OPTN Pancreas Transplantation Committee
Meeting Minutes
October 23, 2019
Chicago, IL

Silke Niederhaus, MD, Chair
Rachel Forbes, MD, Vice-Chair

Introduction

The Pancreas Transplantation Committee (the Committee) met in Chicago, Illinois on 10/23/19 to discuss the following agenda items:

1. Remove DSA and Region from Pancreas Allocation
2. Pediatric and Highly Sensitized Candidate Priority in Pancreas Allocation
3. OPTN Pancreas Transplantation Committee Charter
4. State of Islet Transplantation Currently
5. Policy Oversight Committee (POC) Update

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

1. Remove DSA and Region from Pancreas Allocation

The Committee reviewed public comment feedback, committee and workgroup meeting discussions, and options moving forward to assess how and if the proposed changes should be modified from public comment. The solution proposed for public comment included a 500 nautical mile (NM) circle around the donor hospital with up to four points inside the circle and up to eight points outside the circle (otherwise known as the 500.4.8 variation). Based on Committee discussions and review of relevant data and public comment feedback, the Committee voted on sending a modified proposal of a 250 NM circle around the donor hospital with up to two points inside the circle and up to four points outside (the 250.2.4 variation) to the Board of Directors (BOD) for approval in December.

The Chair provided an overview of the proposal's purpose to remove Donor Service Area (DSA) and region for pancreas allocation to be compliant with the Final Rule. In addition to review of committee and workgroup discussions and public comment feedback, the Committee also reviewed key metrics in KPSAM modeling comparing the 500.4.8 and 250.2.4 variations.

Summary of discussion:

Circle Size

The Committee compared the 500.4.8 and 250.2.4 models as they considered solutions. The 250 solution had been identified as an alternative in the public comment proposal, and was cited as a compromise, transitional step toward continuous distribution during public comment. Specifically, the Committee review included KPSAM metrics for both variations related to travel distance and percent of organs traveling more than 250 NM, transplant rate, waitlist mortality, race, payment status and CPRA. The Committee considered that the reviewed metrics showed similar gains in equity for the 250.2.4 and 500.4.8 models.

A member indicated support for the 250.2.4 model, as traveling farther distances for KPs may discourage acceptance due to the logistical challenges for pancreas surgeons who perform

procurements, as well as due to longer distances potentially increasing cold ischemic time. Another member agreed that 250.2.4 is a good step forward when compared to the 500.4.8 model that could create more logistical issues and possibly negatively impact ischemic time and patient outcomes. The Committee is focused on growing the field of pancreas transplantation overall and supports a solution that would not negatively impact pancreas utilization or access.

A member supported the 250 variation as a step towards continuous distribution that would lessen the logistical impact compared to a 500 NM circle. They suggested that smaller OPOs with fewer staff may be challenged to have the resources to deal with the change compared to larger OPOs. A member with a patient perspective noted that while a larger circle can improve access for candidates, the impact on ischemic time was concerning and led to her support of a smaller circle. The Committee took a straw vote and favored the 250 NM model as the solution for removing DSA from pancreas allocation.

Population Density:

The Committee discussed that there are certain limitations of the fixed distance circle model that were brought up in public comment: namely, that the model doesn't account for variation in population density. Because of population density variation, a 250 or 500 NM circle in one part of the country may encompass a very different population base than a circle drawn in another part of the country. Notably, the Ad Hoc Geography Committee, which was charged with considering different options for moving forward with removing DSA and region from allocation policies, did discuss an alternative system based on population density, but they ultimately opposed such a system because of the difficulty in maintaining it. Specifically, the Geography Committee members expressed concern with deciding what constitutes the "population" that helps define allocation, and when and how often such a system would be updated. The Geography Committee considered the fixed-distance circles an appropriate alternative framework for distributing organs to replace the use of DSAs and regions from allocation, while a more optimized system with continuous distribution is the ultimate framework to pursue.

