group.

Members discussed how to document diabetic ketoacidosis (DKA) and a member expressed their concern that it often occurs in patients due to non-compliance, so how might the review board address those cases. Other members offered that often DKA can occur in compliant patients as well, especially in those without CGMs or adequate access to care. It was also noted that centers often screen for non-compliance during the listing process, as those patients who struggle with compliance might not be adequate candidates for transplant. Members agreed that centers should provide detailed narratives

when submitting medical urgency requests. One member added that providing clear outlines on how the narratives should be written is beneficial for both the center and the reviewers. Staff added that post-implementation monitoring reports and data collected from the applications submitted will aid in refining the process further.

One member asked whether transplant centers will need to resubmit urgency requests on a periodic basis or whether the status remains static once approved. The Chair offered that previous discussions indicated a desire to keep the medical urgency status static, since it is unlikely a candidate will improve before transplant.

Members briefly discussed concerns from public comment that spoke to medical urgency access concerns for PAK and SPK candidates. The Chair vocalized that the goal of the urgency criteria is to identify medically urgent candidates, not to ensure equal outcomes across all transplant types. They suggested post-implementation analysis to assess outcomes and mortality by organ type. Other members agreed, reinforcing that the focus should be on medical urgency, and the process of urgency criteria is not about creating equity across all transplant groups. The Chair recommended that since the goal is to identify patients with highest mortality risks, when conducing the post-implementation review, these groups can be examined to identify whether there was unintentional exclusion and whether further criteria should be developed. Other members agreed to address the concern with post-implementation monitoring.

Members discussed the feedback regarding geographic proximity, the proximity efficiency attribute in pancreas continuous distribution (CD). Members wondered how increasing the weight of the proximity efficiency attribute would affect other attributes, especially qualifying time. A member cautioned that favoring proximity efficiency too much could worse regional disparities or reduce the weight on other attributes such as medical urgency or CPRA. Staff added that these trade-offs and changes in weights can all be reviewed through the match analysis run by staff that would be presented later.

A member asked how the question of multi-organ transplant (MOT) would be addressed within the context of CD. Staff advised that it will be a topic of discussion and will be able to be addressed once final attribute weights are decided. The Chair emphasized the need to understand how the medically urgent candidates score within the CD framework in order to discuss MOT prioritization of pancreas candidates.

Next steps:

The Committee will continue refining and developing the medical urgency criteria in future meetings and will aim to address concerns of proximity efficiency and other attribute weights after reviewing match run analysis data.

2. New Project Discussion

The Committee heard feedback from the OPTN Executive Committee regarding their project to develop a guidance document on procurement of pancreata. The Committee discussed revision of the project and possible development of a new project.

Summary of presentation:

The Executive Committee did not approve the guidance document and recommended the Committee revise the project as either policy or possibly a concept paper which would pave the way for eventual policy.

Summary of discussion:

No decisions made.

Members agreed that developing an enforceable policy would be a good approach. A member offered that should policy be the ultimate goal of this work, then a concept paper might be a good starting point.

Staff shared the Committee's previous project ideas and queried whether they would want to incorporate any of the ideas into the revised project.

A member advised caution about converting common practices into enforceable policy, such as requiring a separate pancreas program director, as it could be counterproductive for pancreas program growth or lead to fewer approved programs. Another member sought clarity on the concept of training opportunities. It was highlighted that the OPTN does not have purview over enforcing training requirements, that remains with independent medical societies. The Chair queried whether it would be possible to create both policy and a guidance document to supplement it, staff advised this is an option. The Chair posited that a concept paper could be the first approach to gather public comment input, a member asked if feedback is negative what are next steps. It was advised that might necessitate a pivoted approach or putting the project on the "back-burner" for a bit.

Next steps:

The Committee will continue discussing this project revision and make a determination on the new project discussion at a future date.

3. Offer Filters Presentation

The Committee received an updated presentation on Offer Filters and learned about opportunities for development of Pancreas Offer Filters.

Summary of discussion:

No decisions made.

A member asked whether a bypass code is input when an offer is screened out due to the filter, staff confirmed this is the case and any offers filtered do not affect acceptance metrics negatively.

Members agreed that any project taking on pancreas offer filters should create separate filters for both pancreas and kidney-pancreas (KP) offers, since there are different criteria evaluated for these organ offers.

Staff clarified that this project would need to be approved by the Policy Oversight Committee (POC) and the Executive Committee before work could begin in earnest, as it would be a data collection project as well as a system change project. Staff also reiterated that there will be more opportunities to provide feedback, this discussion is to better understand which criteria might be useful for the filters, particularly which kidney filters are superfluous for pancreas and which elements might require additional data collection. Members offered that the kidney criteria would be necessary for the KP filters, such as age, BMI, and distance, however, KDPI and serum creatinine would not be applicable for

the pancreas alone filters. A member asked whether donor CRRT or dialysis status is currently collected, it was clarified this data is not collected by the OPTN currently. Another member noted that hemoglobin A1C would be a useful filter as well. It was highlighted that though this is collected, it is often missing from the forms or difficult to find on the forms in the OPTN Computer System.

The Chair suggested open abdomen and recent splenectomy as filter criteria. Lipase was also recommended with the lab specific upper limit for accurate interpretation. It was queried whether glucose level would be a useful filter criterion, but members decided against its inclusion. A member asked whether normothermic regional perfusion is currently collected and if so, it would be a beneficial filter. It was clarified that NRP data is not currently collected, but work is underway by another committee on that.

A member asked if a filter excludes DCD but then the status of the donor changes, would their program still be filtered out. It was clarified that when a donor status changes, the match list is rerun so that programs would have an opportunity for that organ in that circumstance.

