

## Public Comment Proposal

# Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types

*OPTN/UNOS Pancreas Organ Transplantation Committee*

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# Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types

*Affected Policies:* 11.4.A (Kidney-Pancreas Allocation Order); 11.4.D (Blood Type for Kidney-Pancreas Allocation); 11.4.F (Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m<sup>2</sup>); 11.4.G (Deceased Donors More than 50 Years Old or with a BMI Greater than 30 kg/m<sup>2</sup>)

*Sponsoring Committee:* Pancreas Organ Transplantation

*Public Comment Period:* July 31, 2017– October 2, 2017

## Executive Summary

Pancreas transplants continue to decline and the majority of pancreata that are transplanted are done so as part of a simultaneous pancreas-kidney (SPK) transplant. Current blood type restrictions on kidney-pancreas allocation prevent clinically compatible SPK transplants from occurring. Preventing clinically compatible SPK transplants results in many of these pancreata being discarded or not recovered. Modifying current blood type restrictions could lead to an increase in the utilization of pancreata, an overall increase in SPK transplants, and could promote a more efficient allocation system.

This proposal modifies Policy 11.4.D *Blood Type for Kidney-Pancreas Allocation* to loosen restrictions on blood type compatibility for kidney-pancreas (KP) and pancreas alone (PA) allocation: allowing blood type A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B kidney-pancreas and pancreas offers to B candidates, allowing blood type B kidney-pancreas and pancreas offers to AB candidates, and removing restrictions on blood type O compatibility. The proposal also modifies allocation to prioritize high-cPRA ABO-identical candidates above high-cPRA ABO-compatible candidates, then among candidates with cPRA < 80%, prioritize ABO-identical candidates above ABO-compatible candidates.

The Pancreas Committee is pursuing an allocation change that maximizes the increase of KP transplants and minimizes negative impacts on blood type, age, or ethnicity. While the modeling by the Scientific Registry of Transplant Recipients (SRTR) did not project that candidates would be disadvantaged based on age or ethnicity, the modeling projected a slight reduction in blood type O access to transplant, including a simulated 2% decrease for blood type O kidney transplants. There was also a decrease for KP blood type O transplants but an increase of KPs overall. However, the modeling projected a significant increase in the number of SPKs, an increase in the number of median years of benefit, and a net increase in transplants if the blood type restrictions were loosened. The simulation chosen by the Committee predicts the least impact on blood type O candidates except one (Run 6), which showed a smaller increase in the median years of benefit and life years from transplant (LYFT). The increase in SPKs and net increase in transplants projected by the proposal aligns with OPTN Goal 1, to increase the number of transplants.

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

There is no available data on transplanting a blood type A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B kidney-pancreas or pancreas alone into a blood type B recipient, because these transplants have not been previously permitted by OPTN/UNOS policy. In seeking to encourage the use of this compatibility, the Committee seeks feedback on any concerns, questions or experiences that members of the transplant community may have on transplants involving A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B kidney-pancreas or pancreas alone into

blood type B recipients. This feedback will help the Committee create an educational resource for the community to use in conjunction with this policy change.

Also in regards to the A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B to B compatibility, the Committee asks whether transplant programs anticipate using different titer thresholds for an A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B kidney-pancreas or pancreas alone compared to the titer thresholds used for an A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B kidney alone. The programming for this policy would allow transplant programs to indicate a candidate's eligibility to receive blood type A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B organs for kidney, kidney-pancreas, and pancreas. If the kidney-pancreas or pancreas titer thresholds differ, then the eligibility for receiving these organs should be submitted separately.

