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Briefing Paper

Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types

OPTN/UNOS Pancreas Organ Transplantation Committee

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Contents

Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types

Affected Policies:	*8.5.D (Allocation of Kidneys by Blood Type); 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^2); 11.4.G (Deceased Donors More than 50 Years Old or with a BMI Greater than 30 kg/m^2)*
Sponsoring Committee:	*Pancreas Organ Transplantation*
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Executive Summary

Over the last decade, pancreas transplants have declined significantly 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_1 and AB, non-A_1B 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 OPTN/UNOS Pancreas Transplantation Committee (the Committee) is pursuing an allocation change that maximizes the increase of K 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.

What problem will this proposal address?

Pancreas transplants have declined significantly and the majority of pancreata that are transplanted are done so as part of a simultaneous pancreas-kidney (SPK) transplant[1]. 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.[2]

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 from 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 small decrease for blood type O recipient access to kidney and pancreas transplants 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 OPTN/UNOS 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 OPTN 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-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 prioritized over ABO compatible candidates within each classification level. (R3)
- ABO identical candidates with high cPRA prioritized, followed by ABO compatible candidates with high cPRA, identical candidates with low cPRA, compatible candidates with low cPRA (R4)

[1] 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.

[2] Ibid.

- ABO-identical candidates prioritized above ABO-compatible candidates within 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 (see the next section, "How well does this proposal address the problem," for a summary of the KPSAM data and analysis). 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 briefed the Minority Affairs, Pediatric, Operations and Safety, OPO 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 cohort that the SRTR 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 waiting list 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 prioritized over ABO compatible candidates within each classification level. (R3)
- ABO identical candidates with high cPRA 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 within 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 and diagnosis. The simulations also reported the median 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-A1 and AB, non-A1B (in the table, A2 and A2B) to B compatibility.

Table 1: KPSAM Simulated Blood Type Compatibility3

	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

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 Transplants4

Results: Number of Transplants					
Reduced Cohort					
	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
Full Cohort					
	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.

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

[4] 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[5]

Transplants by blood type: KP					
Reduced Cohort					
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%)
Full Cohort					
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

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, 3, and 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 Type6

Transplants by blood type: KIA					
Reduced Cohort					
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%)
Full Cohort					
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.

[5] Ibid.

[6] 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[7]

Transplant Benefit Metrics by KPSAM run					
Projected median years of benefit from transplant					
	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
Projected quality-adjusted median years of benefit from transplant (LYFT)					
	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 projected negative impact on blood type O candidates and kidney alone candidates projected in the simulation. The Committee also reviewed potential impact on minority populations and found no negative impact, noting that blood type B candidates see increases in transplant rates for both KP and kidney alone populations. 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 projected 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.

Was this proposal changed in response to public comment?

This proposal went out for public comment during a 60-day period from July 31, 2017, to October 2, 2017. Overall, a majority of commenters supported the proposal, including a majority of regions, committees, and professional organizations. While six regions supported the proposal, five did not support it. The OPO Committee, Minority Affairs Committee, Operations & Safety Committee, Pediatric Committee supported the proposal while the Kidney Committee did not. Public comment concerns focused on the impact of the proposal on blood type O kidney alone candidates and pediatric kidney alone candidates. The themes from public comment included:

1. Impact on blood type O kidney alone

[7] Ibid

2. Impact on pediatric kidney alone
3. The proposal doesn't address the "real problem" with underutilization of pancreata
4. Not enough evidence to allow A, non-A1 and AB, non-A1B to B for KP and PA transplants
5. The Pancreas Committee should try a variance, or pilot program, first

The Committee carefully reviewed the feedback from public comment and considered each theme.

1. Impact on Blood Type O Kidney Alone Candidates

The Committee received nine public comments related to impact on blood type O kidney alone candidates. The Committee looked at the impact on blood type O candidates in its initial SRTR analysis and found a projected 2% decrease in kidney alone blood type O transplants. All other blood types for kidney alone, including blood type B, were projected to increase. In the public comment proposal, the Committee acknowledged this impact on blood type O candidates but expressed support for the proposed broadening of allocation because of its projected increase in the overall number of kidney transplants (including SPK and kidney alone), higher LYFT benefit, and more efficient use of pancreata.

