

**OPTN Pancreas Transplantation Committee  
Meeting Summary  
March 8, 2024  
In Person Meeting**

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## **Introduction**

The OPTN Pancreas Transplantation Committee (henceforth the Committee) met in Houston, Texas as well as via Cisco WebEx teleconference on 3/8/2024 to discuss the following agenda items:

1. Continuous Distribution Modeling Update
2. Discussion: Medical Urgency
3. Research Update: Pancreas Utilization Trends
4. Update: Offer Filters
5. Public Comment Presentation: Promote Efficiency of Lung Allocation
6. Update: Expeditious Task Force
7. Discussion/Report Outs: New Project Ideas

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

### **1. Continuous Distribution Modeling Update**

The Committee reviewed and discussed a preliminary request for the Scientific Registry of Transplant Recipients (SRTR) to incorporate non-use into an allocation simulation model.

The SRTR plan to prepare simulation models that would study utilization and non-use in relation to pancreas allocation, with the goal of answering research questions and determining the impact of allocation policies on utilization as identified by the Committee.

The Committee were asked to review and provide their feedback on potential research questions based on previous Committee conversations related to non-use:

- **Primary Research Question:** How do the proposed policies impact utilization and non-use of deceased donor pancreata (overall and by donor characteristics (age, BMI, DCD status))?
- **Secondary Research Questions:**
  - How do the proposed policies impact timing and sequence number at acceptance?
  - How do the proposed policies impact cold ischemic time?

#### Summary of discussion:

The Committee's feedback will be synthesized into a formal data request for the SRTR for additional review and analysis.

An SRTR representative clarified further that the focus of this request is the utilization modeling aspect, which is new and hasn't particularly been done in the past. With data request, the SRTR want to know the full spectrum of questions the Committee wants to ask and how they prioritize those questions

(primary versus secondary) to better simulate an answer. The Committee was advised that there may be some questions that the SRTR may be able to answer well more than others and depending on how they are able to design these models, the SRTR may be able to answer one question, but at the expense of being unable to answer other questions.

The Committee Chair stated that from past Committee discussions regarding utilization and non-use, the response has been that this could not be modeled because it is affected by behavior. The Committee Chair followed up by asking what the difference would be now.

The SRTR representative responded that within these simulations, the only thing that changes from one simulation to another is the allocation policy (the way match run is ordered). The behavior in the simulation is a constant across those policies; the only thing that could impact utilization is that policy change (order of the match run). In the past, it was unclear whether the allocation policy itself could impact utilization and now there is more evidence this is the case. The SRTR representative clarified that it was uncertain if this can be modeled but would like to know what questions the Committee want answered that will help determine whether the question can be answered, whether through this simulation or another method.

The Committee Vice Chair asked if it was possible to calculate a scoring system for program aggressiveness into the model. The SRTR representative confirmed that this could be included in the model. In the previous data request for the Kidney and Pancreas Committees, the SRTR included information about particular programs and their behaviors. It is something that can be included in the models and will be investigated.

Another member asked if there is a role for program aggressiveness divided by median wait time for the program's patient. When thinking about kidney and figuring out how to improve allocation efficiency, there is a need improvement in the system that would allow getting to patient 256 on the match run who may benefit from taking a kidney offer – this process is taking too long right now. For pancreas, the lists are not as long and the lack of aggressiveness among programs is most likely due to the fact that those candidates do not wait as long. The member continued by noting that the hardest part of this modeling is behavior and a lot of that includes OPOs and transplant programs learning each other and the behaviors of those programs.

The Committee Chair asked if the modeling would be able to predict what sequence the organ is likely to be accepted. This would help with efficiency and other factors. The SRTR representative stated that this could not be answered right now; the point of this request is to determine if this can be predicted accurately. Knowing that this is something the Committee may be interested in, this could be something the SRTR would work to try to get the models to evaluate this accurately.

A member asked if it was fair to assume that geography and distance will be in this model, or just using cold ischemia as a surrogate? The SRTR representative confirmed that these attributes would be included. Another member agreed with this and stated the importance of factoring in distance as it attributes to cold ischemic time (CIT).

Another member suggested looking at pancreas non-recovery as a secondary point and see if utilization improves.

A member made another suggestion in having an output of how many final acceptances stay true from the pre-operating room (OR) to final results, as opposed to after the OR and there were changes during the allocation process and resulted in the pancreas being used somewhere else.

Another member asked for clarification on defining non-use versus non-utilization. Staff clarified that one is whether or not the organ is procured and then transplanted and the other is even procured at all and could have been transplanted.

The SRTR representative clarified further that from an SRTR perspective, specifically in reference to this request, utilization is used in generic terms of whether or not an organ is used. Knowing from the Committee what the denominator is of relevance is important. For kidney, there's confidence that these organs are all recovered; even if a kidney is not accepted, it will be recovered if it is believed that it could be used. Knowing from the Committee which pancreata is of interest such as all pancreata, only pancreata that has been recovered, or if there is certain criteria that would prevent a pancreas from being used, etc.