## What problem will this proposal address?

Pancreas transplants continue to decline and the majority of pancreata that are transplanted are done so as part of a simultaneous pancreas-kidney (SPK) transplant<sup>1</sup>. Current blood type restrictions on kidney-pancreas allocation prevent clinically compatible SPK transplants from occurring. Preventing clinically compatible SPK transplants results in many of these pancreata being discarded or not recovered.<sup>2</sup>

## Why should you support this proposal?

This proposal is an important step in reversing the decline of pancreas transplants in the United States by increasing SPK transplants. SRTR modeling predicts an increase of 143 SPK transplants, which would represent a 19.9% increase for 2015 SPK transplants. While there is a reduction in kidney alone transplants, by comparison, this reduction is 0.8% of all 2015 deceased-donor kidney transplants. Due to the increase in SPK transplants, the overall increase in the number of transplants is greater than the projected reduction in kidney alone transplants (143.3 compared to 105.1 respectively). While there is a negative impact on blood type O recipients' access to transplant, that is offset by the increase in KPs, the decrease in pancreas discards, and the overall increase in transplant. This proposal represents an opportunity to increase the number of transplants, reduce pancreas discards, and create a more efficient pancreas allocation system by incorporating blood type compatibility.

## How was this proposal developed?

After implementing some programming changes in 2015, the Kidney and Minority Affairs Committees recommended that the Pancreas Committee analyze data relating to the effect of removing blood type restrictions for kidney-pancreas allocation, including potentially using simulation modeling provided by the SRTR.

The Pancreas Committee met in Chicago on October 8, 2015 and agreed that the current restrictions by blood type for kidney-pancreas transplants were not necessary and were deleterious to the current state of pancreas transplantation. The Committee stated that they would like to pursue a project that would revise policy to allow all clinically-compatible blood types in kidney-pancreas allocation. The Committee acknowledged that this effort would rely on continued collaboration with the Kidney and Minority Affairs Committees.

The Committee viewed the current decline in pancreas transplants to be the leading issue for the Committee and considered projects aimed at increasing the number of pancreas transplants to be the highest priority. The leadership of the Pancreas Committee met with SRTR staff on December 7, 2015 to discuss the future use of kidney-pancreas simulation (KPSAM) to model the potential changes to kidney-

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<sup>1</sup> Stratta, Robert J., Jonathan A. Fridell, Angelika C. Gruessner, Jon S. Odorico, and Rainer W.g. Gruessner. Pancreas transplantation: A Decade of Decline. *Current Opinion in Organ Transplantation* 21, no. 4 (August 2016): 386-92. doi:10.1097/mot.0000000000000319.

<sup>2</sup> Ibid.

pancreas blood type restrictions. The aim would be to assess the impact on SPK and kidney alone transplant volumes and waiting times that such a policy change could create.

The Committee submitted a data request to the SRTR for five KPSAM simulations that were compared with a baseline (R1) to assess the impact on the number of transplants, transplants by blood type, age, and ethnicity. The simulations were:

- All compatible blood types allowed (R2)
- All compatible blood types allowed and ABO identical candidates are prioritized. (R3)
- High-cPRA ABO identical candidates prioritized, followed by ABO compatible candidates with high CPRA, identical candidates with low cPRA, compatible candidates with low cPRA (R4)
- ABO-identical candidates prioritized above ABO-compatible candidates according to geographical stratification (local, regional and national classifications) (R5)
- ABO-identical candidates receive offers through the national level, then ABO-compatible candidates offers through the national level (R6)

In October 2016, the Committee reviewed the KPSAM requests and identified a run that maximized the intention of increasing KP transplants and minimized disadvantages to groups by blood type, age, and ethnicity. This simulation, Run 4, prioritized high-cPRA above compatibility, and identical blood type over compatible blood type. In January 2017, the Committee expressed support for sending the project to public comment in the Fall 2017 cycle. The Committee reviewed policy language at its in-person meeting in March 2017, and voted to approve the draft policy language during a May 2017 call.

For outreach, in February 2017, the Committee provided the Kidney Committee leadership with a summary of the project and SRTR analysis for review. In April, the Pancreas Committee Chair spoke with the Kidney Committee Vice-Chair about the proposed changes to ABO allocation. The Vice-Chair expressed concern over blood type O kidney alone candidates and said the Kidney Committee will continue to monitor the proposed changes through public comment. The Pancreas Committee has submitted a summary of the proposal to the Minority Affairs Committee and will brief both the Minority Affairs and Kidney Committees during public comment in the fall.