In response to concerns expressed in public comment, the Committee asked the SRTR to do further analysis on blood type O kidney alone waiting time. SRTR cannot model kidney alone waiting time in the KPSAM, but offered to perform analysis by transplant rate, as transplant rate incorporates waiting time and could serve as an indicator regarding whether waiting times would be significantly impacted. The SRTR performed an analysis on the proposal's impact on transplant rate by blood type, and presented the results to the Committee. Figures 1 and 2 show the transplant rates by blood type for kidney alone and kidney-pancreas.

Figure 1: Kidney Alone Transplant Rates

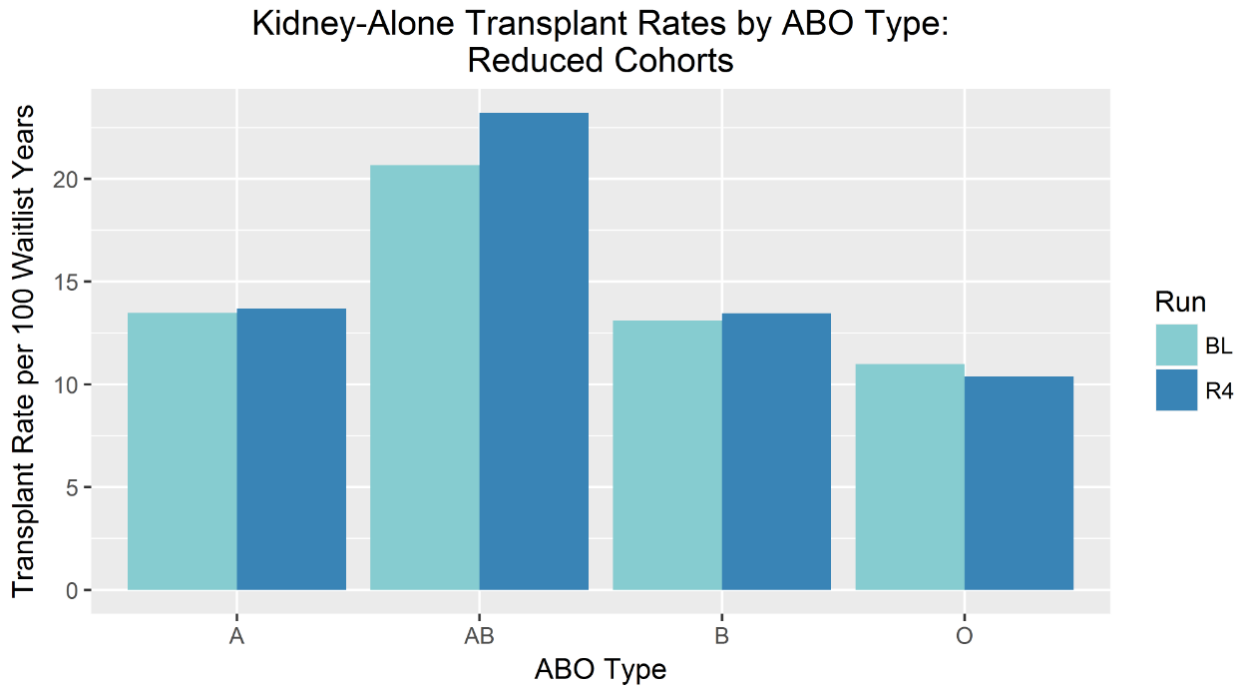
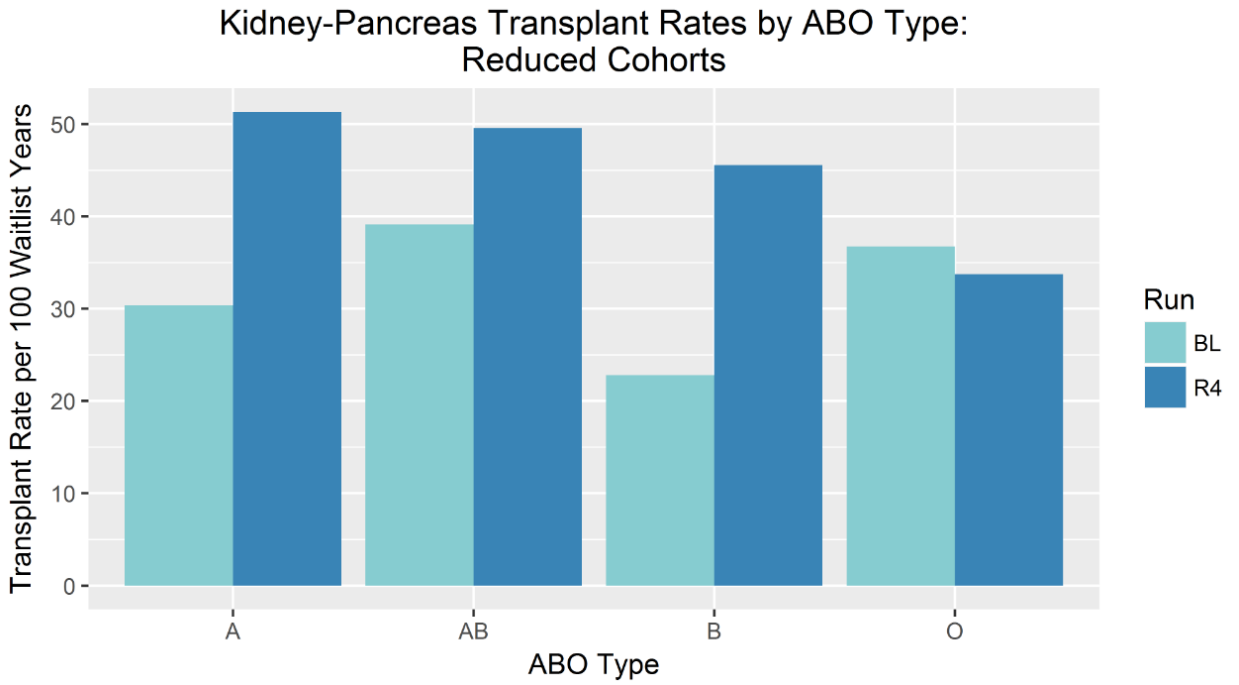