An SRTR representative stated that in looking at past utilization, like SPK donors over age 40, there were three. There may be an interest in looking at the 90th percentile and stay within that range for the denominator for utilization. The SRTR representative continued by suggesting body mass index (BMI) potentially being another good criteria a range could be developed for. It was clarified that this would need to be framed against how kidneys are going to flow into the KP pool. If this is based upon the baseline status as it has been, but changes in the continuous distribution framework, this would not be accounted for in this simulation model. In regard to utilization, the rate of trying to procure pancreas has changed with the declaration of pancreas as a research organ that can be counted as a clinical placement for Centers for Medicare and Medicaid Services (CMS) purposes. The thought is that the change in these policies may have attributed to the current approaches of pancreas procurement; there is currently no data to support this, but there may be some consideration by the Committee into looking at this further. The SRTR representative ended with consideration in looking at the effect on solitary pancreas versus simultaneous pancreas-kidney (SPK); SPK may be easier to model than solitary pancreas. It is known that waiting time for solitary pancreas has increased, but it is not sure if solitary pancreas would be modeled in general due to the rates being so low.

The Vice Chair asked if there was any evaluation at the change in OPO behavior for procurement after the change in CMS regulations. Staff responded that after the changes in CMS regulations, there was no difference found in procurement behavior. The Committee was encouraged to provide feedback on donor characteristics they may want to include to further evaluate how CD policies impact them.

A member commented that distance would be a factor. Additionally, if looking at non-use, it was suggested to look at this by phase, such as organ turndown being made pre-OR or intra-operative.

The Committee Vice Chair voiced agreement with this and added that much of the decision is based on qualitative data and imaging, which would make it challenging to fit these factors into categories of BMI and age. It was suggested that there be consideration of a surrogate of pre-OR declines to a certain number may help better reflect criteria since there is limited ability look at a true denominator.

Staff commented that changing the match run could impact utilization and reminded the Committee the objective for the purposes of this discussion was to update the SRTR's modeling to determine if

utilization can be predicted accurately. Assuming the SRTR is able to develop those models and run them could then lead to running more specific attributes and data.

The Committee Chair stated that utilization depends on organ quality and suggested looking at the parameters of the organ quality against the utilization. This could lead to a future project like pancreas donor risk index (PDRI) in a similar manner as kidney donor profile index (KDPI) for kidney.

There were no additional questions or comments.

Next steps:

The Committee's feedback will be synthesized into a formal data request for the SRTR for additional review and analysis.

## **2. Discussion: Medical Urgency**

The Committee continued their discussions on medical urgency, specifically, finalizing the clinical considerations and respective guidelines that would be included in the Pancreas Review Board criteria.

The Committee previously discussed clinical considerations for pancreas medical urgency, specifically focusing on impaired awareness of hypoglycemia. There are other outstanding items being considered, such as age-based clinical considerations and accessibility to technology.

The Committee welcomed endocrinologist subject matter experts (SMEs) to provide their expertise on the Committee's outstanding clinical considerations and provide insight on potential guidelines for pancreas medical urgency. The SMEs reviewed and provided feedback on the Committee's work to date. Some initial recommendations included the following:

- Agreement with including impaired hypoglycemia awareness
  - This should be the main criteria for prioritizing pancreas transplants; build upon this as more information becomes available with Review Board evaluation

Summary of discussion:

The Committee's discussion will be compiled and included in a draft of the medical urgency criteria. Further review, discussion, and consultation with endocrinologist subject matter experts (SMEs) will continue in the Committee's continued development of this work.

A SME asked for clarification to frame the context the guidelines would be used and asked if the criteria discussed was based on an outpatient basis. The Committee Chair responded that the criteria discussed is outpatient. The Committee Chair added that with heart or liver there are increased short-term mortality, but with pancreas or kidney, the mortality might not be short-term acute, but still a high risk of death. In those instances, the intent of having medical urgency criteria is to help prioritize those patients.

Another SME commented that individuals with impaired awareness of hypoglycemia are at greater risk of severe hypoglycemia. Individuals with impaired awareness of hypoglycemia are going to have severe control on their diabetes. It was stated that cardiac autonomic neuropathy (CAN) is common among patients; there is clinical criteria, however, clinicians do not regularly conduct screening. The SME added that some of the criteria could potentially be assessed pre-transplant. The need for third party

assistance for severe hypoglycemia ranges to 0.3-3 events per year for Type I diabetics. Only a third of those would then need hospitalization.

A SME voiced agreement with this and added that not only is impaired awareness of hypoglycemia harder to measure, it is also very common. The SME suggested the focus being on severe hypoglycemia instead of impaired awareness of hypoglycemia for a better predictive factor. Another SME stated that if documented third party assistance criteria is necessary, then severe hypoglycemia would be the harder criteria and should be seriously considered when assessing for a pancreas transplant.

Another SME clarified by stating that from previous Committee and Workgroup discussions, the definition that was proposed for impaired awareness of hypoglycemia was related to impaired perception, not full unawareness.

A SME commented on the difficulty of separating patients for other urgencies. Clinically, impaired awareness of hypoglycemia is not added to the pancreas list for that reason alone. If patients present with all factors already, the challenge will be to differentiate one factor being more urgent than another. Some of those patients are on CGM that can help somewhat to predict hypoglycemic events, but it can still be challenging for the patient despite the help of the technology. For those individuals who do not have access to the technology, there are different factors to consider. The SME suggested excluding impaired awareness of hypoglycemia for KP but including it to candidates for a kidney transplant. The SME agreed with having a severe third-party event that is documented as a criterion and added that a life threatening event due to hypoglycemia (i.e., car accident due to loss of awareness) should also be considered. The SME continued by stating that adding CAN does not seem helpful to include as there is not a good way to clinically screen, nor is there evidence it would help unless this is in combination with impaired awareness of hypoglycemia. It was suggested to also exclude diabetic neuropathy. The SME added that accessibility to technology needs more discussion.

