

OPTN Pancreas Transplantation Committee

Meeting Summary

October 4, 2021

Conference Call

Rachel Forbes, MD, Chair

Oyedolamu Olaitan, MD, Vice Chair

Introduction

The Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/04/2021 to discuss the following agenda items:

1. Continuous Distribution Update & Discussion
2. Removal of DSA and Region from Pancreas Allocation: 6 Month Report
3. Wrap Up & Next Steps

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

1. Continuous Distribution Update & Discussion

The Committee discussed the following in regards to the kidney and pancreas continuous distribution project:

- Debrief from public comment
 - Themes from public comment feedback
 - Prioritization among pediatrics versus (vs.) multi-organ transplants
 - Weight of attributes
 - Placement efficiency/geography
 - Consideration for disadvantaged patients
 - Waiting time inversion
 - Patient education
 - Post-public comment considerations
 - Medical urgency (pancreas)
 - Impact on disadvantaged populations
 - Ethical implications
 - Uniformity across organs in project approach
 - Placement efficiency/geography
 - Educational materials for programs and patients
- Workgroup's progress
 - Finishing up phase 2, which is converting attributes into points
- Pancreas-specific attributes and rating scale recommendations
 - Islets
 - Binary (Yes/No) rating scale based on current criteria/classification outlined in policy
 - Facilitated pancreas
 - Binary (Yes/No) rating scale under placement efficiency goal
 - Additional points (boost points) for facilitated pancreas

- Pancreas after kidney (PAK)

Summary of discussion:

The Chair stated that the majority of members at regional meetings were just recently introduced to the continuous distribution project, so there will be more opportunities to receive detailed feedback once the Kidney Pancreas Continuous Distribution Workgroup (the Workgroup) has more progress to present.

A member stated that another point to consider that they heard at their regional meeting was a preference in the allocation hierarchy for patients receiving their first deceased donor kidney transplant over those patients that have already received a kidney transplant and need a second transplant.

Islets

The Chair stated that they believe whole organ pancreata should be prioritized over islet patients. The Chair also inquired whether the Workgroup had decided if pancreas candidates will always have priority and whether pancreas and kidney-pancreas candidates will be on a common list. United Network for Organ Sharing (UNOS) staff stated that the Workgroup hasn't had those discussions yet. UNOS staff mentioned that ideally the continuous distribution project is working towards a common list for all organ combinations and that there have been discussions regarding this with internal staff working closely with multi-organ policy; however, it may not be possible until future iterations of the continuous distribution project.

A Scientific Registry for Transplant Recipients (SRTR) representative noted that pancreas donors for islet transplants are different than the donors whose pancreas are used for whole organ pancreas transplants. The SRTR representative stated that this needs to be considered by the Workgroup when making a decision about islet rating scales. For example, it's unusual that pancreata from donors over the age of 40 with a body mass index (BMI) around 30 are accepted for solid organ pancreas transplant. Additionally, a pancreas from a donor that is very young isn't suitable to isolate good islets.

A member expressed support for prioritizing the solid pancreata ahead of islets, so that those organs are not disadvantaged due to their preferences being different. A member also noted that the number of patients waiting for islets seems to be very small.

The Chair inquired whether islets should be considered an attribute or if it should act as its own organ offer. The Chair stated that they believe it should be its own offer that has the same attributes as a whole pancreas candidate would have. A member inquired if there's a situation where an islet candidate who's been waiting 5 years should be prioritized ahead of a pancreas transplant alone (PTA) or a PAK candidate. A member stated yes – for example, a candidate who has been waiting for an islet to get therapy for their insulin deficiency and presumably their Type I diabetes should have a roughly similar wait time to a candidate who has been waiting for a pancreas. In the scenario where the pancreas donor is older and has a higher BMI, then the best use for that organ would be an islet transplant. A member emphasized that islet transplants are so niche that distance, location, and the other considerations for pancreas should also be taken into account.