Impact on Kidney Alone and Pediatrics

The Committee reviewed feedback from public comment regarding the potential impact of an increase in Kidney- Pancreas (KP) transplants on kidney-alone candidates, in particular, impact on pediatric kidney-alone candidates. The Committee discussed that the modeled increase in KP transplants is likely to be somewhat less than projected because pancreas programs tend to exhibit more cautious acceptance practices in reality(this implies that fewer low-KDPI (kidney donor profile index) kidneys may go to KP candidates at the expense of pediatric candidates). The concern about pediatric candidates stems from the fact doctors performing KP and pediatric kidney-alone transplants tend to accept lower KDPI, better quality kidneys. For KP this is because the quality of the pancreas needs to be acceptable to transplant both organs, and donors that have better pancreata tend to have lower KDPI kidneys as well. For pediatric kidney-alone, those transplant surgeons often look for low KDPI kidneys to help maximize the likelihood that the transplanted organ remains healthy long as possible, given the recipient's youth. It is important to remember that KP candidates are also kidney candidates and have a demonstrated need for both organs; this is why they are prioritized above kidney-alone candidates. The Committee agreed it is out of scope for this project to modify prioritization of KP candidates in relation to pediatric or other kidney-alone candidates.

There is a separate issue that was also a theme of public comment relating to pediatric priority within KP allocation. While kidney allocation policy provides priority for pediatric candidates, pancreas allocation does not. There could be scenarios where a pediatric kidney-alone candidate receives an offer for a low KDPI kidney but not for the donor pancreas and the surgeon advises the patient to take the kidney-alone instead of the kidney-pancreas. The Committee agrees with public comment this issue should be looked

into and it is currently a project the Committee is considering. Pediatric priority in KP and pancreas-alone allocation is discussed below in agenda item 4: Pediatric and High-CPRA Priority in Pancreas Allocation.

Kidney Committee Update

A member asked if the Kidney Committee discussed different models with varying points during their meeting. Another member answered that the Kidney Committee had selected the 250.2.4 model. The size of the circle will impact the number of points, so a smaller circle will not need as many proximity points.

While a member acknowledged that OPO performance impacts access, that access also has to do with the inequity faced when centers have varying acceptance/rejection practices.

In reference to the presentation on OPO performance metrics and their correlation to the modeled net changes in kidney alone transplants from Baseline to the proposed policy proposals (both 500.4.8 and 250.2.4), the Committee examined a slide that examined the SRTR Kidney Donation Conversion Ratio. A member asked what changes the SRTR expected were and why they were expecting changes at all. The SRTR responded that there was no assumption for changes, just transition in allocation systems. No trend exists that suggests that the new system will favor low performing OPOs and disadvantage high performing OPOs. Members examined a slide that displayed SRTR Kidney Donor Conversion Ratio. The outliers are the only element that made this SRTR Kidney Donor Conversion Ratio result statistically significant. If the outlier is removed, it is no longer statistically significant, so there is minimal evidence of a shift of kidneys from “high performing” OPOs to “low performing” OPOs.

Proximity Points

The Committee discussed feedback related to proximity points and pancreas allocation. Specifically, there was concern that the proximity points included in the public comment proposal would be too significant in relation to pancreas/KP candidate waiting time. Unlike kidney allocation, pancreas allocation doesn’t include other allocation points currently. The Committee agreed the proximity points should be limited in response to balancing them compared to candidate waiting time. Committee members agreed the alternative proximity points (250.2.4) would better balance proximity and waiting time in the new allocation system, while still providing an efficiency measure in allocation to limit accrued ischemic time.

Logistical Impact of 500 NM Solution

The Committee has previously discussed the public comment feedback received on the proposed public comment solution during September and October teleconferences. One clear theme of public comment related to the logistical impact of the 500 NM solution. Commenters were concerned that additional logistical impact related to transporting more pancreata a further distance would negatively affect pancreas ischemic time and patient outcomes. Specifically, commenters expressed support for finding a solution that better addressed concerns with increased air travel, citing the 250 NM alternative as a potential solution that would be more suitable for ground transportation, because surgeons are more likely to drive than fly to recover organs within a 250NM radius. Committee members agreed with the concerns about logistical challenges should be considered. The Committee discussed that logistical challenges can vary geographically, and having an initial distribution distance that is drivable would allow more flexibility in program and OPO travel to avoid a potential increase in pancreas organ loss due to increased ischemic time, as well as potential poorer outcomes due to increased ischemic time.