## **How well does this proposal address the problem statement?**

This proposal changes the allocation sequence based on SRTR modeling to increase recovery rates and decrease discard rates for pancreata. The simulation chosen by the Committee to emulate in policy shows the greatest increase in KP transplants and the greatest projected median years of benefit from transplant.

The SRTR cohort used in the modeling included all transplant candidates listed on waiting lists for kidney, kidney-pancreas, and pancreas from January 1, 2010 to December 31, 2010. The study population was reduced in a second cohort to account for a reduction in volume seen in 2015 data. This was accomplished by randomly selecting 3,312 KP candidates and 1,373 PA candidates from the 2010 cohort (there were 3,312 KP candidates and 1,373 PA candidates in 2015). Without this reduction, effects on broader ABO compatibility could be exaggerated in the modeling. In the section below, the results from both the full and reduced cohort are shown, although discussion focuses on the reduced cohort since it is a more realistic approximation of the contemporaneous impact of the simulations.

SRTR ran five KPSAM simulations, plus a baseline (R1):

- All compatible blood types allowed (R2)
- All compatible blood types allowed and ABO identical candidates are prioritized. (R3)
- High-cPRA ABO identical candidates prioritized, followed by ABO compatible candidates with high CPRA, identical candidates with low cPRA, compatible candidates with low cPRA (R4)

- ABO-identical candidates prioritized above ABO-compatible candidates according to geographical stratification (local, regional and national classifications) (R5)
- ABO-identical candidates receive offers through the national level, then ABO-compatible candidates offers through the national level (R6)

The SRTR showed the analysis by age, race, blood type, cPRA, HLA mismatch, diagnosis and locality. The simulations also reported the average lifespan post-transplant, graft years of life, years of benefit from transplant versus staying on the waiting list, and life years from transplant (LYFT). The simulations showed minimal changes due to age or ethnicity, but did show a negative impact on blood type O candidates seeking transplant for Runs 2 through 5.

Table 1 shows the simulated blood type compatibility. It is identical to current kidney allocation, except that A, B, and AB candidates can receive organs from O donors without 0-ABDR mismatch, likewise with AB candidates and B donors. Also, the KPSAM allowed A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B (in the table, A2 and A2B) to B compatibility.

Table 1: KPSAM Simulated Blood Type Compatibility<sup>3</sup>

	Candidate: O	Candidate: A/A1/A2	Candidate: B	Candidate: AB/A1B/A2B
Donor: O	I	C	C	C
Donor: A/A1	X	I	X	C
Donor: A2	X	I	C2	C
Donor: B	X	X	I	C
Donor: AB/A1B	X	X	I	C
Donor: A2B	X	X	C2	I

I = Identical

C = Compatible

C2 = Compatible only if candidate meets A2 or A2B eligibility criteria (as for kidney)

X = Incompatible; not allowed

<sup>3</sup> Gustafson, S., B. Thompson, J. Pyke, and A. Israni. "OPTN Pancreas Committee Request: Broader ABO Sharing." May 18, 2016: 2.

For the number of transplants, Runs 4-6 all predicted a net increase in SPK transplants compared to the baseline. Run 4 showed the greatest difference in the increase in SPKs compared to the decrease in kidney alone transplants (143.3 compared to -105.1, respectively, in the reduced cohort). Although the increase in SPKs across R2-R5 is fairly similar (132 – 143), Run 4 simulated a smaller reduction in kidney alone transplants (-105 compared to -135 or greater). As a result, the Committee supported R4 because it resulted in a net increase of +39 transplants compared to other simulations. See Table 2 for a comparison by transplant type.

Table 2: SRTR KPSAM Results by # of Transplants<sup>4</sup>

<b>Results: Number of Transplants</b>					
<i>Reduced Cohort</i>					
	R2-R1	R3-R1	R4-R1	R5-R1	R6-R1
KIA	-135.5	-138.2	-105.1	-136.4	26.1
PA	-2.4	-0.2	0.8	5.9	13.3
SPK	132.3	143.6	143.3	141.9	-16.4
Total	-5.6	5.2	39.0	11.4	23.0
<i>Full Cohort</i>					
	R2-R1	R3-R1	R4-R1	R5-R1	R6-R1
KIA	-140.9	-141.0	-126.6	-125.5	8.9
PA	-6.8	-6.2	-6.6	-4.0	18.6
SPK	136.9	141.1	143.8	145.4	2.0
Total	-10.8	-6.1	10.6	15.9	29.5

Table 2 shows the KPSAM results by the number of transplants. R4-R6 all predicted a net increase in transplants versus R1. R3 did so only in the reduced cohort. Under R2-R5, SPK transplants increased to 144 from 132. For R6 they decreased by 16. PA-alone transplants were stable, with the largest change under R6.