A SRTR representative stated that the tricky part about considering waiting time equivalency between islet and pancreas candidates would be the need for multiple infusions in islet transplantation. An islet candidate may require more than one organ sequentially and it could get tricky with waiting time once the first pancreas has been allocated since the candidate's waiting time would restart. This doesn't work well for islet candidates because they need that transfusion in the near future, not a year or so down the road. The SRTR representative stated that, if the Workgroup is planning to give islet candidates priority for the second or third infusion, then it would be fair to give equivalency in waiting time for the first organ.

The Chair stated that they are having difficulty understanding how islets would be a binary attribute. UNOS staff explained that, in Policy 11.5, islet candidates are at the end of the match run; however, in Policy 11.6, islet candidates are mixed in with pancreas and kidney-pancreas candidates. The question becomes whether the Workgroup wants to put all islet candidates at the end of the list or have them mixed together with pancreas and kidney-pancreas candidates. So, if the Workgroup wants to have islets on the same list as pancreas and kidney-pancreas candidates (mixed together) it would make sense for islets to be considered an attribute, even if it's conditional on donor characteristics.

The Chair inquired if the kidney in kidney-pancreas combinations is being considered as an attribute. Staff stated that, in policy, kidney-pancreas and pancreas are treated the same so there isn't a need to distinguish between the two when transitioning to continuous distribution.

The Chair inquired if the pancreas and kidney-pancreas attributes that the Workgroup had determined to include in the continuous allocation will also be considered for islets. UNOS staff stated that, if the islet attribute is binary, then islet candidates would show up on the same match run as pancreas and kidney-pancreas candidates so they would also get points for the other attributes as well.

A member inquired if there are many pancreas programs that would accept a pancreas from a donor who is over 50 years old or has a BMI greater than 30. A SRTR representative stated that there's data on how many pancreata from those donors are accepted. A member suggested that, in the category of donors over 50 years old or with a BMI greater than 30, islets should have more priority. Staff noted that this idea is called likelihood of acceptance and they don't think the Workgroup will get to that in this iteration of continuous distribution.

The Chair stated they don't envision islets having separate match runs, otherwise programs would have to exhaust the solid organ list and then create a new islet match run. Members agreed that they envisioned one list for pancreas, kidney-pancreas, and islets and they could all fall in different orders depending on the priority each candidate receives from the attributes.

A SRTR representative stated that the concern with that is inefficiency within the system – by the time a program is getting to the islet candidates on the list, they have exhausted the list of donors who are 50 years old or have a BMI of 30. The SRTR representative emphasized that islets need to get procured just like a solid organ, and if the pancreas can't be used then it will be discarded. A member wondered if that could be balanced out by the proper scale for points; so, if the BMI is 30, then there should be a steep curve at the end to favor the islet candidates.

A SRTR representative mentioned that they don't think the lists need to be separated, just that the appropriate amount of priority points need to be allocated for the subsets of donors who are more suitable for islets than pancreas allocation. The SRTR representative also suggested that, once a recipient gets one infusion of islets, then they should receive a significant amount of priority so they can move up the list if they were to need a second or third infusion in a given amount of time.

The Chair inquired if the islet attribute is something that deserves a data request. A member stated that this issue is really important because of efficiency and that data is available on UNet. The member highlighted that two pancreas transplants have been performed with the donor BMI being 30 or greater and the donor age being 35 or greater and zero pancreas transplants have been done when the donor is changed to 40 years old. A member noted that a 35 year old donor with a BMI of 30 is ideal for islet isolation. A SRTR representative inquired if that was including pancreas and kidney-pancreas recipients. The member stated that the data included both because the two transplants had been simultaneous pancreas kidney (SPK) transplants.

Members agreed that donors who are 35-40 years old with a BMI of 30 or greater should be prioritized for islets.

Staff inquired if islets need to be their own attribute. Members believed islets should be treated just like kidney-pancreas and pancreas, so they should not be their own attribute and, instead, be put on a single match run and prioritized depending on the donor characteristics.