Facilitated Placement

In public comment, some commenters expressed support for a more inclusive definition that would allow more pancreas programs to participate in the facilitated pancreas placement policy, grow their program and gain experience. Commenters noted the changes with allocation may impact how programs qualify for facilitated placement. Committee members reviewed data showing how many programs would qualify based on the number of pancreata procured from beyond 250 and 500 NM. Committee members noted that the data did not reflect changes to the current allocation system, which could impact the number of programs that qualify in the future. With a larger initial distribution unit (250 NM instead of DSA), more programs may import pancreata from within that initial distribution unit than transplant pancreata procured farther away. Given the impact of the changes to allocation on the qualifying criteria, the concerns raised in public comment regarding inclusivity, and the proposed change in distribution unit from 500 NM to 250 NM, the Committee supported modifying the proposed qualifying criteria to transplanting two pancreata procured 250 NM or further from the pancreas program in the previous two years. Based on current data, 49 programs could qualify for facilitated placement as compared to the 39 programs qualifying under current OPTN policy. However, the Committee considers that number may be lower given the proposed changes to allocation removing DSA and region and using instead a 250 NM circle.

Import Back Up

Feedback from the community was mixed on import back up. Some commenters considered the solution appropriate, but others considered a smaller circle or center back up a more appropriate option for pancreas in particular. These commenters were concerned with the shorter ischemic time that pancreata can handle, and anecdotally provided evidence that pancreata are rarely re-allocated even more than short distance. Members expressed concern about center back up as an alternative solution because sometimes nearby programs may be able to use the pancreas when the center is unable to. Given that programs may have shorter lists of candidates, it is certainly possible a program may not have another suitable candidate to use the pancreas. However, the Committee agrees with community concerns about the 500 NM circle potentially increasing ischemic time in such a way that negatively impacts efficient placement of pancreata or pancreas utilization. The Committee is very supportive of improving pancreas utilization and avoiding modifications to policy that would negatively impact utilization. The Committee also considers that the modified proposal of 250 NM around the donor hospital impacts the import back up solution, and additional conversations are needed to derive an efficient and effective solution. The Committee agreed to work with the Kidney Committee and other stakeholders to send a solution out for spring public comment to address these concerns.

Alaska Donors

The Committee agreed to recommend allocating pancreata procured from donors in Alaska as if those organs were actually procured in Seattle because of concerns related to utilization. There are currently no pancreas transplant programs in Alaska, so no candidates within a 250 NM circle of an Alaskan donor will appear on a match. The system would then go “national,” and because Alaska is almost 2500 nautical miles from the continental United States, allocation may result in finding a candidate as far away as the East Coast, which would be very inefficient in terms of placing a pancreas, which cannot accrue too much ischemic time without risking a poor transplant outcome or an inability to transplant the organ at all. While there are few pancreas donors from Alaska, pancreas utilization overall is a priority of the Committee, even if the potential impact is small. Proximity points around the SeaTac airport would limit further travel and ischemic time. The proposed change is also consistent with the solution the Kidney Committee is recommending for kidneys recovered from Alaskan donors.

Policy Language, Vote

The Committee reviewed policy language and voted unanimously on the proposed changes:

- 250 NM circle around donor hospital with up to 2 points inside the circle, up to four points outside the circle
- Facilitated placement solution of 2 pancreata procured 250 NM or further from pancreas program in previous 2 years
- Alaska donors treated as if from Seattle

Next steps:

The revised solution to go to the Board of Directors.