Figure 2: KP Transplant Rates



Rates were calculated within subgroup (i.e., within organ type and blood type) as the number of transplants divided by total candidate waiting time during 2010. Waiting time was censored at transplant or removal from the waiting list for any reason, including death. The rates were then multiplied by 100 to express the number of transplants performed per 100 years of wait time. Figures 1 and 2 show projected transplant rates for a reduced cohort, which more accurately reflects current pancreas transplant rates.

The SRTR analysis shows increases in blood types A, AB, and B and a small projected decrease in blood type O kidney alone and kidney-pancreas transplant rates. For blood type O kidney alone, the average transplant rate was 10.40 for the Run 4 reduced cohort and 10.98 for the baseline comparison. For blood type O kidney-pancreas, the transplant rate was 33.74 for the Run 4 reduced cohort and 36.74 for the baseline comparison. This is in line with the projected small decrease in blood type O transplants previously noted and discussed in the public comment document.

The projected transplant rates suggest that any increase in blood type O kidney alone waiting time is likely to be small.

Pediatric Kidney Alone

The SRTR modeling originally performed for the Committee found no impact on pediatric kidney alone candidates. However, public comment concern over whether there could be impact by region or DSA led the Committee to ask the SRTR to analyze the impact on pediatric kidney alone transplants by blood type and by regional variation (the SRTR cannot model by DSA).

Figure 3 shows analysis of the pediatric populations by region, indicating an increase across all regions for both the full and reduced cohort except for region 8. The SRTR analysis suggests that the proposed changes are not projected to have a negative impact on pediatric kidney alone patients.