Facilitated Pancreas

A member inquired if facilitated pancreas allocation is for programs that may be 1,000 miles away and whether they would be coming in to procure the pancreas or if centers would be procuring for them. A member stated that facilitated pancreas can be used for long distances. The member further explained that facilitated pancreas was intended for pancreata that were about to go to the operating room (OR) or that were beyond cross-clamp and then there was a late turndown or the pancreas was the last organ to get allocated so nobody has taken it. A lot of times the pancreas gets discarded because of this. So once the pancreas has been offered to all the programs in that 250 nautical mile (NM) radius and there's still time to allocate it, it can be offered nationally to the top programs that qualify, usually centers that are used to importing organs and that transplant imported organs successfully.

A SRTR representative added that, historically, the idea of facilitated organ procurement was to prevent organ wastage last minute, so aggressive centers would more likely take those offers. The SRTR representative explained that when facilitated pancreas was introduced it was an opt-in list and there was no disincentive to signing up or turning down pancreata. However, over the years it's been shaped into a different mechanism, which is now based on the likelihood of a center using facilitated pancreas. Now, to be on the facilitated list, a center needs to have imported 5 pancreata over the prior two years and then they were automatically included on the list or could opt-out if they wanted to. The SRTR representative also added that whether the pancreas is procured locally or by the transplant hospital doesn't matter in facilitated pancreas allocation.

A SRTR representative stated that it doesn't make sense to keep the 250 NM distance because few of those facilitated centers will be 250 NM from most transplant centers. The SRTR representative also suggested adding islets to facilitated pancreas allocation because there's a small number of programs that will accept islets and then they could be offered the pancreas quickly in order to avoid organ wastage. Members agreed that facilitated pancreas allocation should extend beyond 250 NM and should also include islets.

Members expressed confusion about the use of boost points in the facilitated pancreas recommendation. Staff explained that there are a couple of ways to implement facilitated pancreas in continuous distribution:

- Implement like it is in policy, which is similar to a screening criteria – screen out non-facilitated programs from the match run (points may not be best tool to achieve that)
- Giving facilitated programs boost points before they hit the time limit
 - Identify those aggressive centers and give them points before or do that in addition to applying the screening criteria.

A member stated that the Workgroup needs to be careful in giving boost points because the initial run shouldn't grant priority to centers that are used to accepting imported organs just for the sake of efficiency. The member suggested that these boost points shouldn't be granted to centers too early in the allocation process.

A SRTR representative suggested offering little priority to facilitated programs and then that priority strengthens the closer the pancreas gets to procurement. The SRTR representative stated that this

would also be a priority for the center, so then at that point in time all candidates on the list at that center would receive boost points.

A SRTR representative inquired whether, amongst the facilitated centers, there should be some rearrangement or priority given based on how close they are to the donor, especially since pancreata are more likely to be used the closer the donor and transplant hospitals are to each other.

Staff summarized that members agreed with facilitated pancreas being placed under the placement efficiency goal and with the recommendation of the binary rating scale and boost points, as long as the boost points were gradually given to the facilitated programs. The Committee agreed that the distance component should be included in facilitated pancreas; however, it may need to be extended beyond 250 NM. The Committee also agreed that islets should be included on the facilitated list, which could also include all facilitated islet programs since the number is so small.

A SRTR representative emphasized that the amount of booster points needs to be significantly strong in order to screen out all the non-facilitated centers on the list. A member also stated that a new list would need to be run after the 250 NM distance. The SRTR representative stated that this is assuming the 250 NM list has been exhausted, but if the procurement time window has already been met then the facilitated list could be triggered before the 250 NM list has been exhausted.

A member inquired about expedited pancreas that are allocated initially within the 3 hour procurement window and whether centers would use the initial match run that includes all programs or would the center go straight to the facilitated pancreas list. A SRTR representative stated that the center would go straight to the facilitated pancreas list, although the list may include local centers as well.