A member asked if these criteria should be weighted differently between Type I and Type II diabetics. A SME shared their sentiment that Type I and Type II diabetics should not be weighted differently. For pancreas alone candidates, Type II diabetic patients are treated with insulin, but can still have the same end results of a Type I diabetic patient.

Another SME replied that with Type I and Type II diabetics, it is a matter of semantics if they have both progressed. They are both similar from a management perspective; in either case, severe hypoglycemia is a marker of mortality.

A SRTR representative stated in response to the previous comment of CAN being difficult to measure, there is data showing CAN having a five-fold increase in mortality among diabetic patients. There have been instances across organs where criteria are difficult to define, but over time have figured out how to define those. It was suggested to include CAN due to the mortality factor. The SRTR representative continued by suggesting the Committee should start with something that has a high burden of proof; for severe hypoglycemic events, although a more concrete event, there are hypoglycemia unaware individuals who do not meet that full criteria who might be in the next strata. There may need to be consideration for having different levels of medical urgency; this would be important for simultaneous pancreas-kidneys (SPKs) as opposed to solitary pancreas. Most patients usually have impaired awareness of hypoglycemia, but with SPKs the only criteria is insulin independence to get on the kidney-pancreas list.

A SME commented that the suggestion is not necessarily dismissing CAN, but with a diabetic patient, it is hard to imagine they don't already have CAN. Additionally, the ways CAN is assessed/measured today varies as it is not a routine clinical assessment. This can be researched more, but the suspicion is that most patients would present with CAN who have impaired awareness of hypoglycemia. The SME stated that if the consideration is for patients who need a KP and don't have impaired awareness of hypoglycemia, it might be a good criterion for that.

The SRTR representative replied that there is likely a subset of patients who don't have the symptoms of impaired awareness of hypoglycemia. Although there may not be detailed CAN testing, but when there is a priority for a patient for transplant, these tests are done and should be considered for criteria for those type of patients.

A member stated, from a patient perspective and personal experience, they had not been in an emergency room (ER) or admitted for hypoglycemia since the age of nine. Two days ago, their blood sugar was 50 and was unaware. The member continued by voicing uncertainty in whether an ER report or an in-patient report would be an accurate depiction of the events a patient may experience. The member stated that with the ability to treat their hypoglycemia events, it is usually resolved within 30 minutes to an hour. The member added that they would go to the ER with diabetic ketoacidosis (DKA). The member suggested the use of the CGM report for documentation as it can show how often hypoglycemia events have occurred, however, it may provide some challenges for those individuals who do not have access to this technology.

Another member stated that exhausting dialysis access is a medical urgency criterion for kidney and suggested also including this as a criterion for pancreas/KP. The member then asked for clarification on the operationalization of this process, specifically if there would be a separate Review Board for pancreas. Staff confirmed that there would be a separate Review Board for kidney and pancreas/KP.

The member continued by stating that in regard to the specific criteria and granularity of it, there should be a lot of "or's" and not "ands", but there is a sense of who these patients are. The member stated that CGM is a good idea for those who have it and it is not felt that financial background is the main issue when it comes to access to technology. The member added that in serving a rural area, it's the access to care that is a challenge; health literacy is another factor. Those with a higher level of health literacy might be able to better manage their diabetes.

The Committee Chair shared their observation of some patients who receive the transplant which their insurance will cover but will not cover the CGM. A SME agreed with this and added that that are instances where insurance will cover the transplant but not with the management of the disease prior to the transplant.

A member added that there are also patients who are having severe hypoglycemia events and are able to manage it on their own; those patients should not be disadvantaged.

A SME recommended that when it comes to CGM, there should be caution about how much data is needed to review. The SME stated, from their clinical experience, the focus is on the last three months normally; what if the last hypoglycemia event was six months ago for a patient. The range of the CGM data will need to be defined.

A member reminded the Committee that the focus is on the patient. There is no perfect policy but something needs to be put forward so that the Committee can evaluate, measure, and adjust as needed. With liver, heart, and lung, extensive testing is done; this is different for pancreas and kidney, but there should be some consideration in following a similar practice in testing. The member stated that in thinking of medical urgency, it is thought of something immediately lifesaving and asked when a pancreas transplant improved CAN.

A SRTR representative replied that there is no data for the impact pancreas transplantation does for CAN. There is some data on autonomic neuropathy in other areas (such as lower gastrointestinal (GI), upper GI); when a patient is of advanced neuropathy, it is not reversed, but the continuing nerve damage can be halted. It is unclear by stopping the progression of CAN if it can halt the curve or competing risk factors, but it is known that CAN is the single biggest driver of mortality.

A SME commented that in recognizing the disparities, the impact of technologies that was not felt by the patient, or an event that requires third party intervention, it was suggested that to start with a broader definition first. This could give equal priority given available data or these factors could be weighted different points of priority depending on what is observed by available data.

The SRTR representative commended the member sharing their patient perspective and commented that their story demonstrated imperfections in that patients do not always fit those criteria. It is those patients who have impaired awareness of hypoglycemia but then in addition don't have access to CGM. This raises the question of a scoring system. The SRTR representative continued by pointing out the Clarke and Gold hypoglycemia scores. These scores are based on a questionnaire/survey, but these tools are available there for a reason; although not a prerequisite for transplant, it can provide insight on candidacy as well as outcomes. The SMEs were asked for their sentiments on using these scores in the criteria (maybe for a second or third strata of impaired awareness of hypoglycemia) and if there is some validity to use these scores for prioritization.