2. Pediatric and Highly Sensitized Candidate Priority in Pancreas Allocation

The Committee discussed organizing a data request to begin exploring two new projects. One project the focuses on pediatric candidates and the other on highly sensitized candidates. As of now these projects aim to explore opportunities to assist vulnerable populations in accessing pancreas transplants.

Summary of discussion:

Members agreed that pediatric priority may be an important factor to include in pancreas allocation and a data request was not needed to ascertain that pediatric priority was an important equity factor. Specifically, members noted that pediatric candidates receive priority for low KDPI kidneys, but may not receive the offer for the pancreas of the donor with the low KDPI kidney, and may be advised by their surgeons to take the kidney-alone when the pediatric candidate needs both a kidney and a pancreas. The number of pediatric pancreas candidates is low, and therefore data may be difficult to assess and may be limited in aiding the Committee decide that pediatric priority is appropriate. The Committee did review data on the number of KP and pancreas pediatric additions as well as transplants. The Committee discussed the following with regard to pediatric pancreas candidates:

- Number of pancreas- alone KP pediatric pancreas candidates.
- Different ways to measure how long these candidates wait: What age are they listed vs. the age at transplant, How long it takes for these patients to get their first kidney offer, How long it takes for these patients to receive a kidney transplant.
- After they receive a kidney- Where are they on the pancreas list and when would they receive a pancreas offer?
- What should be done to ensure that highly sensitized pediatric patients receive KP transplants as opposed to a kidney alone, as they will have little chance of ever finding a suitable pancreas?

Ultimately, the Committee supported a data request for CPRA candidates and decided to move ahead with pediatric priority irrespective of a data request, given that the equitable impetus remained regardless of data, which was limited and may not help the Committee identify how pediatric priority should be changed.

Based on the Committee discussion and follow up with Committee leadership, the Committee requested the following data on highly sensitized patients:

- For adult (age 18 - 60) Type 1 diabetic kidney-alone candidates with BMI < 30 waiting at the end of 2018, provide tabulation of candidates also listed for kidney-pancreas, stratified by cPRA.
- For adult (age $\geq$ 18) kidney-pancreas and pancreas candidates, stratified by cPRA, the following metrics will be provided:
    - Transplant Rates
    - Mortality Rates
    - Offer Rates

Next steps:

The research analyst will summarize the Committee's request.

3. OPTN Pancreas Transplantation Committee Charter

The Pancreas Committee reviewed their charter describing the work and focus of the Committee. After review and slight modification, the Committee voted on the updated charter.

Summary of discussion:

The Committee previously reviewed their charter in August 2019. The Committee decided to add language specifying that the focus of the Committee extends to pancreas and islet candidates and recipients. The updated charter reads:

"The Pancreas Transplantation Committee is charged with considering medical, scientific, and ethical aspects related to pancreas and islet organ procurement, distribution, and allocation. The Committee will consider both the broad implications and the specific member situations relating to pancreas and islet issues and policies. The goal of the committee's work is to develop evidence-based policies aimed at reducing the burden of disease in pancreas and islet candidates and recipients, increasing pancreas and islet utilization, improving access to pancreas and islet transplantation as appropriate, and improving the health outcomes of pancreas and islet recipients."

Next steps:

The Executive Committee will review all charters at the Board of Directors meeting in December.

4. State of Islet Transplantation Currently

A committee member gave an update on the status of islet transplantation in the United States. This member believes that islets should be regulated under the same system as organs.

Summary of discussion:

A member suggested having fewer, but central locations for islets may drive price down. The presenting member responded that we would save money by doing this in addition to allowing islets to be regulated similarly to organs with less regulation. Other members suggested regionalizing locations that work with islets.

Next steps:

This member will continue his work with islet transplant and the FDA.

5. POC Update

A member gave an update on Policy Oversight Committee's (POC) new themes and role.

Summary of discussion:

The Pancreas Committee agreed that they need to collaborate with the Kidney Committee in the development of new projects. The Committee will consider what criteria is important to pancreas patients when weighting elements of continuous distribution. The Committee expressed being ready to move forward with Continuous Distribution.

