Broadened Allocation of Pancreas Transplants across Compatible ABO Blood Types

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Abstract:

Background: Current Organ Procurement and Transplantation Network (OPTN) policy restricts certain blood type compatible SPK transplants. Using the Kidney Pancreas Simulated Allocation Model (KPSAM), we examined the effects of five alternative allocation sequences that allowed all clinically compatible ABO transplants

Method: The study cohort included kidney (KI), simultaneous pancreas and kidney (SPK), and pancreas alone (PA) candidates waiting for transplant for at least one day between January 1, 2010 and December 31, 2010 (full cohort), and kidneys and pancreata recovered for transplant during the same period. Additionally, because the waiting list has shrunk since 2010, the study population was reduced by random sampling to match the volume of the 2015 waiting list (reduced cohort).

Results: Compared to the current allocation sequence, R4 and R5 both showed an increase in SPK transplants, a nearly corresponding decrease in KI transplants, and virtually no change in PA transplants. Life years from transplant and median years of benefit also increased. The distribution of transplants by blood type changed, with more ABO:A, B, and AB transplants performed, and fewer ABO:O across all transplant types (KI, SPK, PA), with the relative percent changes largest for SPK.

Discussion: Broadened ABO compatibility allowances primarily benefitted SPK ABO:A and AB candidates. ABO:O candidates saw potentially reduced access to transplant. The simulation results suggest that modifying the current allocation sequence to incorporate broadened ABO compatibility can result in an increase in annual SPK transplants.

Simultaneous kidney and pancreas transplantation (SPK) is the treatment of choice for select candidates with type 1 diabetes and with end stage diabetic nephropathy. However, despite improving outcomes and the high prevalence of Type 1 diabetes, the number of pancreas transplants performed in the United States continues to decline[1, 2]. The majority of pancreas transplants in the US are performed as SPK transplants and particularly from local donors.

The ABO blood group is the most important of all the blood group systems. There are four different ABO blood groups (Table1), determined by whether or not an individual's cells carry the A antigen, the B antigen, both A and B antigens (AB) or neither (O). Normal healthy individuals, from early in childhood, make antibodies against A or B antigens that are not expressed on their own cells. Organ recipients may receive organs from donors with the same or compatible blood types, meaning to which they do not make antibodies. Additionally, there are potentially compatible combinations that involve the donor blood type A2 and instances where incompatible transplants are acceptable[3-9]. However, there is limited data on the outcomes of pancreas transplants using non identical ABO donors[10]. Current Organ Procurement and Transplantation Network (OPTN) policy restricts certain blood type compatible SPK transplants from occurring (Table 2). Specifically, blood type O donors are only shared with compatible non-identical donors in situations where the recipient is highly sensitized (cPRA≥80) and has a 0-ABDR HLA mismatch. Similarly, blood group B donor organs are exclusively shared with ABO identical recipients. Note that these policies exclusively apply to SPK allocation, with broader sharing allowed across all compatible ABO groups for isolated pancreas transplants such as PAK and PTA. Since currently the vast majority of pancreas transplants performed in the United States are SPKs, the restricted ABO allocation for SPK transplants fails to capitalize on the benefits of broader sharing for the majority of pancreas transplants. The broader sharing combinations allowed for PAK and PTA transplants were intended to mirror kidney allocation,

where there is a significant gap between the high number of candidates waiting and the limited number of kidneys and policy was designed to maximally utilize kidneys. For pancreas transplantation, however, where volumes are decreasing, it is unfortunate when there are situations where a pancreas allograft could be transplanted but is discarded because suitable recipients within the allowable ABO combinations are exhausted, yet other suitable ABO compatible recipients remain on the list. Broader use of blood group compatible but non identical pancreas allografts may encourage local use of organs, which is currently the best opportunity to place a pancreas allograft, and may lead to greater utilization of this scarce and underutilized resource.

In order to determine the impact of broader sharing across compatible blood types, we examined the effects of five alternative allocation sequences that allowed all clinically compatible ABO transplants using the Kidney Pancreas Simulated Allocation Model (KPSAM). The goal was to determine if broadened ABO compatibility would increase the number of annual SPK transplants.

Methods

Study Population

Scientific Registry of Transplant Recipients (SRTR) data were used for KPSAM modeling. The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the US, submitted by the members of OPTN. The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors. All transplant candidates on the kidney, simultaneous kidney-pancreas (SPK), and pancreas (PA) waiting lists from January 1, 2010, to

December 31, 2010, and any kidney or pancreas donors whose organs were offered for transplant during this period were included.

