

**OPTN Pancreas Committee
Meeting Summary
April 16, 2020
Conference Call**

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Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Citrix GoToTraining teleconference on 04/16/2020 to discuss the following agenda items:

1. Public Comment Update: Modifications to Released Kidney and Pancreas Allocation
2. Feedback Request – Simultaneous Liver Kidney Transplant (SLK) Emergency Policy
3. Policy Oversight Committee (POC) Update
4. Six-Month Monitoring of Changes to Kidney-Pancreas Waiting Time Criteria Data Analysis
5. Graft Failure Data Analysis
6. Continuous Distribution
7. Public Comment Review: Distribution of Kidneys and Pancreata from Alaska
8. Discussion: Transition Plan for Pancreas Allocation Policy
9. Project Ideas

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

1. Public Comment Update: Modifications to Released Kidney and Pancreas Allocation

The Committee reviewed and provided feedback to the proposed policy language for the Organ Procurement Organization Committee's Modifications to Released Kidney and Pancreas Allocation proposal.

Summary of discussion:

A member inquired about how center backup would work for kidney-pancreas transplants when the original center can no longer place the organs. The member emphasized that, by having to continue down the original match list until it gets to a candidate at the same center, this center backup solution would be prolonging the cold time while the center that wants to use it is waiting for other centers to decline. Another member agreed that logistics should be a priority and that's why this proposal works – because it doesn't specifically say you have to do center backup a certain way.

A member inquired about the reallocation backup distance for kidneys alone. United Network for Organ Sharing (UNOS) staff explained that the distance is 250 nautical miles (NM) from the accepting center and that center backup would only be for pancreas, unless there's a kidney-pancreas.

A member stated that this solution allows organ procurement organizations (OPO) to decide to use center backup with kidney-pancreas transplants; however, OPOs should not use center backup for kidneys alone.

A member stated that, before the organs even leave their OPO, the receiving center knows whether or not they are going to use center backup.

A member inquired about whether there are cities that have two pancreas programs within the 250 NM and if there are equity issues with center backup when the center across town has a higher patient on the match list. A member explained that the OPO has the discretion to decide to offer it to the patient across town and not to the original transplant center's backup. A member suggested monitoring the number of candidates who were not offered the center's local backup following the implementation of this policy.

A member stated that it's very rare to see kidney-pancreas being used at another center once the organs have already been shipped to the original center with an intended patient.

Next Steps:

- The Committee's feedback will be shared with the OPO Committee as they finalize proposed policy language.

2. Feedback Request – Simultaneous Liver Kidney Transplant (SLK) Emergency Policy

The Committee reviewed and discussed a proposed SLK emergency policy. This policy would extend the 60-365 day timeframe for prior liver recipients to receive prioritization for a kidney.

Summary of discussion:

Members of the Committee agreed that this seemed reasonable, as long as there was a time frame for how long this policy would be in affect.

A member mentioned that the intent of this policy was to catch every patient who, within their first 12 months post liver transplant, had a low GFR. Another member stated that the side effect of this is granting patients, who are 14-15 months post liver transplant and haven't had labs taken in months, prioritization and disadvantaging the patients that had frequently gotten their labs taken and their GFR didn't drop until 13 months post-transplant.

UNOS staff explained that the population of kidney candidates who are not on dialysis and who fell into this safety net was very small (about 30 candidates in 2018).

A member stated that the biggest issue now are the patients approaching the 12 month mark and facing issues; however, within a couple months these patients would have received their prioritization and the extension should be lifted. UNOS staff emphasized that this policy is temporary and will be reassessed depending on the Board of Director's actions and the current situation of Coronavirus Disease 2019 (COVID-19).

A member stated that there are challenges with recipients trying to coordinate home visits and telemedicine. The Committee Chair added that there are patients experiencing challenges in getting their labs because their support is affected by COVID-19. Patients should not be disadvantaged by this; a set timeframe for extension seems to be the most reasonable.

Members agreed that, while the number of candidates using this safety net was low, this emergency policy would still be worthwhile, as long as there was a time limit on extension. Members suggested that the extension should only last for three months because, by then, candidates should have been able to get their labs drawn.

Next Steps:

- The Committee's feedback will be used in the consideration of the assessment of the emergency policy proposal.

3. Policy Oversight Committee (POC) Update

The Vice Chair of the Committee provided an update on new project ideas from POC.