Figure 3: Pediatric Kidney Alone Transplant Counts by Region

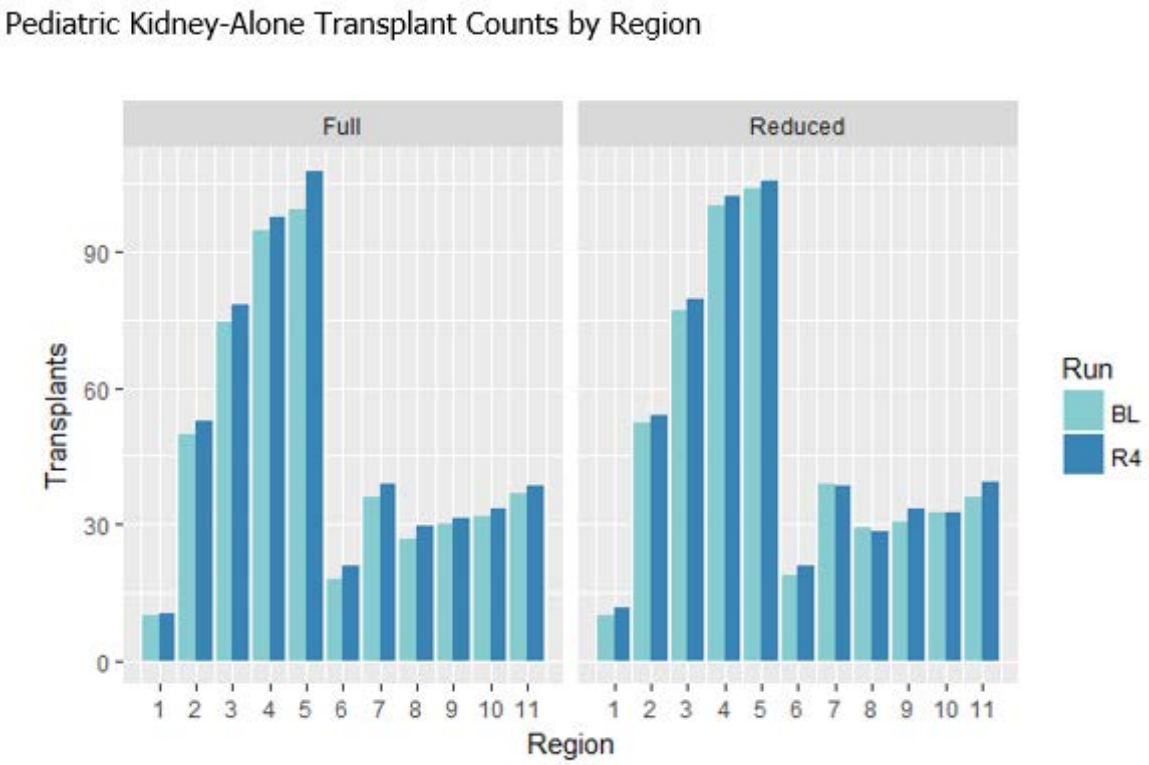
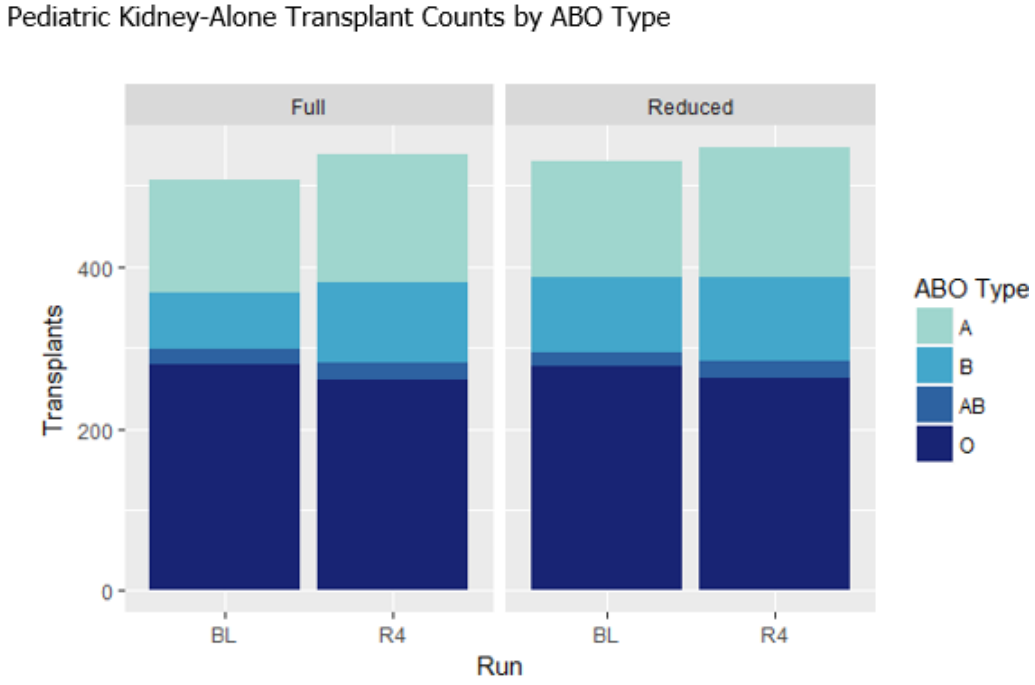


Figure 4 shows SRTR modeling of pediatric kidney impact by blood type for both the full and reduced cohorts. The SRTR analysis indicates that pediatric impact by blood type is similar to the general population: projected increases in blood types A, B and AB and a slight decrease in blood type O.

