



Removal of DSA from KP/Pancreas Allocation

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Abstract

Purpose of Review This review describes the Organ Procurement and Transplantation Network (OPTN) recently implemented policy to remove donation service area (DSA) and region from combined kidney and pancreas (KP) and pancreas (PA) allocation. It also highlights the OPTN 6-month post-implementation monitoring report data analysis findings and discusses the next steps in terms of continuous distribution.

Recent Findings Post-implementation data demonstrates an increase in transplantation rates and volumes for KP and PA post-policy implementation. Distance from donor hospital to transplant center increased for KP but decreased for PA, with minor increases in cold ischemia time for KP. Kidney transplant rates and volumes also increased.

Summary As predicted, the elimination of DSA has resulted in improvement in access and utilization of pancreata for transplant with increases in both KP and PA volumes without detriment to kidney alone volumes. Minimal increases in CIT and increased utilization are encouraging for pancreas transplantation overall and are seemingly positive indicators for a continuous distribution.

Keywords Kidney-pancreas · Pancreas · Fixed circle · Donation Service Area (DSA) · Organ Procurement and Transplantation Network (OPTN) · Pancreas allocation · Continuous distribution

Introduction

On March 15, 2021, the Organ Procurement and Transplantation Network (OPTN) enacted an agreed upon policy to remove Donor Service Area (DSA) and OPTN region from kidney and pancreas (KP), pancreas (PA), and kidney allocation which eliminates the artificial geographic barriers established by DSAs and OPTN regions. The modeling for this new allocation system also predicted there would be an improvement in access for KP transplant candidates and for key groups of KP candidates including highly sensitized, female, African American candidates and those with Medicare as their primary insurance [1, 2]. In an effort to monitor for both intended and unintended consequences of this allocation system, a 6-month post-implementation monitoring report was performed and released by UNOS in October

2021 [3]. The policy and the results of the monitoring report will be summarized and discussed in this review.

Rationale to Eliminate DSA and OPTN Region

In response to legal action, the OPTN enacted an emergency change to lung allocation on November 24, 2017, to eliminate the DSA and OPTN region which were a violation of the Final Rule that states that policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required.” The OPTN Board of Directors then carried out a directive to all organ-specific United Network of Organ Sharing (UNOS) Committees to eliminate DSA and OPTN regions from their organ allocation system with the goal to improve equity in access regardless of candidate residence or place of listing. This change would hopefully better uphold the OPTN Final Rule since the geographic location of candidates remains one of the largest disparities in access to transplant [1, 2, 4–9]. The legal action was taken in 2017 that affected lung allocation and the removal of DSA for that organ system accelerated the timeline and importance of the OPTN to enact changes to eliminate DSA and OPTN region for all organs. However, despite the urgency,

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significant thought went into developing the new pancreas allocation system, including idea-gathering, modeling, discussion, revision, public comment, and ultimately policy implementation, followed now by ongoing evaluation of the policy.

Expected Changes Based on Prior Modeling

Statistical Simulation Modeling

Although the OPTN Final Rule desires to decrease geographic barriers, geography can be considered to allow for efficient placement of organs, minimizing cold ischemic time and decreasing organ discard to maximize the optimization of outcomes and utilization. When evaluating potential changes to kidney-pancreas and pancreas organ allocation, the OPTN utilizes the SRTR (Scientific Registry of Transplant Recipients) Kidney-Pancreas Simulation Allocation Model (KPSAM). In 2019, the SRTR modeled changes in allocation system with removal of DSA and regions and replacement with 150, 250, or 500 nautical miles (NM) radii centered around the donor hospital, including varied proximity points within and outside of the designated circle size for KP, PA, and kidney [4]. The main findings of the simulation report demonstrated that the number of transplants varied by fewer than 200 cases across all runs and subpopulations, resulting in almost no change from baseline. This model also demonstrated that as the pancreas circle size increased, so did the kidney-pancreas transplant rate. This negatively impacted PA and kidney volumes, although the kidney volume was likely exaggerated by the model considering that more than 200 offers would lead to a kidney discard. Subpopulations of KP candidates such as the highly sensitized, female, African American candidates, and those on Medicare were expected to have increased access. The KPSAM results also demonstrated that proximity points lead to a decrease in travel within the designated circle but did not have any effect on national allocation [4, 10].

Critiques for the Elimination of DSA and OPTN Regions

Limitations certainly existed in the KPSAM modeling for the elimination of the DSA and OPTN region. As mentioned, concerns were raised regarding organ discard rate and efficient placement of organs. Although there is information on certain variables such as cold ischemia time, there is no logistics information readily available when driving vs. flying is utilized to transport an organ. For this reason, although pancreas transplant rates were increased at 500 NM, there was a desire to keep organs in driving distance

with the 250-NM radius in the first iteration. Additionally, concerns around kidney volumes and its subpopulations including pediatrics seemed most balanced in the 250 NM circle vs. 500 NM. The proximity points were set at 2 proximity points from the donor hospital decreasing linearly to 0 at 250 NM, with 4 proximity points restarting just outside of the 250 NM circle and going to 0 points at 2500 NM to maximize allocation efficiency.