A SME replied that clinically evaluating the patient and doing those questionnaires is reliable together, but they are not good in classifying within gradients. If a clinician has evaluated from a patient's history to have impaired awareness of hypoglycemia, their score will match that, but it would not be able to determine if one score versus another is better or worse. The scores can be used to list patients, but there is no confidence these tools will help in ranking these cases by urgency.

An SRTR representative summarized that there is the ability to detect someone with some reliability but an inability to stratify granularity. The SRTR representative commented that granularity is not necessarily needed at this time.

A member asked if a composite score was needed for medical urgency with multiple attributes. Additionally, the member suggested that the medical urgency attribute could be a yes or no, and then based on that score, medical urgency points could then be determined. A SME suggested adding CGM and CAN testing to allow for multiple check points.

A member asked if there were any data on patients who've been listed who would meet medical urgency criteria based on the criteria the Committee is working to develop.

Another member asked, in talking about medical urgency, is this referencing medical urgency for listing patients or going to Review Board and having them determine medical urgency? The member continued

by stating that to this point, everyone who would be on the Review Board would know about these patients because they all have to be pancreas related. The Committee is tasked with developing some objective criteria that can be applied when a program asks the Review Board for additional points for a patient.

A member commented that the data is currently unavailable, but comparing that to the general population, if everyone receives priorities then nobody would receive an advantage. With there being no available data, it is hard to determine.

The Committee Chair agreed that there is not enough data on impaired awareness of hypoglycemia and stated that this is the challenge with this discussion. In clarifying a previous question posed, it is difficult to develop medical urgency priority, however, the Committee's goal is to identify those patients who could meet the criteria. The criteria developed will give guidance to the Review Board on how to determine who receives medical urgency points. It was acknowledged that this will not be perfect; it was also noted that the criteria does not have to be too restrictive because then it would become policy which could result in patients being excluded (and would not want to exclude patients who do use a CGM because they can still experience severe hypoglycemia events). The Committee Chair suggested criteria, for example, where if a patient has CGM and they stay in the hypoglycemic range for 20-30% of the time, priority should be given; another example are those patients who have to carry and use glucagon to resolve a hypoglycemic event. The Committee Chair suggested the Committee further discuss CAN; CAN may not need to have criteria now, but there could be a recommendation that presentation of CAN could lead to receiving some priority.

A member voiced hesitation with including CAN as criteria for medical urgency and suggested it being a better fit in the continuous distribution framework. CAN is not an immediate life-threatening problem. For kidney medical urgency, clinical considerations pertain to what could cause mortality in the next seven days and suggested CAN would not fall within this definition.

Another member stated that medical urgency is currently a binary variable, but suggested that stratification could provide thresholds within the criteria. Staff commented that the Committee has talked about scaling in the past and that it will depend on what the Committee determines those thresholds should be. Everything is open for discussion.

Staff continued by summarizing the Committee's discussion in that there was agreement with moving forward with impaired awareness of hypoglycemia as the focus for medical urgency at this time. For CAN, the Committee couple potentially include this, but it may be better placed as a surrogate within impaired awareness of hypoglycemia and developing a guideline that includes assessment of CAN; Staff reminded the Committee that with incorporating the medical urgency attribute within the Review Board, it will be a starting point to collect additional information that will help to further define pancreas medical urgency and additional considerations.

A member asked if patients whose diabetes is managed by their primary care physicians (PCPs) were evaluated differently for those criteria. Should there be a requirement for endocrine input for listing? A SME replied that it is essential to include an endocrinologist as a pre-transplant evaluation team. Additionally, glucagon utilization could also be a good marker.



Another member asked if some priority could be given to CAN patients – not necessarily medical urgency, but instead with continuous distribution adding with scaling. Staff stated that this is an option the Committee could look into further.

A member stated that with pancreas transplant it's hard to predict who would get better from CAN afterwards. Sometimes it's better, sometimes not. This makes it challenging to develop criteria for medical urgency.

The Committee Vice Chair commented that unlike other organs where medical urgency is tied to mortality, for most pancreas patients it's in relation to improving quality of life and stopping the progression of disease. More data is needed and the Committee has been able to identify some categories by which some data could be collected, but this then poses the question of how this will be done without an excessive burden on transplant programs. The Committee Vice Chair suggested it may be a good start to begin with some yes/no questions about the clinical considerations, which will allow the opportunity to gather data and further understand the prevalence of these clinical cases that could potentially inform a later decision.

A SME voice agreement that the surveys are more qualitative than quantitative. They also aren't dependent on CGM access and/or use. The challenge with impaired awareness of hypoglycemia are those patients who would be eligible already have a lack of awareness; there may be fewer points for those than patients who have severe hypoglycemic events.

A member stated that data collection is needed. This should not be burdensome on transplant programs as the number of patients is small and it would be beneficial for Review Board evaluation. An SRTR representative stated that getting the data is challenging. For example, in trying to define graft failure in the past, there was a desire to collect data on A1C, but it was unreliable with 80% of the data missing this information. Unless there is something put in place that data is required as part of the review, the data may be hard to collect. Another way of looking at prioritization is in evaluating cases for those patients who may have conditions such as CAN that could infringe upon their candidacy for transplant if their condition worsens.