Members recommended inclusion of dialysis status as a filter option. It was also recommended to remove solution type, donor sex, and HLA mismatch from the potential filter list as these are not widely considered useful for evaluating organ offers. The Vice Chair noted that donor sex might be a useful candidate exclusion criteria.

Staff presented on the offer filters model that was used for previous project design and sought Committee input on the evidence threshold as well as cohort period, asking how many declined offers need to be considered for a filter (kidney requires 20, heart requires 10) and over what time frame should program behavior be analyzed (kidney originally had a 2 year period but that was reduced to 1 year based on feedback).

A member indicated they only do 10-15 pancreas transplants a year, and so a longer cohort period might be preferrable, since program volumes are smaller for pancreata overall. The Vice Chair agreed that a smaller threshold of 10 declined offers is preferable and indicated that a 1-year cohort period would be advisable too, since it reflects current practices more closely due to staff turnover. Other members agreed with this assessment.

Next steps:

The Committee will consider this as a potential new project and staff will develop a project form.

4. Match Run Dashboard

Staff presented the match run dashboard developed to aid Committee review of CD attribute weights. This dashboard will enable the Committee to assign a weight to the medical urgency attribute and analyze if additional changes need to be made to the other attribute weights.

Summary of presentation:

Review of pancreas CD attributes and policy goals:

- Proximity efficiency – the distance organs must travel
- Organ registration – whether the candidate is listed for a whole pancreas or pancreas islets
- CPRA – the candidate's calculated panel reactive antibody
- Qualifying time – how long the candidate has been listed
- Pediatric candidates
- Prior living donor status
- Medical urgency – still under development

Rating scales used for each attribute and how candidates receive points:

- Proximity efficiency uses a piecewise linear scale with a steep slope to prioritize candidates closer to the donor hospital.
- Qualifying time also uses a piecewise linear scale, with an inflection point at five years.
- CPRA has a steep, nonlinear scale to give high priority to highly sensitized candidates, without overly prioritizing those with moderate sensitization.
- Pediatrics, prior living donor, and organ registration are binary attributes—candidates either receive points or they do not.

The Committee also previously decided to include a donor weight modifier for the organ registration attribute. The goal is to prioritize:

- Whole pancreas candidates for younger donors (≤45 years old) with a BMI ≤30, as these donors tend to be better suited for whole pancreas transplants.
- Islet candidates for older donors (>45 years) or those with a BMI >30, since these donors are rarely used for whole pancreas transplants but can be excellent for islet transplants.

For donors 45 or younger with a BMI of 30 or less, whole pancreas candidates receive points for the organ registration attribute, while islet candidates do not. Conversely, for older or higher-BMI donors, islet candidates receive the points, and whole pancreas candidates do not. This is also a binary and the Committee had previously decided to give this attribute a 20% weight.

Staff showed the attributes based on a previously developed 1.6:1 ratio of proximity efficiency : qualifying time, but iterated that the dashboard is flexible and various other scenarios can be run, but this was one the Committee had shown a preference for in previous discussions.

Staff then demoed the new match run analysis dashboard that had been specially developed for the Pancreas Committee by UNOS, it calculates draft composite allocation scores, allowing the Committee to explore different attribute weights to finalize CD policy.

Summary of discussion:

No decisions made.

Members were very appreciative of the dashboard tool, highlighting that it will make decision-making easier and they are looking forward to working with it more in developing the attribute weights. The Chair asked whether it would be possible to compare the different weight scenarios of 1.3:1 and 1.6:1 to see how attribute weights might shift. Upon reviewing the two scenarios members agreed that there is not a large difference between the two. Staff shared that future meetings could show both options side by side to enable easier comparison. Additionally, the proximity efficiency weight remains the same in both scenarios, therefore travel distance will not change with any statistical or clinical significance.

A member sought clarification on the graph comparing median distance from donor hospital under current policy versus CD. Staff clarified that under CD there would be a slightly higher median distance, indicating less geographic compactness. The member questioned whether that increase in distance is clinically significant and whether the Committee should consider a higher proximity efficiency weight. Another member offered that even small increases of distance matter since geographic compactness is significant for the community.

The Vice Chair queried whether in the whole organ registration category it might be worth considering giving pancreas-alone candidates slightly more weight than kidney-pancreas candidates, as pancreas

alone candidates often wait longer. This would also enable pancreas candidates' access to living donation by allowing for a pancreas after kidney (PAK) transplant pathway. Another member noted that the medical urgency attribute may help prioritize those pancreas alone candidates given the criteria discussed. The Vice Chair offered that the medically urgent population is most likely a small percentage and would not address the broader PAK/living donor issue.

Next steps:

The Committee will continue reviewing the match run dashboard to finalize attribute weight for CD and the composite allocation score.

Upcoming Meetings

- May 5, 2025
- June 2, 2025

Attendance

- **Committee Members**
  - Asif Sharfuddin
  - Colleen Jay
  - Diane Cibirk
  - Dean Kim
  - Mallory Boomsma
  - Muhammad Yaqub
  - Neeraj Singh
  - Oyedolamu Olaitan
  - Piotr Witkowski
  - Shehzad Rehman
  - Stephanie Arocho
  - Girish Mour
  - Todd Pesavento
  - Ty Dunn
  - Jason Morton
  - Jessica Yokubeak
  - Patrick McGlone
  - Rupi Sodhi
  - David Lee
- **SRTR Representatives**
  - Bryn Thompson
  - Nick Wood
  - Raja Kandaswamy
  - Peter Stock
- **UNOS Staff**
  - Stryker-Ann Vosteen
  - Dzhuliyana Handarova
  - Cole Fox
  - Carlos Martinez
  - Cass McCharen
  - Keighly Bradbrook
  - Asma Ali