Summary of discussion:

The Vice Chair stated that if the Kidney and Pancreas Committees are going to begin work on continuous distribution, there will be a need to start working on making value judgements. Balancing value judgements will probably differ from organ to organ. Relative priorities of pediatric kidney transplants and kidney-pancreas would also need to be addressed. There were no additional comments or questions.

4. Six-Month Monitoring of Changes to Kidney-Pancreas Waiting Time Criteria Data Analysis

The Committee reviewed the 6-month monitoring of changes to kidney-pancreas waiting time criteria.

Summary of discussion:

A member inquired whether the number of candidates with a Body Mass Index (BMI) greater than 30 had increased. The member explained that if the number of these candidates had not increased, the waiting time wasn't affected by this policy. UNOS staff explained that they didn't have this data, but could send it out to the Committee.

A member stated whether some kidney-pancreas candidates with a BMI up to 53 are receiving transplants. Another member explained that the number of those candidates with a BMI above 30 could be because they are listed and won't receive the transplant until their BMI decreases.

A member inquired if the cluster transplants shown in the data are included in the insulin dosage question. UNOS staff explained that this question pertains to candidates on the waitlist that were reported to be on insulin. A member mentioned that this may refer to some patients that have a high end-stage renal disease (ESRD) and have decreased insulin requirements; those patients can be listed, but won't accumulate waiting time.

A member inquired whether each era had the same time frame. UNOS staff clarified that each era represented a 6 month time frame. Another member stated that it would be helpful to stratify candidates by diabetes type. UNOS staff explained that they can stratify by diabetes type in the one year monitoring plan.

A member inquired about whether the observation point for insulin dosage was pre or post-transplant. UNOS staff explained that this data would be collected from anyone receiving the 6 month Transplant Recipient Follow-up (TRF) Form. A member explained that this can be hard to interpret since data is being collected from someone that may be 2 weeks post-transplant or 5-months post-transplant.

A member inquired how many total kidney-pancreas candidates there are. UNOS staff stated that the responses were from 427 kidney-pancreas candidates.

Members agreed it would be useful to include this data in the next follow up period:

- High BMI patients stratified by pre and post-transplant
- High BMI patients stratified by diabetes type
- Type 2 diabetes patients stratified by pre-transplant c peptide levels

A member stated that it might be helpful in data analysis to include the total number of candidates, instead of percentages, because one of the hopes of decreasing restrictions would be an increase in kidney-pancreas transplants.

A member emphasized that it would be important to send this data to pediatric stakeholders in order to highlight that this change in policy hasn't affected pediatrics in a significant way.

5. Graft Failure Data Analysis

The Committee reviewed the 1-year post-policy monitoring of the pancreas graft failure definition.

Summary of discussion:

In February 2018, the OPTN Board of Directors approved policy went into effect clarifying definitions for when a pancreas graft has failed. The data reviewed was focused on the 6-month and 1-year follow up collected from the Transplant Recipient Registration Form (TRR) and the Transplant Recipient Follow-up Form (TRF). Additionally, the data included comparisons of two cohorts: pre-policy era (February 28, 2017 and February 27, 2018) and post-policy era (February 28, 2018 and February 27, 2019). It was noted that due to an Office of Management and Budget (OMB) change in 2018, weight had been removed from the adult kidney-pancreas and pancreas follow up form. The data used in this data analysis came from the weight value reported on the TRR form.

A member voiced concern in weight being excluded from the kidney-pancreas and pancreas follow up forms. There are a number of patients who gain a significant amount of weight post-transplantation. It is counterproductive to exclude the post-transplant weight. Weight is an easy variable to assess and should be added back to the follow up forms.

The Committee Chair agreed with this and stated that this is a huge issue with analysis. It seems to be an oversight on the Committee's behalf when the form was resubmitted to OMB. The weight field should be on the form.

The analysis showed the following:

- Pancreas graft survival was lower in kidney-pancreas recipients post policy
 - Likely due to changes in definition of graft failure
 - Not a true decline in pancreas graft survival
- Issues with required data elements reported via Status field and clinical values not reported
- Issues with pancreas graft failure definition threshold
 - One or more missing data elements make it unable to calculate
 - Recipient weight no longer on follow up forms

There is one more monitoring plan in place that will have a longer follow up period for graft and patient survival, which should allow the ability to observe the data in more depth and stratify bit more to potentially compare differences among centers.

A member stated that hemoglobin A1c (HgA1c) should be considered as one metric for graft failure. Those patients with very high HgA1c's could be in graft failure.

UNOS Research staff clarified that the data report includes information around HgA1c values within 6 months and 1 year. This information was not included in the presentation as it did not seem to be a focus in the new definition of graft failure that went into effect.