A SME provided an example where the Clark score might be a good tool for pre- and post-data, not necessarily as a pre-urgency. It's important to have some information for the future. The SME added that most patients carry glucagon, and many may never need to use it. The SME suggested that this criteria could be further defined to those patients who carry glucagon and have to administer it.

Staff summarized the discussion that the Committee was in agreement with including impaired awareness of hypoglycemia. There is potential of including CAN, but it would be more of a surrogate within impaired awareness of hypoglycemia and developing a guideline to collect more information for the Committee to review to help further define. Additionally, the Committee discussed including dialysis in the guidelines. As kidney currently includes dialysis use in their medical urgency criteria, there will be additional discussion with the Kidney Committee to determine how best to potentially incorporate this in the Pancreas Review Board guidelines. The Committee will not include pediatrics as there is already priority being placed for these patients within the composite allocation score (CAS). Accessibility to technology will also not be included as the variations in accessibility is complex and concern in potentially disadvantaging patients. The Committee will not include diabetic neuropathy, due to lack of data and being too complex to measure. Staff suggested the Committee consider if there were any data

collection that would be of interest as this would be a good opportunity to include those data fields for this project.

A member asked about including DKA as it requires hospitalization. Another member commented that DKA comes out of not doing your things you are supposed to do. It is uncommon for a compliant diabetic to get DKA.

A member voiced some disagreement with this and stated that pancreas transplant is to prevent patients from dying of hypoglycemia and for those patients who cannot avoid severe hypoglycemia events. The Committee Chair stated that DKA might have been seen as a form of non-compliance but isn't indicative of post-transplant non-compliance. It might be able to be ranked by severity of disease.

A member stated that the times they experienced DKA, it was due to technology (pump failure). Another member stated that DKA can be challenging to define and there should be caution in how it is defined as it came come across as judgement of the patient. There are various factors that can contribute to DKA. A member added that they have had patients who are insulin compliant but still have DKA and suggested DKA be considered in including.

An SRTR representative commented that this brings up a good point in that there are patients who are compliant and can still present with DKA. Usually, impaired awareness of hypoglycemia is involved with these cases of DKA and these patients could potentially be captured under the impaired awareness of hypoglycemia category. This could potentially be included in a ranking system for medical urgency.

The Committee Chair suggested the Committee try to define the extremes of impaired hypoglycemia unawareness. When the Review Board is implemented, the Committee will evaluate the data collected to further refine pancreas medical urgency.

There were no additional questions or comments.

#### Next steps:

- The Committee's discussion will be compiled and included in a draft of the medical urgency criteria.
- Further review, discussion, and consultation with endocrinologist subject matter experts (SMEs) will continue in the Committee's continued development of this work.

### **3. Research Update: Pancreas Utilization Trends**

The Committee received an update on research analysis of pancreas utilization trends. The data showed the following:

- Volume of "reasonable" pancreas donors has increased
- Proportion of donors with these characteristics has decreased dramatically
- Utilization of "reasonable" pancreas donors has declined steadily
- More research needed to understand factors contributing to this decline

#### Summary of discussion:

This agenda item was informational. No further action was requested of the Committee at this time.

A member asked if this study looked at the size of the waitlist over the timeframes that were evaluated. The member continued by hypothesizing that the size of the national number of candidates listed as pancreas on the waitlist may have also declined. The member suggested potentially adjusting for median wait time for a pancreas which may also explain a decline in utilization as there are less referrals for pancreas which would result in less pancreas transplants. For non-use, the member summarized that the denominator was pancreas recovered (procured with the intent to transplant and then ultimately not transplanted) seems too high (1 in 5).

The Committee Vice Chair commented that the thought is this likely is due to these organs being pulled because the organ procurement organization (OPO) is trying to aggressively place the organ and then ultimately not accepted.

A member asked if the way that pancreata has been procured changed within the last 15-20 years. It appears that some surgeons feel procurement is happening out of their hands more, which presents some concern in having someone who may not have procured as many organs as compared to the pancreas surgeon procuring the organs themselves. Another member replied that, from the perspective of a medical director and surgeon, broader allocation has meant that it is cost prohibitive to send teams as distant as done in the past. Programs are relying more on local recovery, meaning that the host OPOs would have someone recover the organ; the expertise of the person recovering the organ may or may not be the same. The member continued by stating that the procurement is often driven in the abdomen by the liver team where liver surgeons are sent out to procure the organ, which is also changing. There are liver surgeons who don't want to or have the capability to procure the pancreas which is not discovered until late in the process. A member agreed with this and stated that it is not so much as those programs who are not able to send out a recovery team having distrust in the local recovery teams, and more to the fact of the local surgeon declining the organ.

A member asked how often for those who accept offers, with the list being so small, are waiting for a particular offer. The member continued by stating from a pediatrics perspective, because those candidates receive several offers, they would not accept a hard-to-place organ, but instead wait for the best offer. It was inquired if this was the same for pancreas. The Committee Chair commented that this is happening to an extent with pancreas offers.

The Committee Vice Chair agreed with these points and commented that there are also manpower concerns related to these processes. Transplant programs are stretched for manpower and many staff who do pancreas transplants also cover kidney transplants. Additionally, as living donor activity increases in some programs as well as paired exchange, this can also put strain on staff.