Figure 4: Pediatric Kidney Alone Transplant Counts by ABO Blood Type



1. Should Focus on Underutilization

One concern was that pancreata aren't being utilized within blood type now and the proposed solution does not adequately address the problem of underutilization. The Committee acknowledged that some pancreata aren't being optimally utilized currently because centers may deprioritize this type of transplant and are more selective with organ utilization. However, organs that are of suitable quality for transplantation could be accepted by higher volume centers, but are not currently offered if the organ is a non-identical blood type and the candidate isn't highly sensitized. If these organs were offered to candidates at these higher volume centers, Committee members suggested it might actually decrease overall waiting times because the higher volume centers account for a larger proportion of the overall transplant volume. It could also increase the access to transplantation for highly sensitized primary or retransplant candidates by allowing crossmatching to more donors.

2. Data

Several comments expressed concern that there is no data available on transplanting blood type A, non-A1 and AB, non-A1B kidney-pancreas or pancreas alone organs into B recipients. Commenters expressed concern that there may be different immunogenic factors and suggested may be too soon to change the policy to allow these types of transplants. The Committee acknowledges the issue related to lack of data for A1 and AB, non-A1B candidates. However, it is difficult to evaluate the potential for A, non-A1 and AB, non-A1B to B SPK or pancreas alone transplants unless policy allows them to happen. Preliminary single center data suggests that, similar to kidney alone transplants, A1 and AB, non-A1B to B SPK transplants can be successful.[8] The implementation plan in the proposal includes monitoring these outcomes to see how the compatibility is utilized and what issues are faced.

3. Variance

The other suggestion from public comment was for a pilot study or "variance" that would allow regions, DSAs or individual programs to opt in to pilot the proposed solution and its effects. The Committee expressed concern that the low number of pancreas transplants would make evaluating the results of a pilot program difficult, compared with variances or pilot programs for higher volume organs.

The Committee did not support a pilot program because of concerns about evaluating the variance: with pancreas being a low volume organ transplant, it would be difficult to evaluate the data from participating centers or regions.

Vote on Current Proposal

The Committee voted 15 yes, 1 no, and 0 abstentions to send the current proposal that went out for public comment to the Board without modification. The Committee considered the current proposal to be the most substantive change in terms of alignment with the strategic goal, increasing the number of transplants, and it showed the highest benefit from LYFT. Committee members expressed concerns with modifying the without further modeling to see whether the modifications still result in an overall increase in the number of KP transplants and transplants overall. The Committee also felt that post-public comment analysis clarified that overall pediatric kidney alone candidates are not projected to be negatively impacted, even when regional variation is taken into account.

Additional analysis by the SRTR regarding concerns about blood type O kidney alone candidates was in line with the estimates previously established in the public comment proposal: a small projected decrease in blood type O transplants, and a slight decrease in blood type O transplant rate, for both kidney alone and kidney-pancreas. The Committee felt this impact was warranted for the benefit ensuing from an increase in pancreas transplants and transplants overall, high LYFT benefit, and utilization of pancreata. Since a majority of public comments supported the proposal, and because additional analysis by the SRTR clarified the projected impact of the proposed changes on pediatric and blood type O candidates, the Committee felt the original proposal would be the best option going forward.

[8] Nelson, et al. "Increased Access to Transplantation for Blood Group B Cadaveric Waiting List Candidates by Using A2 Kidneys: Time for a New National System?" American Journal of Transplantation, 2: 94–99. doi:10.1034/j.1600-6143.2002.020115.x

Which populations are impacted by this proposal?

The SRTR showed the analysis by age, race, blood type, cPRA, HLA mismatch and diagnosis. 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 (n=266) and 13% for kidney-pancreas transplants (n=25). All other blood types experience an increase in transplant under this simulation and there was an overall net increase in SPK transplants.

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, i.e. a net overall increase in the total number of kidney 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 programming in UNetSM. The UNOS IT cost estimate is very large (750-1,659 hours). This is due in part to A, non-A1 and AB, non-A1B eligibility, because there are several places in WaitlistSM that need to modified. Any allocation changes require extensive testing in UNetSM, which also contributes to the IT estimate. This proposal will require a small instructional program to educate the community on the changes to policy and the system.

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-A_1 or blood type AB, non-A_1B pancreas or kidney-pancreas.
2. Establish a written policy regarding its program's titer threshold for transplanting a blood type A, non-A_1 or blood type AB, non-A_1B pancreas or kidney-pancreas into candidates with blood type B. If transplant programs have titer thresholds already established for A, non-A_1 or blood type AB, non-A_1B kidneys, the transplant program should consider whether to modify the written policy regarding the threshold to indicate that the policy applies also to the kidney-pancreas and pancreas. If the transplant program establishes a separate titer threshold for the kidney-pancreas or pancreas, the written policy must reflect that.
3. Confirm the candidate's eligibility every 90 days (+/- 20 days), as is currently required in kidney policy.