<sup>4</sup> Gustafson, S., B. Thompson, J. Pyke, and A. Israni. "OPTN Pancreas Committee Request: Broader ABO Sharing." October 28, 2016.

Results by blood type showed an increase for blood type A and B (8% and 4%, respectively for Run 4 in the reduced cohort), and a reduction in blood type O (13% for Run 4 in the reduced cohort). The only exception was Run 6, which showed an opposite trend but to a smaller degree. Table 3 illustrates the impact on blood type.

Table 3: SRTR KPSAM Results for KP Transplants by Blood Type<sup>5</sup>

<b>Transplants by blood type: KP</b>					
<i>Reduced Cohort</i>					
Blood Type	R2-R1	R3-R1	R4-R1	R5-R1	R6-R1
A	+142 (+13%)	+109 (+8%)	+107 (+8%)	+106 (+8%)	+7 (+2%)
AB	+14 (+1%)	+6 (0%)	+5 (0%)	+7 (0%)	-4 (-1%)
B	+80 (+8%)	+56 (+5%)	+56 (+5%)	+50 (+4%)	-24 (-4%)
O	103 (-23%)	-27 (-14%)	-25 (-13%)	-21 (-13%)	+4 (+2%)
<i>Full Cohort</i>					
Blood Type	R2-R1	R3-R1	R4-R1	R5-R1	R6-R1
A	+148 (+13%)	+96 (+6%)	+97 (+6%)	+100 (+7%)	+3 (0%)
AB	+12 (+1%)	+2 (-1%)	+3 (-1%)	+2 (-1%)	-10 (-2%)
B	+93 (+10%)	+64 (+7%)	+67 (+7%)	+59 (+6%)	+6 (+1%)
O	-116 (-24%)	-21 (-12%)	-23 (-13%)	-15 (-12%)	+3 (0%)

*KPSAM results showed consistent sizeable increases in ABO:A and ABO:B transplants, except in the reduced cohort of R6. Small increases in ABO:AB transplants. Reduction in ABO:O transplants between 12% and 24%, except in R6*

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<sup>5</sup> Ibid.

Similarly, kidney alone transplants saw an increase in blood type A and blood type B transplants, and a reduction in blood type O transplants. The reduction for blood type O kidney alone transplants was slightly less for Run 4 than for simulations 2 through 5, though it was more than the simulated reduction in Run 6. The changes reflect small percentages due to the high volume of kidney transplants. Table 4 shows the effect on kidney alone transplants, by blood type.

Table 4: SRTR KPSAM Results for KIA Transplants by Blood Type<sup>6</sup>

<b>Transplants by blood type: KIA</b>					
<i>Reduced Cohort</i>					
Blood Type	R2-R1	R3-R1	R4-R1	R5-R1	R6-R1
A	+94 (+1%)	+44 (+1%)	+54 (+1%)	+54 (+1%)	+36 (0%)
AB	+5 (0%)	+60 (+1%)	+60 (+1%)	+66 (+1%)	+64 (+1%)
B	+45 (+1%)	+34 (+1%)	+48 (+1%)	+28 (+1%)	+44 (0%)
O	-282 (-2%)	-276 (-2%)	-266 (-2%)	-278 (-2%)	-105 (-1%)
<i>Full Cohort</i>					
Blood Type	R2-R1	R3-R1	R4-R1	R5-R1	R6-R1
A	+82 (+1%)	+53 (+1%)	+38 (+1%)	+34 (+1%)	+26 (0%)
AB	+9 (0%)	+70 (+1%)	+60 (+1%)	+63 (+1%)	+61 (+1%)
B	+48 (+1%)	+18 (0%)	+37 (+1%)	+37 (+1%)	+30 (0%)
O	-287 (-2%)	-289 (-2%)	-268 (-2%)	-263 (-2%)	-90 (-1%)

*KPSAM results showed ABO:A and ABO:B consistently increased (26 to 94 and 18 to 48, respectively); ABO:AB increased by 5 to 70. ABO:O transplants decreased by between 263 to 289 (R2-R5) and 90 to 105 (R6). Because the total number of kidney transplants is high, the percentage changes are small.*

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<sup>6</sup> Ibid.