Additionally, because the SPK/PA waiting list is now notably smaller than in 2010, the study population was reduced by random sampling to match the volume of the 2015 period prevalent SPK/PA waiting list. Specifically, there were 3770 SPK candidates and 1663 PA candidates in 2010, and 3312 and 1373, respectively, in 2015. Therefore, the SPK candidate pool was reduced by 12% and the PA candidate pool by 17%. Because SPK and PA candidates are prioritized over kidney-alone (KI) candidates through the first five levels of the SPK/PA allocation system, and because deceased organ donation is roughly constant from year to year, not accounting for this reduction in candidate volume would overestimate the impact of broader ABO compatibility definitions, and kidney candidates would appear more disadvantaged by the change in allocation than they would be in reality. This will be referred to as the "reduced" cohort, and the entire study population as the "full" cohort.

Proposed Changes to ABO Compatibility

Under current policy, several restrictions apply to blood type compatibility of offered kidneys/pancreata. Simultaneous kidney-pancreas offers must meet certain restrictions with regard to blood type compatibility (Table 3). Specifically, offers must be ABO-identical, except in the case of A donors to AB candidates, and in the case of O candidates who are a 0-ABDR HLA mismatched with the donor organs and have a calculated panel-reactive antibody (cPRA) value of at least 80%. In contrast, pancreas-without-kidney offers can be made to any ABO-compatible (i.e., biologically compatible) candidate. Neither policy is in direct alignment with the policy for KI offers.

An alternate set of ABO compatibility requirements for both SPK and PA offers was proposed (Table 4). It is equivalent to the current policy guiding KI offers, with the exception of allowing ABO:O donor organs to go to ABO:O candidates in the absence of a 0-ABDR HLA mismatch.

Proposed Changes to Allocation Policy

We evaluated several variations on existing SPK and pancreas-without-kidney allocation policy (also called run 1 [R1], or baseline). Table 5 shows how these alternatives differ from existing policy. First, we allowed for all compatible blood type exchanges (run 2 [R2]). Next, we allowed ABO-identical candidates complete priority over ABO-compatible candidates (run 3 [R3]). Next, we allowed ABO-identical candidates some priority over ABO-compatible candidates, but only within high-cPRA (≥ 80%) designation and locality (run 4 [R4]). Then, we allowed ABO-identical candidates priority over ABO-compatible candidates within locality only (run 5 [R5]). Lastly, we gave ABO-identical candidates complete priority over ABO-compatible candidates (run 6 [R6]). Kidney-pancreas/pancreas allocation policy allows an organ procurement organization (OPO) to switch back and forth between the simultaneous SPK/PA waiting list and the KI waiting list, once all local offers have been made. For the purposes of kidney-pancreas simulated allocation model (KPSAM), we assumed that OPOs aim to maximize the number of organs placed by always prioritizing kidney-pancreas (KP)/PAs over KIs within a geographic division (local/regional/national), and with the exception of mandatory shares related to cPRA and 0-ABDR HLA mismatches. Therefore, OPOs were simulated to switch to KI allocation after local SPK/PA offers, allocate kidneys through the local level (and if a KI is accepted, the pancreas will be offered to pancreas candidates on the combined KP/PA list), then switch back to the KP/PA list for regional offers, switch back to the KI list for regional offers,

switch back to the KP/PA list for national offers, and finally, switch to the KI list for national offers. Islet candidates and offers are not simulated in KPSAM.

Modeling Approach

The study conducted simulations using the KPSAM, a program routinely used by the OPTN committees to assess policy proposals. The KPSAM simulates the arrival of donated organs and new candidates on the waiting list over a 1-year period; checks compatibility of organs with candidates on the waiting list at the time an organ becomes available; creates ordered lists of compatible candidates (candidates with more points have priority for receiving the organ over candidates with fewer points in each ordered list); simulates candidate acceptance or refusal of organ offers using a logistic regression model based on organ acceptance behavior in 2010; calculates numbers of transplants performed and organs discarded; and uses linear approximations to Cox proportional hazard models to project outcomes such as median allograft and patient survival for each transplant. Allograft failure was defined as need for dialysis or retransplant. The KPSAM repeated this process 10 times each for the current (1) and proposed (5) allocation policies, each time randomly permuting the order of donor arrivals and generating new random numbers to determine organ offer acceptance. Each of the six proposed allocation sequences was run using both the full and the reduced cohorts. Since the same donors and candidates are used in each of the simulations, and they are the actual donors and candidates from calendar year 2010 and not independent samples, statistical tests of comparisons are not possible. Instead, the average and the minimum-maximum range of results for the 10 iterations are described for the current and the new allocation policies. Of note, this range reflects variability of the simulation modeling, not variability in actual organ allocations.