Another member stated that HgA1c was considered when they started this project a few years ago, but at that time it was decided that HgA1c would not be included. It was decided that HgA1c would be added to the TRR and TRF forms so that it could be monitored to determine if the definition needs to be modified to include these values.

The Committee Chair stated that HgA1c was not one of the values that was considered for the definition. With more value that may be collected, it could very well help in modification of the definition.

A member asked if there was a difference between the two kidney-pancreas groups. Were there any factors that played into this or were there donor differences between the two groups?

The Committee Chair stated that it may be that an observed increase of kidney-pancreas transplants for high risk Type 2 diabetics may have resulted in the increase of kidney-pancreas graft failure.

A member stated that in looking at the data and seeing what the risk factors are, there could be a multi-variate analysis that could be done to get more information.

Another member stated that there is a problem with Type 2 diabetes overall. Overtime, there will be changes observed in the kidney-pancreas Type 2 population. There is variation in this population and it may be helpful to see this population separately from the other variables.

A member stated that the weight of the patient post-transplantation is important to have. There is a huge problem with this population in increased body weight. Graft failure is often observed due to increased weight gain.

Another member stated that Type 2 diabetics should be excluded to observe Type 1 diabetics to see what the difference is pre- and post- graft failure definition. It may help to give a clearer picture of what is going on.

A member suggested the Committee work to review and revise the TRF form as well as adding the weight data field back to the TRF form. The Committee agreed with this.

There were no additional comments or questions.

Next Steps:

- The Committee will discuss revisions of the TRF form to include weight as a data field.

6. Continuous Distribution

The Committee reviewed the Continuous Distribution project process done by the OPTN Thoracic Committee and the began to discuss the potential project plan for the Pancreas Committee.

Summary of discussion:

The goal of the Continuous Distribution project is to change allocation from a classification-based system to a points-based system that is in alignment with the Final Rule. The Committee would be tasked in discussing and determining a list of organ-specific attributes that would include: criteria defining, establishing attribute impact, and weighting those attributes.

A member asked how would it possible to differentiate between a pancreas alone offer and a kidney-pancreas offer. Additionally, how do you determine if a donor will be a kidney-pancreas or pancreas alone allocation?

UNOS staff stated that with the Lung Committee, they did not want to give boost points for being a multi-organ candidate. With kidney-pancreas, pancreas, and islets, the Committee would need to discuss prioritization of those different combinations. An attribute could be created for this. Additionally, there could be different rating scales if there are different donor characteristics that would

apply to candidates differently. For example, if the ischemic time limits for kidney and pancreas are different, there would need to be different rating scales for those.

Another member stated that their understanding is that continuous distribution won't affect the way organs are allocated, but will instead rearrange patients on the current matches that are generated. Continuous Distribution won't change the sequence of allocation.

A member stated that there is still more work that needs to be done on the current system. There are some issues that have not been adequately addressed among the Committee, such as sensitization and how to address it. There may need to be more work done upfront compared to lung on attributes like medical priority (CPRA, etc.).

The Committee Chair clarified that this work may actually help make that work easier since continuous distribution will help to prioritize these various attributes.

A member stated that there are different attributes that may be important for the each of these multi-organ subtypes

Another member voiced concern about the greater transplant community who may not have detailed knowledge of the field weighing in on the attributes being proposed. This may skew or dilute the responses received by experts in the field.

UNOS staff clarified that the Committee and the Board would ultimately make the decision. To help the community better understand the concept, there will be outreach efforts to provide education. When the information is collected, the respondents will have the ability to provide their input on which attributes they feel is most important, how much more important is the attribute, and the ability to comment on their reasoning. All of this information will be for the Committee to review and consider.

Next Steps:

- The Committee will continue to discuss the development of this project.

7. Public Comment Review: Distribution of Kidneys and Pancreata from Alaska

The Committee reviewed and discussed the public comment response of the Distribution of Kidneys and Pancreata from Alaska.

Summary of discussion:

The Committee cosponsored a policy proposal addressing the potential inefficiency that could impact organ utilization in kidney and pancreas allocation in Alaska. There was overall support among all of the regions, transplant community and public for policy proposal.

The American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), American Nephrology Nurses Association (ANNA), the Organization of Transplant Professionals (NATCO), and the Association of Organ Procurement Organizations (AOPO) all supported the policy proposal. ASTS recommended regular reassessments to all new organ allocation policies and an extension of the circle to 500 NM. NATCO voiced agreement that this proposal "should decrease cold ischemic time and promote greater utilization of these organs". Based on the public comment sentiment received, no changes to the proposed policy language is currently being considered at this time.