The KPSAM modeling also evaluated the results based on projected median years of benefit from transplant, and projected quality-adjusted median years of benefit from transplant (LYFT). In both metrics in the reduced cohort, Run 4 showed the greatest benefit from transplant. Table 5, showing median years of benefit from transplant, illustrates the difference in the extra years of life afforded by transplant, as compared to remaining on the waiting list.

Table 5: SRTR KPSAM Results for Transplant Benefit Metrics<sup>7</sup>

<b>Transplant Benefit Metrics by KPSAM run</b>					
<i>Projected median years of benefit from transplant</i>					
	R2-R1	R3-R1	R4-R1	R5-R1	R6-R1
Reduced	117.8	133.1	249.2	174.2	102.5
Full	266.9	330.0	417.7	415.7	202.2
<i>Projected quality-adjusted median years of benefit from transplant (LYFT)</i>					
	R2-R1	R3-R1	R4-R1	R5-R1	R6-R1
Reduced	79.8	101.0	240.3	150.5	100.5
Full	200.9	264.0	368.3	376.5	165.4

*All simulations predict a net increase in the metrics previously used by the OPTN Kidney Committee to evaluate policy changes. Median years of benefit from transplant versus waiting list is the extra years of life that a candidate could expect to achieve with a kidney transplant versus never undergoing transplant. QA means that all time spent on dialysis or the waiting list was "discounted" to be 80% the value of time with a functioning graft. The increase is due to a shift to more kidney-pancreas transplants, which on average have a higher LYFT and QA-LYFT than kidney-alone transplants. The full cohorts predicted more total transplants than the reduced cohorts, which is why the total LYFT in the full runs is higher.*

The Committee supported Run 4, which was viewed as the best simulation because it increased the number of KP transplants by 143, showed a greater effect on KP transplants than the decrease in kidney alone transplants, and showed the greatest increase in median years of benefit and LYFT compared to the other simulations. This solution addresses the problem by a projected increase in the number of transplants and reduction in discarded pancreata.

The Committee acknowledges the negative impact on blood type O candidates and kidney alone candidates projected in the simulation. Having kept the Kidney Committee and Minority Affairs Committee informed of the projected impacts, the Pancreas Committee is supportive of the proposed changes because of the benefits that outweigh the negative impacts by potentially increasing the number of transplants and creating the greatest increase in median years of benefit and LYFT compared to the other simulations.

## Which populations are impacted by this proposal?

The SRTR showed the analysis by age, race, blood type, cPRA, HLA mismatch, diagnosis and locality. The simulations also reported the average lifespan post-transplant, graft years of life, years of benefit from transplant versus staying on the waiting list, and life years from transplant (LYFT). The simulations showed minimal changes due to age or ethnicity, but did show a negative impact on blood type O candidates seeking transplant for Runs 2 through 5. For the simulation chosen by the Committee to broaden blood type allocation (Run 4), the reduced cohort showed blood type O candidates were reduced by 2% for kidney alone transplants (266) and 13% for kidney-pancreas transplants (25). All other blood types experience an increase in transplant under this simulation.

<sup>7</sup> Ibid

The proposed solution is projected to impact the number of kidney pancreas transplants and kidney alone transplants. Modeling projected a decrease of 105 fewer kidney alone transplants and an increase of 143 SPK transplants.