Limitations of KPSAM

KPSAM currently models organ acceptance based on acceptance patterns from 2010 organ offers. Acceptance patterns are related to the allocation rules under which the organ was allocated. Since 2010, major changes have occurred to the allocation systems for both the kidney-alone list and the combined KP/PA list. KPSAM does not change acceptance patterns when a new set of allocation rules is modeled, but in reality a change in allocation rules would likely lead to a change in acceptance patterns. For example, groups with a relative gain in priority under new rules would likely become more selective, and groups with a relative loss in priority would likely become less selective.

All input files use 2010 candidate and donor data; since 2010, the kidney-alone list has grown, and the combined KP/PA list has shrunk. Additionally, recovery of kidneys for transplant has increased.

KPSAM provides results from only 1 year of organ allocation/waitlist dynamics. Effects of some changes to organ allocation policy may be spread over several years, and would not be fully identified by KPSAM output. Results should be viewed with these limitations in mind.

Results

In general, R2 was the most generous in that ABO-identical exchanges were not prioritized over ABO-compatible exchanges at any level of allocation; R6 was the most conservative, as ABO-identical offers received absolute priority (i.e., through the national level) over ABO-compatible offers. Here, we focus on results from R4, R5, and R6, with R1 shown for comparison.

Simulations R4 and R5 predicted an increase in SPK transplants, a near equivalency in PA transplants, and a decline in KI transplants, while R6 predicted a small decrease in SPK transplants and consequent increases in PA and KI transplants (Table 6). Some discrepancy

occurred between the actual (observed in 2015) and simulated "baseline" (R1) results, which may be explained by changes in acceptance practices since 2010 (the KPSAM acceptance module was built using acceptance data from 2010) and a slightly higher deceased donor supply in 2015 than in 2010. Waitlist mortality rates were nearly constant across runs (data not shown).

All simulations predicted a net increase in the metrics previously used by the OPTN Kidney Committee to evaluate policy changes (Table 7), specifically: "median years of benefit from transplant," which is calculated per transplant recipient as the difference between estimated survival after transplant minus estimated survival on the waiting list, and "quality-adjusted life years from transplant (QA-LYFT)," which is the same concept but with years without a functioning graft (i.e., on the waiting list or on dialysis) weighted less (0.8) than years with a functioning graft (1.0). The increase in both metrics is due to a shift to more KP transplants, which have on average a higher QA-LYFT than KI transplants. The full cohorts predicted more total transplants than the reduced cohorts, which is why the total QA-LYFT per run is higher. These metrics can be calculated only for kidney and kidney-pancreas recipients.

As expected, the distribution of transplant recipients by blood type changed substantially under the alternate allocation systems R4 and R5. For SPK transplants, numbers of ABO:A and ABO:B recipients increased by approximately 100 and 50, respectively. ABO:O transplants declined by 15 to 25, while ABO:AB transplants were roughly stable. As percentages, ABO:A transplants increased in prevalence by 6% to 8%, and ABO:B by 4% to 7%; ABO:O transplants decreased by 12% to 13%. Changes by blood type under R6 were minimal, within 10 in either direction, except for ABO:B under the R6 reduced cohort, which declined by 24. Although the total number of PA transplants did not vary by more than 20 across runs, a shift occurred toward

more ABO:A (+7 to +13) and ABO:B (+3 to +4) transplants, and fewer ABO:O transplants (-1 to -19).

KI transplants changed in a similar manner, with ABO:A transplants increasing by 26 (R6) and 54 (R5), and ABO:O transplants declining by 90 (R6) and 278 (R5). ABO:B and ABO:AB transplants both increased, from 28 (R5) to 48 (R4), and 60-66, respectively. As percentages, ABO:A transplants increased in prevalence by 0.1% to 0.9% and ABO:B by 0.2% to 0.6%; ABO:O transplants decreased by 1% to 2%.

The distribution of recipients changed minimally by race and age. Importantly, the increase in SPK transplants occurred approximately equally across race groups, with a slight relative increase for white recipients and a slight relative decrease for black and Hispanic recipients. The largest change was a decrease of 1% in the prevalence of Hispanic recipients and an increase of 1.7% in the prevalence of white recipients in the R5 full cohort. Likewise, the decrease in KI transplants was spread equitably across races, with the largest change at -0.3% in white recipients in the R4 reduced cohort. There was no consistent pattern of change for PA transplants by race; the largest change was +2.5% in the prevalence of white recipients in the R4 reduced cohort.