A member asked in regards to the data reviewed and in looking at the trends if there was an ability to pinpoint based on the codes for non-use in pancreas. Staff replied that in looking at the non-use codes, there was no specific indications to the reasoning; many of the codes

entered were “other” and even in looking at the free text fields, there wasn’t anything substantial to report.

Another member stated that in their region, a lot of the pancreata were procured locally. Now, as more donor recovery centers are coming up; the donor organs are going to these recovery centers which results in increased cold ischemic time (CIT) and non-use.

A member asked if there were any changes observed with the most recent allocation change. Staff responded that there were no changes seen looking at utilization, but when looking at non-use rates (when the policy was implemented in 2021), there was an increase observed in 2021 – 2022 with circles going away, but then decreased in 2023.

A member asked what the training requirements were for organ procurements. An SRTR representative stated that there is currently a database for accreditation that is maintained by the United Network for Organ Sharing (UNOS). The OPOs are the ones who are inputting the names into this database; for trainees, their certification is based upon the program director certifying the fellows as proficient in procurement of certain organs. The representative continued that their program has their own internal criteria; there is no national criteria for this, but this might be changing. The American Society of Transplant Surgeons (ASTS) had a standards committee initiative and developed some standards of criteria for procurement for donation after circulatory death (DCD), what the surgeon requirements are and for organ procurements, which is currently on the ASTS website. The hope is that these requirements would be incorporated into the current database and making this more standardized.

The SRTR representative continued by commenting to the increase in volume of pancreas donors and suggested starting with calling out that it may be helpful to highlight that the volume of donors overall have substantially increased and that the “reasonable” pancreas donors increased minimally in comparison. The SRTR representative added that there are factors that could contribute this such as blood type, solitary versus simultaneous pancreas-kidney (SPK), and the recovery team that comes out to procure the organ. These variables tend to be underappreciated and it would be helpful to factor these variables into the SRTR simulation, if possible.

A member asked if the data reviewed included all pancreata or if this also included SPK or pancreas alone. Staff confirmed that the data reviewed included all pancreata which may have been part of a KP or pancreas transplant. The member commented that it may be helpful to highlight this in the study.

Another member commented that it seems that at some point, there should be a mandate that OPOs have their donor surgeons credentialed/certified to procure pancreas. There are many instances where there is not a recovery team, and a charter flight is used to come and evaluate the organ.

An SRTR representative commented that charter flights come in two forms – 1) flying the organ into the local procurement team and 2) a program sending their own team to procure the organ. The representative continued by suggesting adding the wait times since 2013 for KP and the wait list. It would be helpful to provide some context and hypothesis as to why these trends are happening.

There were no additional questions or comments.

#### 4. Update: Offer Filters

The Committee received an overview of offer filters, an update on offer filters work and progress, and discussed potential considerations for offer filters for pancreas/KP.

##### Summary of discussion:

The Committee will continue to receive updates and provide feedback when applicable.

The Committee was asked for their feedback on several questions relating to potential enhancements for Pancreas offer filters. The following questions were presented to the Committee for additional review:

- Would you have different filters for your Kidney-Pancreas (KP) candidates versus Pancreas-alone candidates?
- Do you have any additional suggestions for donor filtering criteria?
- Do you have additional suggestions for candidate exclusion criteria?
- Should any kidney criteria not be in KP filters?

One member offered the suggestion that for KP filters, criteria that talk about the quality of the pancreas, such as the A1C of the donor or the sugars. The member affirmed that A1C and sugars are already data elements collected in DonorNet, and so incorporating them into offer filters shouldn't be too difficult.

Another member suggested that for the Kidney candidate exclusion criteria items such as gender and weight, in addition to age, should be added. It was also highlighted that including dialysis status, either pre-emptive or on dialysis, would be beneficial for the candidate exclusion criteria.

Maintaining Body Mass Index (BMI) as a criterion was viewed as critical for pancreas allocation. The SRTR representative recommended adding history of pancreatitis and HLA match for pancreas alone transplants, but not necessarily for simultaneous pancreas-kidney (SPK) or kidney-pancreas (KP) transplants. While the number of offers is currently low, suggestions were made to potentially add lipase level with a high threshold (e.g. 4-5x normal) as an exclusion criterion, as well as the type of flush solution used, which can vary by transplant program's preferences.

Members noted increasing trends of using remote recovery teams and flying in pancreata from distant donor locations. Collecting data on programs' willingness to split charter flights could be valuable for organ procurement organizations (OPOs) and transplant programs where air transport is required.

In addition to collecting data on charter flight cost splitting, other areas of transportation efficiency were highlighted as being more dependent on flight routes and schedules rather than solely nautical miles. The Committee Vice Chair recommended that an OPO name filter could allow programs to customize acceptance for locations they can readily access.

Members raised concerns about over-reliance on the Kidney Donor Profile Index (KDPI) filter, arguing it does not fully capture donor quality for pancreas/kidney allocation and could detrimentally restrict the donor pool if strictly applied. As a middle ground, allowing programs to set custom KDPI filters while avoiding recommending restrictive KDPI thresholds in the model was proposed. Best practice alerts were suggested to mitigate the "slippery slope" of only accepting organ offers from a narrow KDPI range. Data indicates pancreata from KDPI >50% donors tend to go unused currently.

Additional logistical factors mentioned included whether the pancreas is machine perfused prior to transplant and the ability for programs to prioritize organ offers from OPOs where established relationships exist, though implementing the latter as a conditional filter may prove difficult.

Next steps:

The Committee will continue to receive updates and provide feedback when applicable.