The KPSAM modeling showed the results for projected median years of benefit from transplant, and projected quality-adjusted median years of benefit from transplant (LYFT). In both metrics in the reduced cohort, Run 4 showed the greatest benefit from transplant. Median years of benefit from transplant illustrates the difference in the extra years of life due to a transplant, as compared to staying on the waiting list. Run 4 showed a projected median years of benefit from transplant of 249.2 and a LYFT of 240.3 for the reduced cohort.

## How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* Revising current blood type restrictions on kidney-pancreas allocation would increase the number of simultaneous pancreas-kidney transplants and increase the number of utilized pancreata.
2. *Improve equity in access to transplants:* Removing blood type restrictions for kidney-pancreas allocation would increase equity in access to candidates across blood types. The current restrictions prevent candidates with specific blood types from receiving offers from clinically compatible donors.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

## How will the OPTN implement this proposal?

This proposal will require a small instructional program to educate the community on the changes to policy and the system. Instructional Innovations will follow this project throughout its development to define the specific need of instruction. This proposal will require programming in UNet<sup>SM</sup>. The IT implementation will include changes to the match system and possible creation of a new blood type compatibility chart consistent with policy.

## How will members implement this proposal?

### Transplant Hospitals

Transplant programs must:

1. Obtain written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A1 or blood type AB, non-A1B pancreas or kidney-pancreas.
2. Establish a written policy regarding its program's titer threshold for transplanting a blood type A, non-A1 or blood type AB, non-A1B pancreas or kidney-pancreas into candidates with blood type B.  
If transplant programs have titer thresholds already established for A, non-A1 or blood type AB, non-A1B kidneys, the transplant program should consider whether to modify the written policy regarding the threshold to indicate that the policy applies also to kidney-pancreata and pancreata. If the transplant program establishes a separate titer threshold for kidney-pancreata or pancreata, the written policy must reflect that.
3. Confirm the candidate's eligibility every 90 days (+/- 20 days), as is currently required in kidney policy.

## Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection. However, programs that mark candidates as eligible for A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B kidneys will automatically be marked eligible for A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B kidney-pancreases and pancreases.

## How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. In addition to the monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

The proposed language will not change the routine allocation monitoring of OPTN members. UNOS allocations staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to policy requirements and will continue to investigate potential policy violations.

The following change to routine site surveys will occur, based on the proposed language:

### **Policy 11.4.D: Blood Type for Pancreas and Kidney-Pancreas Allocation**

At transplant hospitals, site surveyors will:

- Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:
  - Pancreas or kidney-pancreas transplant recipients with blood type B who received a pancreas or kidney-pancreas from a donor with blood type A, non-A<sub>1</sub> or blood type AB, non-A<sub>1</sub>B provided written informed consent to accept a pancreas or kidney-pancreas from a donor with these blood types

Verify that the transplant program has a written policy regarding its titer threshold for transplanting blood type A, non-A<sub>1</sub> and blood type AB, non-A<sub>1</sub>B pancreas and kidney-pancreas into candidates with blood type B

## How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

UNOS staff will determine if the proposal increased the total number of SPK transplants by blood type and present the results to the Committee. The Committee will also evaluate the effect of this policy on post-transplant survival and waitlist outcomes of SPK and KI candidates and recipients pre and post implementation. Median time to transplant will be an outcome of interest for both SPK and KI candidates by blood type for the Committee to review as well.

## Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

### 11.4 Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings

#### 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 must offer the kidney and pancreas according to classifications 1–510 in *Tables 11-4: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m<sup>2</sup> and 11-5: Allocation of Kidneys and Pancreas from Donors more than 50 Years Old or with a BMI greater than 30 kg/m<sup>2</sup>.*
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*.
  - b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas candidates, according to the remaining classifications in *Table 11-4* 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.D Blood Type for Pancreas and Kidney-Pancreas Allocation