For SPK transplants, the benefit of more transplants occurred across all ages younger than 65 years, but inconsistently; the largest change was +2.2% among recipients aged 18-34 years in the R4 full cohort. There was a trend toward more KI transplants at the tails of the distribution, i.e., ages younger than 18 years and 50 years or older; however, all changes for KI transplants were less than 0.5% in magnitude. The distribution of PA transplants changed slightly, with relatively more transplants in candidates aged 35-49 years (+0.1% to +2.7%) and relatively fewer in candidates aged 18-34 years (-0.5% to -2.4%).

There were no consistent or sizeable changes by primary diagnosis, 0-ABDR HLA mismatches, or cPRA (data not shown). Of interest, transplants did not decrease for cPRA 98+ KI candidates. The relative frequency of local PA and SPK transplants increased under R4/R5 by 5% to 10% and 2% to 3%, respectively. The pattern was mixed under R6, with a decrease of between 0.7% and 2% for local PA, and inconsistent change for local SPK. The decline in KI transplants was primarily for shared transplants (-0.3% to -0.6%), with local transplants slightly more common.

Discussion

The observed decline in pancreas transplantation in the US is associated with a high discard rate of usable pancreata and fewer candidates receiving a life changing transplant. Any barrier to pancreas transplantation must, therefore, be reviewed and, if an unnecessary obstacle, removed. The results of the KPSAM simulations show that allowing ABO compatible blood type allocation increases the total number of transplants, increases median years of benefit from transplant, shows no significant impact on candidates based on race or age, and would be a step towards a more efficient allocation system by making the schema the same for SPK and PA transplants.

In examining how alternative allocation sequences allowing clinically compatible ABO transplants increased the number of annual SPK transplants, R4 and R5 appear superior to the other simulations in attaining these goals with greater increases in SPK and median years of benefit. Between the two, R4 and R5 are similar in impact on SPK, KI and PA transplants but R4 shows a smaller reduction in KI transplants and thus a larger net increase overall. Similarly, R4 showed a greater impact on QA-LYFT than R5, indicating that R4 seems the optimal simulation

to enact in policy for an efficient allocation system. Interestingly, R4 is in the middle in restricting priority of ABO-identical blood types over ABO-compatible blood types.

Broadened ABO compatibility allowances primarily benefitted SPK ABO:A and AB candidates, since they could receive offers from all donors (with the exception of ABO:B donors for ABO:A candidates). ABO:O candidates saw reduced access to transplant, as they now compete with all other candidates for their only compatible organs. Assuming no changes in acceptance practices under a changed allocation system, no other aspects of kidney-alone transplants were meaningfully affected. The simulation results suggest that modifying the current allocation sequence to incorporate broadened ABO compatibility can result in an increase in annual SPK transplants.

It makes little sense to prohibit clinically compatible transplants from occurring when the number of pancreas transplants continues to decline. Any barrier to transplant must be highly justified or eliminated. In pursuit of this effort to reverse the decline of pancreas transplantation, the OPTN/UNOS Pancreas Transplantation Committee is submitting a proposal to enact the R4 simulation (prioritizing high-cPRA ABO-identical candidates, then high-cPRA compatible candidates, then all identical, then all compatible). The Committee has also pursued other avenues to increase utilization of pancreas transplantations by eliminating or modifying the body mass index (BMI) cap for KP wait time criteria, and providing guidance on pancreas after kidney (PAK) transplantation.

These concordant efforts to increase pancreas transplantation provide the dual benefits of preventing transplantable organs from discard and providing life changing transplantation for more candidates than would receive it otherwise. An effort to improve the kidney-pancreas

allocation system by allowing ABO blood type compatibility as modeled in R4, therefore, is an important step in the right direction.

Table 1

Blood Type	Antibodies in circulation	Compatible blood type
O	Anti-A, anti-B, anti AB	O
A	Anti-B	A, O
B	Anti-A	B, O
AB	None	AB, A, B, O

Table 2 Current OPTN allocation schema for SPK transplants (Adapted from Policy 11.4.D and Table 11-3 Allocation of Kidney-Pancreas by Blood Type)

Kidney-Pancreas from Deceased Donors with Blood Type:	Are Allocated to Candidates with Blood Type:
O	O
O	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
A	A or AB
B	B
AB	AB

Table 3. Blood type compatibility restrictions, SPK and PA transplants

	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	X	C
Donor: B	X	X	I	X for KP; C for PA
Donor: AB/A1B	X	X	X	I
Donor: A2B	X	X	X	I

*for SPK allowable only for 0-ABDR HLA mismatch, cPRA ≥ 80% for SPK; for PA, all allowable.