Next steps:

The Committee was asked to send in any project ideas that align with the POC's themes.

Upcoming Meeting

- November 20, 2019 (teleconference)

Attendance

- **Committee Members**
  - Tarek Alhamad
  - Doni Bell
  - Rachel Forbes
  - Michelle Goble
  - Angelika Gruessner
  - Robert Harland
  - Daniel Keys
  - Liise Kayler
  - Jerry McCauly
  - Matthew Mulloy
  - Silke Niederhaus
  - Jon Odorico
  - Andie Perona
  - David Scott
  - Jill Stineburg
  - Piotr Witkowski
  - Muhammad Yaqub
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Robert Walsh
- **SRTR Staff**
  - Sally Gustafson
  - Raja Kandaswamy
- **UNOS Staff**
  - James Alcorn
  - Nicole Benjamin
  - Matt Cafarella
  - Matthew Chauklin
  - Beth Coe
  - Scott Castro
  - Craig Connors
  - Abigail Fox
  - Chelsea Haynes
  - Sara Moriarty
  - Rebecca Murdock
  - Joel Newman
  - Delany Niles
  - Kelley Poff
  - Leah Slife
  - Read Urban
  - Ross Walton

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

6. 1.2 Definitions

~~Zero antigen~~ 0-ABDR mismatch
A candidate is considered a ~~zero antigen~~ 0-ABDR mismatch with a deceased or living donor if *all* of the following conditions are met:

1. At least one donor antigen is identified for each of the A, B, and DR loci
2. At least one candidate antigen is identified for each of the A, B, and DR loci
3. The donor has zero non-equivalent A, B, or DR antigens with the candidate's antigens
4. The donor and the candidate have compatible or permissible blood types

In cases where a candidate or donor has only one antigen identified at an HLA locus (A, B, or DR), the antigens are considered to be identical at that locus. A ~~zero antigen~~ 0-ABDR mismatch may also be referred to as a zero mismatch or ~~0 ABDR~~ zero antigen mismatch.

Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets

7. 11.2 Pancreas Allocation Score

Candidates receive an allocation score according to the total of all points assigned in *Table 11-1*.

Table 11-1: Allocation Points

If the candidate:	Then the candidate receives this many points:
Is registered for pancreas or islet transplant	1/365 points for each day since candidate's registration date
Is registered for kidney-pancreas transplant and meets the qualifying criteria described in *Policy 11.3: Waiting Time*	1/365 points for each day since meeting the qualifying criteria in *Policy 11.3: Waiting Time*
Meets the qualifying criteria described in *Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital*	See *Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital*

Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital

For purposes of this section, distance is calculated in nautical miles between candidate's hospital of registration and the donor hospital.

If the candidate is:	Then the candidate receives this many points:
Registered at a transplant program that is 250 nautical miles or less away from the donor hospital	$2 - \left[\left(\frac{2}{250 - 0}\right) \times distance\right]$
Registered at a transplant program that is more than 250 nautical miles but 2,500 nautical miles or less away from the donor hospital	$4 - \left[\left(\left(\frac{4}{2500 - 250}\right) \times distance\right) - \left(4 \times \frac{250}{2500 - 250}\right)\right]$
Registered at a transplant program that is more than 2,500 nautical miles away from the donor hospital	0

11.4.A Kidney-Pancreas Allocation Order

If a host OPO has both a kidney and a pancreas to offer for allocation, then the host OPO ~~must offer the kidney and pancreas in the following order~~:

1. ~~The host OPO m~~Must offer the kidney and pancreas according to classifications 1~~–5~~4 in *Table~~s~~ 11-~~4~~5: Allocation of Kidney~~s~~ and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m^2* and *Table 11-~~5~~6: Allocation of Kidney~~s~~ and Pancreas from Donors more than 50 Years Old or with a BMI greater than 30 kg/m^2*.