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

11-3: Allocation of Pancreas and Kidney-Pancreas by Blood Type

<u>Pancreas and Kidney-Pancreas</u> from Deceased Donors with:	Are Allocated to Candidates with:
<b>Blood Type O</b>	Blood type O, <del>or blood type A, B, or AB if the candidate has a zero antigen mismatch with the deceased donor and a CPRA greater than or equal to 80 percent</del>
<b>Blood Type A</b>	Blood type A or AB
<b>Blood Type B</b>	Blood type B <u>or AB</u>
<b>Blood Type AB</b>	Blood type AB
<b><u>Blood Types A, non-A<sub>1</sub> and AB, non-A<sub>1</sub>B</u></b>	<p>Blood type B who meet <i>all</i> of the following criteria:</p> <ol style="list-style-type: none"> <li>1. <u>The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A<sub>1</sub> or blood type AB, non-A<sub>1</sub>B blood type pancreas and kidney-pancreas.</u></li> <li>2. <u>The transplant program establishes a written policy regarding its program's</u></li> </ol>

Pancreas and Kidney-Pancreas from Deceased Donors with:	Are Allocated to Candidates with:
	<p><u>titer threshold for transplanting blood type A, non-A<sub>1</sub> and blood type AB, non-A<sub>1</sub>B pancreas and kidney-pancreas into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).</u></p>

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

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<sup>2</sup> will be allocated to candidates according to *Table 11-4* based on waiting time.

**Table 11-4: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m<sup>2</sup>**

Classification	Candidates that are within the:	And are:
1	OPO's DSA	<p><del>Zero antigen mismatch</del><u>0-ABDR mismatch</u>, CPRA greater than or equal to 80%, <del>and either pancreas or kidney-pancreas candidates,</del> <u>and blood type identical to the donor</u></p>
2	OPO's DSA	<p>CPRA greater than or equal to 80%, <del>and either pancreas or kidney-pancreas candidates,</del> <u>and blood type identical to the donor</u></p>
3	OPO's region	<p><del>Zero antigen mismatch</del><u>0-ABDR mismatch</u>, CPRA greater than or equal to 80%, <del>and are either pancreas or kidney-pancreas candidates,</del> <u>and blood type identical to the donor</u></p>
4	Nation	<p><del>Zero antigen mismatch</del><u>0-ABDR mismatch</u>, CPRA greater than or equal to 80%, <del>and either pancreas or kidney-pancreas candidates,</del> <u>and blood type identical to the donor</u></p>
5	OPO's DSA	<p><del>Pancreas or kidney-pancreas candidates</del></p>
6	OPO's region	<p><del>CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates</del></p>
7	OPO's region	<p><del>Pancreas or kidney-pancreas candidates</del></p>
8	Nation	<p><del>CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates</del></p>
9	Nation	<p><del>Pancreas or kidney-pancreas candidates</del></p>
10	OPO's DSA	<p><del>Islet candidates</del></p>
11	OPO's Region	<p><del>Islet candidates</del></p>

Classification	Candidates that are within the:	And are:
<b><u>12</u></b>	<u>Nation</u>	<u>Islet candidates</u>
<b><u>5</u></b>	<u>OPO's DSA</u>	<u>0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor</u>
<b><u>6</u></b>	<u>OPO's DSA</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor</u>
<b><u>7</u></b>	<u>OPO's region</u>	<u>0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor</u>
<b><u>8</u></b>	<u>Nation</u>	<u>0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor</u>
<b><u>9</u></b>	<u>OPO's DSA</u>	<u>Pancreas or kidney-pancreas candidates and blood type identical to the donor</u>
<b><u>10</u></b>	<u>OPO's DSA</u>	<u>Pancreas or kidney-pancreas candidates and blood type compatible to the donor</u>
<b><u>11</u></b>	<u>OPO's region</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type identical to the donor</u>
<b><u>12</u></b>	<u>OPO's region</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor</u>
<b><u>13</u></b>	<u>OPO's region</u>	<u>Pancreas or kidney-pancreas candidates and blood type identical to the donor</u>
<b><u>14</u></b>	<u>OPO's region</u>	<u>Pancreas or kidney-pancreas candidates and blood type compatible to the donor</u>
<b><u>15</u></b>	<u>Nation</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type identical to the donor</u>
<b><u>16</u></b>	<u>Nation</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor</u>
<b><u>17</u></b>	<u>Nation</u>	<u>Pancreas or kidney-pancreas candidates and blood type identical to the donor</u>
<b><u>18</u></b>	<u>Nation</u>	<u>Pancreas or kidney-pancreas candidates and blood type compatible to the donor</u>
<b><u>19</u></b>	<u>OPO's DSA</u>	<u>Islet candidates</u>
<b><u>20</u></b>	<u>OPO's region</u>	<u>Islet candidates</u>

Classification	Candidates that are within the:	And are:
<u>21</u>	<u>Nation</u>	<u>Islet candidates</u>

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

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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<sup>2</sup> are allocated to candidates according to *Table 11-5* based on waiting time.