A member mentioned that an opt-in option could be left in for facilitated pancreas, so the local organ procurement organization (OPO) triggering the facilitated list could wait to trigger it if they know there's a local center that might be interested in the pancreas. However, the downside to this is that the intent of facilitated pancreas might be diluted if the point at which to start allocating from the facilitated list is left up to discretion.

A SRTR representative stated that the Workgroup needs to consider if the same prioritizations that exist in the general list should exist in the facilitated list, especially with islets being included on the facilitated match run.

Pancreas after Kidney (PAK)

A SRTR representative stated that, because PAK wait times are almost 3-4 times that of SPK waiting times, there's a disincentive for candidates to find a living donor kidney before a PAK transplant when they could choose to be listed for an SPK and wait a shorter time. The SRTR representative presented the following points that was discussed by the Workgroup:

- Time limit - should a recipient of a living donor kidney who received the organ 20 years ago still get priority for the PAK?
- Should a PAK after a deceased donor kidney transplant be prioritized the same as a PAK after receiving a living donor kidney transplant?

The SRTR representative explained that this would mostly effect PTA candidates, since SPK candidates dominate the top of the list due to dialysis time, the number of SPK candidates, and waiting time. The SRTR representative stated that this priority may have a negative effect on PTA waiting times, but it may also balance out by the points for hypoglycemic unawareness that are going to PTA patients if they do have hypoglycemic unawareness.

A SRTR representative inquired if the push to prioritize PAKs was to incentivize living donation. A member responded that that was the goal.

Members agreed with giving priority to PAK candidates who received a living donor kidney transplant. A member noted, however, that the priority given to them shouldn't be so much that it pushes SPKs with the same waiting time below them. A SRTR representative stated that there are many reasons that could contribute to why the PTA wait times are much higher than the SPK wait times, which may make it difficult to determine the appropriate amount of priority. The SRTR representative suggested that the goal for the KP CD Workgroup should be to create enough of a priority so that PAK candidates can get a transplant within a year after their living donor kidney transplant.

A member also noted that the Workgroup shouldn't assign too much priority for PAKs after receiving a living donor kidney because it will probably effect minorities as well. A SRTR representative stated that programs could probably list PAK candidates prior to their kidney transplant as SPK candidates and get wait time back from when they started dialysis; however, there is a greater percentage of pre-emptive transplants done as living donor kidney transplants followed by PAKs.

Staff summarized that there is general consensus from the Committee on giving priority to PAKs after receiving a living donor kidney transplant, but it seems there needs to be more discussion on the weight of that priority given. Staff inquired if this is something that should be worked on in the same sense that pancreas medical urgency is and if it would be beneficial to create a subgroup. Members agreed with that and thought a subgroup meeting would help determine what data to include in a data request. A SRTR representative inquired about what initial data would be useful.

Members suggested the following data:

- How great of a difference is there in the PAK population in regards to vulnerable populations?
- What percentage of the active PAK list received a prior living donor kidney versus deceased donor kidney?
 - If it's a small percentage that received a deceased donor kidney, they can be included in the priority since it won't have a huge impact.

A SRTR representative stated that the Workgroup also discussed the kidney after liver (KAL) safety net. This brought up the point that there is a population of underserved pancreas patients who are uremic and do not qualify for a kidney transplant based off of their glomerular filtration rate (GFR) or dialysis status; however, these patients have life-threatening hypoglycemic unawareness that precludes them from getting a PTA. The SRTR representative stated that these patients could benefit from a safety net, or prioritization, in the case that they go into kidney failure and would have to wait 5-7 years for a subsequent kidney transplant. Members agreed that this should be discussed by the Workgroup and other stakeholder committees.

A member stated that it's reasonable to have similar criteria across all organ groups; however, the issue will be other organ-specific committees agreeing with it. The SRTR representative further explained that there are two ways to think about the prioritization:

1. The patient will get waiting time for kidney if their GFR is below 30 and they have hypoglycemic unawareness
 - Need to have good measures of hypoglycemic unawareness and use a higher GFR threshold
2. Patients with a GFR between 20 and 40 who receive a PTA and their kidney fails (their GFR goes below 20) or they are put on dialysis would be able to access the safety net kidney.