C, compatible; cPRA, calculated panel-reactive antibody; SPK, simultaneous kidney-pancreas; PA, pancreas without kidney.

Table 4. Alternate ABO compatibility requirements for SPK and PA offers

	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	X	I
Donor: A2B	X	X	C2	I

C, compatible; C2, compatible only if candidate meets A2 or A2B eligibility criteria (as for kidney); I, identical; PA, pancreas without kidney; SPK, simultaneous kidney-pancreas; X, incompatible, not allowed.

Table 5. Simulated alternate allocation sequences

Run 1/Run2	Run 3	Run 4	Run 5	Run 6
1. Local 0-ABDR, cPRA ≥ 80%	1, ABO-identical 1, ABO-compatible	1-4, ABO-identical	1-5, ABO-identical	1-5, ABO-identical
2. Local, cPRA ≥ 80%	2, ABO-identical 2, ABO-compatible	1-4, ABO-compatible	1-5, ABO-compatible	
3. Regional 0-ABDR, cPRA ≥ 80%	3, ABO-identical 3, ABO-compatible			
4. National 0-ABDR, cPRA ≥ 80%	4, ABO-identical 4, ABO-compatible			
5. Local	5, ABO-identical 5, ABO-compatible	5, ABO-identical 5, ABO-compatible		
OPO may begin offering the kidney to kidney-alone waiting list	*OPO may begin offering the kidney to kidney-alone waiting list*	*OPO may begin offering the kidney to kidney-alone waiting list*	*OPO may begin offering the kidney to kidney-alone waiting list*	*OPO may begin offering the kidney to kidney-alone waiting list*
6. Regional cPRA ≥ 80%	6, ABO-identical 6, ABO-compatible	6, ABO-identical 6, ABO-compatible	6-7, ABO-identical	6-9, ABO-identical
7. Regional	7, ABO-identical 7, ABO-compatible	7, ABO-identical 7, ABO-compatible	6-7, ABO-compatible	1-9, ABO-compatible
8. National cPRA ≥ 80%	8, ABO-identical 8, ABO-compatible	8, ABO-identical 8, ABO-compatible	8-9, ABO-identical	
9. National	9, ABO-identical 9, ABO-compatible	9, ABO-identical 9, ABO-compatible	8-9, ABO-compatible	
10. Islet (local, regional, national)	10	10	10	10

Note: Run 1is the current allocation sequence in policy.

cPRA, calculated panel-reactive antibodies; OPO, organ procurement organization.

Table 6. Number of transplants by KPSAM run

		Simulation Run				Difference		
	2015 Actual	R1	R4	R5	R6	R4-R1	R5-R1	R6-R1
Full cohort								
KI	11,469	10,766.0	10,639.4	10,640.5	10,774.9	-126.6	-125.5	8.9
PA	144	151.2	144.6	147.2	169.8	-6.6	-4.0	18.6
SPK	717	683.7	827.5	829.1	685.7	143.8	145.4	2.0
Total	12,330	11,600.9	11,611.5	11,616.8	11,630.4	10.6	15.9	29.5
Reduced cohort								
KI	11469	10771.9	10666.8	10635.5	10798.0	-105.1	-136.4	26.1
PA	144	112.9	113.7	118.8	126.2	0.8	5.9	13.3
SPK	717	652.0	795.3	793.9	635.6	143.3	141.9	-16.4
Total	12330	11536.8	11575.8	11548.2	11559.8	39.0	11.4	23.0

KI, kidney alone; KPSAM, kidney-pancreas simulated allocation model; PA, pancreas without kidney; SPK, simultaneous kidney-pancreas.

Table 7. Projected Benefit Metrics by KPSAM run

	Simulation Run				Difference		
	R1	R4	R5	R6	R4-R1	R5-R1	R6-R1
Median years of benefit*							
Reduced cohort	58,837	59,086	59,011	58,939	249	174	102
Full cohort	58,679	59,097	59,095	58,881	418	416	202
QA-LYFT†							
Reduced cohort	66,464	66,704	66,614	66,564	240	151	101
Full cohort	66,343	66,711	66,720	66,508	368	377	165

*Projected median years of benefit from transplant vs. waiting list.

†Projected quality-adjusted life years from transplant vs. waiting list.

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