**5. Public Comment Presentation: Promote Efficiency of Lung Allocation**

The Committee received a presentation on the OPTN Lung Transplantation Committee's *Promote Efficiency of Lung Allocation* proposal.

Summary of discussion:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.
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The Pancreas Transplantation Committee thanks the OPTN Ad Hoc Multi-Organ Transplantation Committee for their efforts on the *Modify Effect of Acceptance Policy* proposal.

The Committee is in support of this proposal and provided some feedback for consideration:

- The Committee asked clarifying questions on the impact of a transplant hospital's acceptance rate if there were a need to reallocate an organ. It was suggested that programs not be penalized in their acceptance rate since the reasoning why the organ was not accepted would be documented. There was agreement that education to clarify this further would be beneficial to have a better understanding.
- There was concern raised that there could be issues present for pancreas, such as cold ischemic time (CIT) for pancreas; there should be some idea about what an acceptable CIT for pancreas is; if there is a liver-kidney and/or some thoracic-kidney offer, the kidney-pancreas (KP) list can be tied up. It was discussed that for scenarios where there is a liver-kidney and/or heart-kidney offers, and the next patient on each list needs a kidney, OPOs tend to hold those kidneys, which disadvantages the pancreas.
- There is some bidirectionality when it pertains to KP; the pancreas is not the lifesaving organ. In contrast to the other examples provided (liver-kidney and heart-kidney), the program would not move forward with the pancreas alone. The offer may move forward with a kidney alone; however, it may not be the best thing for the patient based on what is already known about outcomes for deceased donor kidneys and pancreas after kidney. It was suggested that this be looked at as something that is unique to KP and consideration on what would be an exclusion for this.

The Committee was in overall agreement that this proposal is a good move forward to address efficiency.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

## 6. Update: Expeditious Task Force

The Committee received an update on the OPTN Expeditious Task Force.

### Summary of discussion:

The Committee will continue to receive updates and provide feedback when applicable.

The Committee Chair raised their concerns around the need for greater involvement from the Centers for Medicare & Medicaid Services (CMS) in the discussions, given CMS's role as the primary payer for transplant-related costs and the influence of their policies on the field.

Members discussed the ambitious goal of increasing the annual number of deceased organ donors by approximately 50% from 40,000 to 60,000 by 2026. Questions were raised regarding whether the necessary infrastructure and workforce capacity currently exists to support such a significant increase in organ volume over just a two-year period, including sufficient air transportation, surgical staff, operating rooms, inpatient beds, and associated resources.

It was voiced that this 50% increase aspiration is modeled after the practices of the top 20% performing transplant programs nationally. Members articulated their concerns that substantially increasing organ volumes without appropriate planning could paradoxically worsen patient outcomes if it leads to greater utilization of more marginal organ quality donors.

Discussions centered on treating organ transplantation with a similar operational priority as a trauma system, engaging hospital executive leadership to ensure dedicated resources. Aligning performance metrics and payment incentives between the Organ Procurement and Transplantation Network (OPTN) and CMS was highlighted as crucial to achieving the increase in an effective, sustainable manner.

A member mentioned the potential benefit of incentivizing transplants for organs like kidneys that are cost-saving over the long-term compared to dialysis/chronic care costs.

Members sought clarification on the specifics of how variance proposals from Organ Procurement Organizations (OPOs) to work with select transplant centers would be governed, including the criteria and processes for determining participating centers and any linked incentives.

Concerns were raised that current post-transplant outcome metrics utilized by regulatory bodies are punitively designed rather than fostering improvement. A member mentioned a recent presentation that offered a newer definition of a transplant candidate based on whether that patient would fare better with the organ than without the organ. They offered that the current definition is based on strict thresholds compared to median national graft and patient survival rates.

Other members affirmed their concerns with the seemingly opposing nature of the metrics. One member voiced that to increase transplants, they will need to accept riskier organs, but are also trying to decrease non-use and non-utilization. Members agreed that the metrics need to be carefully scrutinized so that they are logical and do not have unintended consequences.

### Next steps:

The Committee will continue to receive updates and provide feedback when applicable.

## 7. Discussion/Report Outs: New Project Ideas

The Committee discussed and identified potential new projects ideas. The project ideas were broken out into three groups: Improve Offer Acceptance Rate; Optimize Organ Use; and Enhance OPTN Efficiency.

### Summary of discussion:

The Committee will review and further outline the potential new projects identified and determine the sequence of projects.

#### Improve Offer Acceptance Rate:

The group identified increasing organ offer acceptance rates and broader utilization of normothermic regional perfusion (NRP) as key strategies to expand pancreas transplantation opportunities. Emphasis was placed on supporting Organ Procurement Organization (OPO) partners through initiatives such as facilitating training of surgeons in pancreas procurement techniques and empowering OPOs to leverage NRP methodologies in an effort to convert donation after circulatory death (DCD) pancreas offers into viable, transplanted organs.

Inaccurate assessments of pancreas quality and suboptimal surgeon availability were highlighted as frequently cited barriers to pancreas utilization. Geographical considerations and reliance on commercial air transport schedules or extended ground transport were noted as critical logistical factors that significantly impact the feasibility of pancreas acceptance for individual transplant centers. Exploring enhanced regulations governing the use of commercial aviation for organ shipments was proposed as a potential opportunity area.