There were no comments or questions. The Committee was called to vote. The Committee voted unanimously in support of the proposal to be submitted for review and vote by the OPTN Board of Directors.

Next Steps:

- The policy proposal will be submitted for review and vote by the OPTN Board of Directors.

8. Discussion: Transition Plan for Pancreas Allocation Policy

The Committee reviewed and discussed next steps for the Board approved pancreas allocation policy eliminating the use of DSA and regions.

Summary of discussion:

The Pancreas Committee's Eliminate the Use of Donation Service Area (DSA) and Region in Pancreas Allocation policy proposal was passed by the OPTN Board of Directors in December 2019. The anticipated implementation of the policy will be in December 2020.

The Final Rule requires that when the OPTN revises organ allocation policies, it should "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies."¹. Although the Committee discussed the impact the revised policy may have on these patients, the Committee wanted to discuss the following questions and determine if a transition procedure should be considered:

- Are there any populations that may be treated less favorably under this new allocation policy than they would have been treated under the DSA based policy?
- If so, is a transition plan for these populations necessary?

The Committee Chair stated that it may be hard to pinpoint specific populations that may be disadvantaged. There may be patients impacted on a program-specific level in some cases. If a patient who was at a relatively low waiting time program currently, they may be at a disadvantage and their waiting time may be increased by changing the allocation system that may include programs with higher waiting times.

A committee member stated that there may be disadvantages in the beginning for patients located at the east and west coasts in comparison to those patients located in the middle of the country because the 250 NM are different depending on location. Over time that disparity will probably work itself out.

Another member stated that in general there is a dramatic decrease in the number of donors and transplants being observed right now due to the COVID-19 pandemic. These volumes may stay low for a while which could negatively impact programs. Programs that generally experience low volumes could be doubly impacted with a relatively dramatic decrease in their transplant volume.

A member commented that this is currently being seen in Indiana. Although programs are open for transplants, they are not receiving any offers.

Another member added that it is hard to entertain backup offers at this time while they are trying to get their candidates tested for COVID-19.

¹ 42 C.F.R. §121.8(d).

A member asked if there will be any changes to the implementation timeline due to COVID-19.

UNOS staff stated that this concern is suspected to be discussed further as more information is learned about the pandemic situation but that currently, the timeline is still moving forward as planned.

A member commented that there is no need for a transition plan. As the allocation policies will be completely disrupting our system, why do we need to elongate that process?

The Committee Chair agreed with this. The COVID-19 pandemic may actually be a benefit to disrupting the whole system since there is more downtime to try to address issues that would come up, especially on the kidney side. On the pancreas side alone, the numbers are not that high that a transition plan would make as much sense as it might for kidney.

The Committee Vice Chair stated that one thing that may be a little different is programs' reliance on their own teams for pancreas procurement. It may be worthwhile to establish that local teams or programs do have pancreas procurement.

The Committee Chair replied that depending on the organ offer, teams may choose to travel based on a certain distance or the quality of one individual organ offer. This would be more of a case-specific question.

A member stated that one way to not disadvantage patient already on the waiting list would be that the new allocation policy only applies to those newly being added to the list after the policy is implemented. This would generate two lists. The Committee agreed that such a system would be confusing, and therefore determined that the same policy would have to be implemented to all patients on the waiting list. It is acknowledged that this would disadvantage some patients in some areas and advantage patients in other areas relative to where we are now, but the Committee ultimately determined that it does not recommend adopting any transition plans or procedures to mitigate this impact.

The Committee Chair asked if there were any thoughts on whether a transition plan would be valuable for the revised allocation policy. There were no comments provided.

Next Steps:

- The Committee's conclusion that transition procedures for this policy is not required will be synthesized and packaged with the feedback received by the OPTN Kidney Transplantation Committee and be reported to the Board for their consideration.

9. Project Ideas

The Committee discussed potential project ideas.

Summary of discussion:

The Committee Chair asked if there were any potential project ideas that the Pancreas Committee should consider working on. The Committee suggested the following project ideas for consideration and further discussion on during upcoming meetings:

- Rework Graft Failure Definition
- Decouple medical priority from continuous distribution. It was noted that medical priority may need to be its own project.
- Monitoring patients who are not compliant post-transplant

Next Steps:

- The Committee will continue to discuss these project ideas in further detail during future Committee meetings.

Upcoming Meeting

- May 20, 2020 (Teleconference)