2. Then, the host OPO may do *either*:
   a. Continue to offer the kidney and pancreas according to the remaining classifications in *Table 11-~~4~~5* and *Table 11-~~5~~6*.
   b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas candidates, according to the remaining classifications in *Table 11-~~4~~5* and *Table 11-~~5~~6* and offer the kidney to kidney candidates according to *Policy 8: Allocation of Kidneys*.

The host OPO may switch between options 2.a and 2.b above at any time after completing step 1 above.

11.4.B Pancreas Allocation When a Kidney is Unavailable

If a host OPO only has a pancreas, but not a kidney to offer for allocation, then the host OPO must offer the pancreas to pancreas and islet candidates but not kidney-pancreas candidates according to *Table~~s~~ 11-~~4~~5: Allocation of Kidney~~s~~ and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m^2* and *Table 11-~~5~~6: Allocation of Kidney~~s~~ and Pancreas from Deceased Donors more than 50 Years Old or with a BMI Greater than 30 kg/m^2*.

OPOs may not allocate a kidney to a potential pancreas recipient who is receiving the pancreas offer due to the match run prioritization of the potential recipient's isolated pancreas registration.

11.4.C Organ Offer Limits

Any pancreas that will be ~~shared~~ allocated as ~~zero antigen~~ 0-ABDR mismatches, either alone or in combination with kidneys, must be offered within eight hours after procurement.

If there are at least 10 ~~zero antigen~~ 0-ABDR mismatched potential recipients on the match run, the pancreas must be offered to the first 10 ~~zero antigen~~ 0-ABDR mismatched potential transplant recipients. If there are less than 10 ~~zero antigen~~ 0-ABDR mismatched potential transplant recipients, the pancreas must be offered to all ~~zero antigen~~ 0-ABDR mismatched potential transplant recipients.

If these offers are not accepted then the host OPO must:

- Allocate the ~~organ~~ kidney according to the match run under *Policy 8.5: Kidney Allocation Classifications and Rankings* and allocate the pancreas according to *Policy 11.4: Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings*~~-~~.
- Allocate the organ for the remaining ~~zero antigen~~ 0-ABDR mismatched potential recipients.

11.4.D Blood Type for Kidney-Pancreas Allocation

Within each classification, kidney-pancreas will be allocated to candidates according to the blood type matching requirements in *Table 11-~~3~~4* below:

11-~~3~~4: Allocation of Kidney-Pancreas by Blood Type

Kidney-Pancreas from Deceased Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O or blood type A, B, or AB if the candidate has a ~~zero antigen~~ 0-ABDR mismatch with the deceased donor and a CPRA greater than or equal to 80 percent
Blood Type A	Blood type A or AB
Blood Type B	Blood type B
Blood Type AB	Blood type AB

11.4.E Sorting Within Each Classification

Within each allocation classification, pancreas, kidney-pancreas, and islet candidates are sorted in the following order: ~~based on waiting time (longest to shortest).~~

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

11.4.F Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m^2

Pancreas, kidney-pancreas, and islets from donors 50 years old or less and who have a BMI less than or equal to 30 kg/m^2 will be allocated to candidates according to *Table 11-~~4~~5* ~~based on waiting time~~.

Table 11-4: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m2

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
2	OPO's DSA	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
3	OPO's region	Zero antigen mismatch, CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
4	Nation	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
5	OPO's DSA	Pancreas or kidney-pancreas candidates
6	OPO's region	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
7	OPO's region	Pancreas or kidney-pancreas candidates
8	Nation	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
9	Nation	Pancreas or kidney-pancreas candidates
10	OPO's DSA	Islet candidates
11	OPO's Region	Islet candidates
12	Nation	Islet candidates

Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m^2

Classification	Candidates that are	And registered at a transplant program that is at or within this distance from the donor hospital:
1	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	250NM
2	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	250NM
3	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	Nation
4	Pancreas or kidney-pancreas candidates	250NM
5	Either pancreas or kidney-pancreas candidates, and CPRA greater than or equal to 80%	Nation
6	Pancreas or kidney-pancreas candidates	Nation
7	Islet candidates	250NM
8	Islet candidates	Nation

11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m^2

Pancreas, kidney-pancreas, and islets from deceased donors more than 50 years old or from deceased donors who have a BMI greater than 30 kg/m^2 are allocated to candidates according to *Table 11-~~5~~6* ~~based on waiting time~~ below.