The implementation effort for transplant hospitals is projected to be minimal and require some clinical and administrative time. It is unlikely to require additional hours among salaried staff. Staff will develop local protocol, consent procedures, and waitlist analysis to determine eligibility to implement the change in policy. Development of patient education may also be small cost to produce. Maintaining candidate eligibility, such as repeat titer testing, on the waitlist may include some additional staff time.

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 an A, non-A_1 and AB, non-A_1B kidney will automatically be marked eligible for an A, non-A_1 and AB, non-A_1B kidney-pancreas and pancreas.

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_1 or blood type AB, non-A_1B 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_1 and blood type AB, non-A_1B 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 at 12 month intervals. 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~~).

RESOLVED, that changes to Policies 8.5.D (Allocation of Kidneys by Blood Type), 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/m2), and 11.4.G (Deceased Donors More than 50 Years Old or with a BMI Greater than 30 kg/m2), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

8.5.D Allocation of Kidneys by Blood Type

Transplants are restricted by blood type in certain circumstances. Kidneys will be allocated to candidates according to the blood type matching requirements in *Table 8-4* below:

Table 8-4: Allocation of Kidneys by Blood Type

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O. For offers made to candidates in 0-ABDR mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.
Blood Type A	Blood type A or blood type AB.
Blood Type B	Blood type B. For offers made to candidates in 0-ABDR mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
Blood Type AB	Blood type AB.
Blood Types A, non-A_1 and AB, non-A_1B	Kidneys may be transplanted into candidates with blood type B who meet *all* of the following criteria: 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A_1 or blood type AB, non-A_1B blood type kidney. 2. The transplant program ~~establishes~~ develops and complies with a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 and blood type AB, non-A_1B kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

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–~~5~~10 in *Tables 11-4: 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 *11-5: 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*.
    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

Pancreas and 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 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 or AB
Blood Type AB	Blood type AB

Pancreas and Kidney-Pancreas from Deceased Donors with:	Are Allocated to Candidates with:
Blood Types A, non-A_1 and AB, non-A_1B	Blood type B who meet *all* of the following criteria: 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a blood type A, non-A_1 or blood type AB, non-A_1B pancreas and kidney-pancreas. 2. The transplant program develops and complies with a written policy regarding its program's titer threshold for transplanting blood type A, non-A_1 and blood type AB, non-A_1B pancreas and kidney-pancreas into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

11.4.F Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m2

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* 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^2

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Zero antigen mismatch0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates, and blood type identical to the donor
2	OPO's DSA	CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates, and blood type identical to the donor
3	OPO's region	Zero antigen mismatch0-ABDR mismatch, CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates, and blood type identical to the donor
4	Nation	Zero antigen mismatch0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates, and blood type identical to the donor
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

Classification	Candidates that are within the:	And are:
~~**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~~
5	OPO's DSA	0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor
6	OPO's DSA	CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor
7	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor
8	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor
9	OPO's DSA	Pancreas or kidney-pancreas candidates and blood type identical to the donor
10	OPO's DSA	Pancreas or kidney-pancreas candidates and blood type compatible to the donor
11	OPO's region	CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type identical to the donor
12	OPO's region	CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor
13	OPO's region	Pancreas or kidney-pancreas candidates and blood type identical to the donor
14	OPO's region	Pancreas or kidney-pancreas candidates and blood type compatible to the donor
15	Nation	CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type identical to the donor

Classification	Candidates that are within the:	And are:
16	Nation	CPRA greater than or equal to 80%, pancreas or kidney-pancreas candidates, and blood type compatible to the donor
17	Nation	Pancreas or kidney-pancreas candidates and blood type identical to the donor
18	Nation	Pancreas or kidney-pancreas candidates and blood type compatible to the donor
19	OPO's DSA	Islet candidates
20	OPO's region	Islet candidates
21	Nation	Islet candidates

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* 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^2

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Zero antigen mismatch0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates, and blood type identical to donor
2	OPO's DSA	CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates, and blood type identical to donor
3	OPO's region	Zero antigen mismatch0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates, and blood type identical to donor
4	Nation	Zero antigen mismatch0-ABDR mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates, and blood type identical to donor
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

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

52

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