Collaboration with the OPO Committee on developing professional guidance documents and supplemental educational materials was recommended as a prospective project initiative. The importance of acknowledging and addressing the reasons underpinning pancreas offer refusals and turndowns, which can vary drastically based on a program's geographic region, was underscored.

The inability to accommodate prolonged cold ischemic times was emphasized as a pronounced limitation specific to pancreas transplantation. Differential reimbursement models, where hospitals more readily recoup costs for certain organ types compared to pancreata, were identified as a potential area for policy adjustments to enhance financial incentives and drive increased pancreas utilization.

Overall, the discussion centered on multi-stakeholder strategies spanning training, technology, logistics, reimbursement and data-driven process improvements to responsibly maximize pancreas utilization while addressing inherent clinical and geographic constraints.

#### Optimize Organ Use:

Members discussed the benefits of bolstering the procurement workforce by having Organ Procurement Organizations (OPOs) employ dedicated pancreas procurement surgeons was proposed as a potential solution to improve pancreas recovery rates. Another idea members discussed was addressing knowledge gaps through expanded educational initiatives, as resistance to pancreas transplantation persists among certain programs. Augmenting training pathways for safe pancreas procurement techniques was recommended, as current training requirements may be inadequate. It was voiced that many centers do not provide sufficient opportunities for interested clinicians to develop proficiency in pancreas procurement. Exploring a "safety net" paradigm to transplant pancreata into patients with moderately reduced renal function (GFRs 30-40 ml/min) who may require subsequent kidney transplantation in the near future was discussed as an avenue to drive increased utilization.



It was noted that pancreas non-utilization will likely persist as long as pancreas waitlist times remain relatively short, as this diminished sense of urgency contributes to the limited referral volumes and demand observed currently. Given the scarce pancreas candidate pool, programs tend to be highly selective when evaluating pancreas offers.

A suggestion was made to engage in active dialogue and collaborative initiatives with the American Diabetes Association to garner their organizational support, which could catalyze increased interest and pursuit of pancreas transplantation among their member patients and providers.

Emphasis was placed on ensuring that any laboratory criteria employed for pancreas offer filtering, such as lipase levels or acute kidney injury, are evidence-based and not arbitrarily restrictive in nature.

Members also discussed incorporating donor-specific factors like gender, body mass index, and age into a multifactorial model, as this intersectional approach could enable more granular optimization of pancreas offer acceptance parameters.

#### Enhance OPTN Efficiency:

The group highlighted that efficiency is a complex challenge and is intermingled with the previous topics. One proposed strategy was to require all pancreas transplant centers to implement and actively use offer filters within the organ allocation system.

It was noted that while some high-performing centers have effectively utilized expanded donor criteria like donation after circulatory death (DCD) pancreata to drive their volumes, this practice is not universally adopted across all pancreas programs. Instituting a mandatory requirement for filters could help optimize organ placement by ensuring offers for DCD pancreata are preferentially routed to centers willing to accept and transplant those organs.

Logistical barriers like flight times and geographic constraints were recognized as difficult systemic challenges requiring coordination across multiple stakeholders and disciplines to overcome. However, enforcing the consistent use of individualized offer filters was viewed as a relatively straightforward change to implement.

Additionally, it was recommended that pancreas programs be required to formally review and update their filter settings at routine intervals, such as every 6 months. Establishing this as a standardized process could drive continuous re-evaluation and refinement of filter parameters in alignment with evolving clinical practices and organ acceptance criteria.

Members discussed whether to prioritize implementing components to increase efficiency in the pancreas allocation system before introducing continuous distribution (CD) of organ offers.

The consensus seemed to be that focusing first on optimizing offer filters, maximizing placement efficiency, and expedited placement pathways should take precedence over transitioning to a continuous distribution model at this stage. Introducing CD could potentially add more operational stress to the system before foundational improvements in efficiency are realized.

It was suggested to evaluate the efficiency components in the context of how CD could eventually be incorporated.

There was interest in analyzing the most common refusal codes and reasons why pancreas organs are declined by programs. Assessing if organ quality is frequently cited as the primary reason could inform strategies. Additionally, examining accountability measures for programs with high non-utilization rates was raised as an area to explore.

The Committee was informed that the Data Advisory Committee (DAC) had previously looked at refusal codes and non-utilization efforts, so reviewing that prior analysis could provide relevant insights.

Next steps:

The Committee will review and further outline the potential new projects identified and determine the sequence of projects.

**Upcoming Meetings**

- April 1, 2024 (Teleconference)

## Attendance

- **Committee Members**
  - Oyedolamu Olaitan
  - Ty Dunn
  - Asif Sharfuddin
  - Colleen Jay
  - Neeraj Singh
  - Girish Mour
  - Jason Morton
  - Dean Kim
  - Diane Cibrik
  - Mallory Boomsma
  - Rupi Sodhi
  - Nikole Neidlinger
  - Todd Pesavento
  - Muhammad Yaqub
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jon Miller
  - Bryn Thompson
  - Raja Kandaswamy
  - Nick Wood
  - Ajay Israni
- **UNOS Staff**
  - Joann White
  - James Alcorn
  - Kristina Hogan
  - Kim Uccellini
  - Lauren Motley
  - Kaitlin Swanner
  - Carlos Martinez
  - Sarah Booker
  - Stryker-Ann Vosteen
- **Other Attendees**
  - Marie Budev
  - Robert Eckel
  - Antonio di Carlo
  - Betul Hatipoglu
  - Dan Rubin