~~Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m^2~~

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~1~~	~~OPO's DSA~~	~~Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates~~
~~2~~	~~OPO's DSA~~	~~CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates~~
~~3~~	~~OPO's region~~	~~Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates~~

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~4~~	~~Nation~~	~~Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates~~
~~5~~	~~OPO's DSA~~	~~Pancreas or kidney-pancreas candidates~~
~~6~~	~~OPO's DSA~~	~~Islet candidates~~
~~7~~	~~OPO's region~~	~~Islet candidates~~
~~8~~	~~Nation~~	~~Islet candidates~~
~~9~~	~~OPO's region~~	~~CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates~~
~~10~~	~~OPO's region~~	~~Pancreas or kidney-pancreas candidates~~
~~11~~	~~Nation~~	~~CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates~~
~~12~~	~~Nation~~	~~Pancreas or kidney-pancreas candidates~~

Table 11-6: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m^2

Classification	Candidates that are:	And registered at a transplant program that is at or within this distance from the donor hospital:
1	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	250NM
2	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	250NM
3	Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%	Nation
4	Pancreas or kidney-pancreas candidates	250NM
5	Islet candidates	250NM
6	Islet candidates	Nation
7	Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%	Nation
8	Pancreas or kidney-pancreas candidates	Nation

11.5 Reallocation of Unsuitable Islets

Islets must be allocated to the most medically suitable candidate based on the transplant ~~hospital~~ program's Investigational New Drug (IND) application, as approved by the United States Food and Drug Administration (FDA). After islet processing is completed, the transplant ~~hospital~~ program must determine and document *both*:

1. Whether the islet preparation meets the transplant ~~hospital~~ program's islet product release criteria contained in the IND.
2. Whether the islets are medically suitable or medically unsuitable for the candidate that accepted the islets.

If the islets are found medically unsuitable for the candidate, the transplant ~~hospital~~ program must document the reason the islets were determined to be medically unsuitable for the candidate.

If the transplant ~~hospital~~ program determines that the islets are medically unsuitable for the candidate, the transplant ~~hospital~~ program will reallocate the islets according to *all* of the following criteria:

1. To a candidate that is medically suitable
2. To a candidate that is registered at a transplant ~~hospital~~ program covered by the same IND
3. The candidate's ~~waiting time (ranked longest to shortest)~~ allocation score according to *Table 11-1: Allocation Points*

The transplant ~~hospital~~ program that reallocates the islets must document that it followed this ~~P~~policy.

8. 11.6 Facilitated Pancreas Allocation

11.6.A Transplant Program Qualifications

A transplant program qualifies to receive facilitated pancreas offers if within the two previous years it has transplanted a minimum of ~~five~~ two pancreas recovered from deceased donors located at hospitals more than 250 NM away from the transplant program. ~~recovered from deceased donors outside its DSA.~~ This includes pancreas transplanted as part of a multi-organ transplant.

11.6.B Facilitated Pancreas Offers

OPOs and the ~~Organ Center~~ OPTN Contractor are permitted to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery. The OPO or ~~Organ Center~~ OPTN Contractor must offer the pancreas only to potential transplant recipients registered at a transplant program that participates in facilitated pancreas allocation. Facilitated pancreas offers must be made in the order of the match run, and OPOs will only have access to facilitated allocation after all ~~local~~ pancreas and kidney-pancreas offers made to candidates registered at transplant programs within 250 nautical miles of the donor hospital have been declined.

11.7 Administrative Rules

11.7.A Location of Donor Hospitals

For the purpose of determining the location of the donor hospital for allocation of pancreas, kidney-pancreas, or islets, kidneys and pancreata procured in Alaska will be considered procured from the Seattle Tacoma Airport, Seattle, Washington.

#