**Table 11-5: Allocation of Kidneys and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m<sup>2</sup>**

Classification	Candidates that are within the:	And are:
<b>1</b>	OPO's DSA	<del>Zero antigen mismatch</del> 0-ABDR mismatch, CPRA greater than or equal to 80%, <del>and either</del> pancreas or kidney-pancreas candidates, <u>and blood type identical to donor</u>
<b>2</b>	OPO's DSA	CPRA greater than or equal to 80%, <del>and either</del> pancreas or kidney-pancreas candidates, <u>and blood type identical to donor</u>
<b>3</b>	OPO's region	<del>Zero antigen mismatch</del> 0-ABDR mismatch, CPRA greater than or equal to 80%, <del>and either</del> pancreas or kidney-pancreas candidates, <u>and blood type identical to donor</u>
<b>4</b>	Nation	<del>Zero antigen mismatch</del> 0-ABDR mismatch, CPRA greater than or equal to 80%, <del>and either</del> pancreas or kidney-pancreas candidates, <u>and blood type identical to donor</u>
<b>5</b>	OPO's DSA	Pancreas or kidney-pancreas candidates
<b>6</b>	OPO's DSA	Islet candidates
<b>7</b>	OPO's region	Islet candidates
<b>8</b>	Nation	Islet candidates
<b>9</b>	OPO's region	<del>CPRA greater than or equal to 80% and either</del> pancreas or kidney-pancreas candidates
<b>10</b>	OPO's region	Pancreas or kidney-pancreas candidates
<b>11</b>	Nation	<del>CPRA greater than or equal to 80% and either</del> pancreas or kidney-pancreas candidates
<b>12</b>	Nation	Pancreas or kidney-pancreas candidates
<u><b>5</b></u>	<u>OPO's DSA</u>	<u>0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to donor</u>

<b>Classification</b>	<b>Candidates that are within the:</b>	<b>And are:</b>
<b><u>6</u></b>	<u>OPO's DSA</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to donor</u>
<b><u>7</u></b>	<u>OPO's region</u>	<u>0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to donor</u>
<b><u>8</u></b>	<u>Nation</u>	<u>0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to donor</u>
<b><u>9</u></b>	<u>OPO's DSA</u>	<u>Pancreas or kidney-pancreas candidates and blood type identical to donor</u>
<b><u>10</u></b>	<u>OPO's DSA</u>	<u>Pancreas or kidney-pancreas candidates and blood type compatible to donor</u>
<b><u>11</u></b>	<u>OPO's DSA</u>	<u>Islet candidates</u>
<b><u>12</u></b>	<u>OPO's region</u>	<u>Islet candidates</u>
<b><u>13</u></b>	<u>Nation</u>	<u>Islet candidates</u>
<b><u>14</u></b>	<u>OPO's region</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type identical to donor</u>
<b><u>15</u></b>	<u>OPO's region</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to donor</u>
<b><u>16</u></b>	<u>OPO's region</u>	<u>Pancreas or kidney-pancreas candidates and blood type identical to donor</u>
<b><u>17</u></b>	<u>OPO's region</u>	<u>Pancreas or kidney-pancreas candidates and blood type compatible to donor</u>
<b><u>18</u></b>	<u>Nation</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type identical to donor</u>
<b><u>19</u></b>	<u>Nation</u>	<u>CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to donor</u>
<b><u>20</u></b>	<u>Nation</u>	<u>Pancreas or kidney-pancreas candidates and blood type identical to donor</u>
<b><u>21</u></b>	<u>Nation</u>	<u>Pancreas or kidney-pancreas candidates and blood type compatible to donor</u>