A member noted that, after doing a liver alone or heart alone transplant, there's hope that the kidney function will improve; however, after a PTA, there may not be a lot of hope that the kidney function gets better and the patient is put on calcineurin inhibitors. The member was more in favor of having these patients listed for an SPK at a higher GFR threshold in that situation with hypoglycemic unawareness rather than the safety net. The SRTR representative stated that perhaps there can be an overlapping group of patients that would access the safety net – those with a GFR of 30-40 who may not go on dialysis after PTA, but may go on dialysis years afterwards.

A member stated that the OPTN Heart Committee and OPTN Lung Committee discussed safety nets with the Ad Hoc Multi-Organ Transplantation (MOT) Committee. The member stated the OPTN Lung Committee suggested, if the kidney function does not improve after the lung transplant, extending the safety net time or having a higher GFR. The MOT Committee pushed back on that suggestion and the consensus was to keep the lung kidney safety net similar to that of liver kidney. The member suggested the Committee should gather feedback from the MOT Committee as well.

2. Removal of DSA and Region from Pancreas Allocation: 6 Month Report

The Committee reviewed the 6 month monitoring report on the Removal of DSA and Region from Pancreas Allocation. The following is a summary of the results:

- Kidney-pancreas and pancreas transplant volumes increased
- More pancreata are distributed outside the donor hospital DSA, but most stay within 250 NM
- Overall pancreas discard rate decreased
- Some of the results aligned with kidney pancreas simulation allocation model (KPSAM) modeling used to inform policy development

Summary of discussion:

A SRTR representative noted that there was an increase in the number of pancreas transplants being done for Type II diabetes and an increase in the percentage of pancreas transplants that were done in different ethnic groups. The SRTR representative asked if there was data on the number of pancreas transplants performed on Type II diabetics according to different ethnicities, which may show that Type II diabetics have a more balance ethnic distribution and would account for both of these increases. Staff stated that that break down was not included in this report, but they can make a note to include in future reports.

A member inquired, if centers are transplanting more pancreas candidates and pancreas discards are lower, then why did death on the waitlist increase. The Chair inquired if there was a back log of patients who waited longer due to Coronavirus 2019 (COVID-19) or if more patients died from COVID-19 on the wait list. Staff explained that pre-policy was 12/1/2020 to 3/14/2021, so it's 3.5 months pre-policy and 3.5 months post-policy. Staff explained that it's been 6 months post-implementation but due to the data lag, they were only able to look at 3.5 months of data before and after.

A member pointed out the inconsistency between the mortality on the kidney-pancreas and pancreas waiting lists and thought it may be related to COVID-19 as well. The member inquired if there's data on the cause of death on the waiting list. UNOS staff stated that that's an interesting point, but that data wasn't included in this report.

The Chair stated that the overall trends for pancreas transplants is encouraging: increase in pancreas transplants, decrease in discard rates, and that the modeling predicted some of these results.

3. Wrap Up & Next Steps

Committee members should review the Transplant Recipient Follow-up (TRF) form before their discussion during the next meeting.

Upcoming Meetings

- November 15th, 2021 (teleconference)

Attendance

- **Committee Members**
 - Rachel Forbes
 - Oyedolamu Olaitan
 - Silke Niederhaus
 - Daniel Keys
 - Dean Kim
 - Maria Friday
 - Megan Adams
 - Nikole Neidlinger
 - Parul Patel
 - Pradeep Vaitla
 - Randeep Kashyap
 - Todd Pesavento
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Bryn Thompson
 - Jonathan Miller
 - Peter Stock
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Rebecca Brookman
 - Anne McPherson
 - Amber Wilk
 - James Alcorn
 - Katrina Gauntt
 - Leah Slife
 - Lindsay Larkin
 - Matthew Prentice
 - Nicole Benjamin
 - Sarah Booker