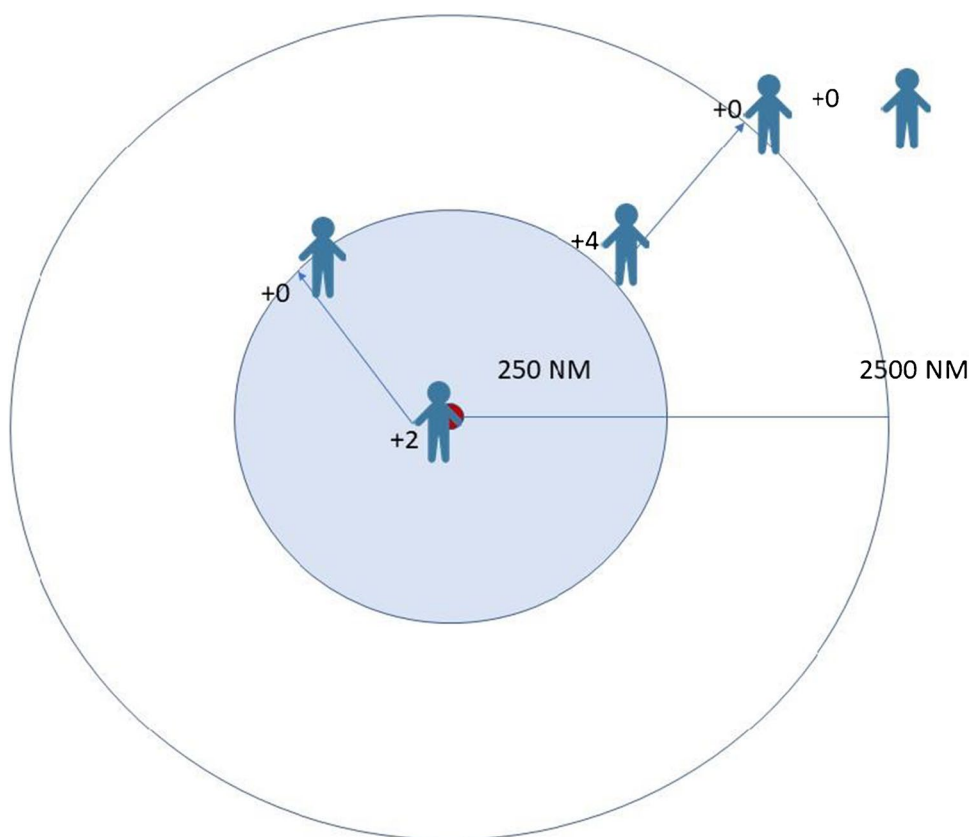
Another concern with fixed circles for allocation was raised by Goldberg et al. who propose implementing a standardized donation metric that would identify low-performing DSAs that could then benefit and improve performance so that there would not be a perceived movement of organs from the highest performing DSAs to the lowest [11]. Finally, the release of the new allocation system was occurring during the COVID-19 pandemic, and concerns were raised about making significant changes during this era. These concerns and others were raised in a critical comment addressed by the Secretary of Health and Human Services, Alex M. Azar II, who supported the immediate elimination of DSA and OPTN regions with the implementation of the policy on March 15, 2021.

Summary of Policy Changes

The KP and pancreas policy implemented on March 15, 2021, removed DSA and UNOS regions as the units for allocation for the KP and PA allocation. The first unit of allocation was replaced with a 250-NM fixed-distance circle, centered around the donor hospital. The policy is also modified by the addition of new points for a candidate's total allocation score which reflects the distance between the transplant hospital (where the candidate is listed) and the donor hospital. The points are allotted as follows: candidates located within the 250-NM circle receive a maximum of 2 points decreasing linearly to the border of the circle at which no additional points are given. Once all candidates within the initial circle are offered the organ, it will then be offered outside of this circle to all remaining candidates listed nationally. Proximity points start at 4 points at the 250-NM circle and decrease linearly to 2500 NM, after which no proximity points are assigned (Fig. 1) [2, 7, 12]. A special exception was made in the policy for the allocation of kidneys and pancreata recovered in Alaska since there are no transplant centers in Alaska: Seattle-Tacoma International Airport (SEA) would be the substitute for the donor hospital, meaning that the 250-NM circle will center around SEA as the "donor hospital" [7].

Although the focus of this review is KP and PA allocation, all work was done in close collaboration with the OPTN Kidney Transplant Committee since kidney alone allocation is intimately entangled with KP and PA allocation. Thus, kidney

Fig. 1 Fixed-circle allocation with proximity points ending at 2500 NM [2, 4, 7]. Within the circle if the donor hospital (red dot), the candidate gets 2 proximity points linearly to the edge at which points there is none. Once outside of the 250-NM circle, the candidate gets 4 proximity points linearly till the border at which no candidate gets additional proximity points



alone allocation was considered closely since the majority of pancreas recipients also receive a kidney as part of a KP transplant. An additional policy was approved in June 2020, addressing medically urgent kidney transplant candidates. This policy provided a new definition for medical urgency for kidney alone candidates and ensured that those candidates receive appropriate priority. Due to the new system, criteria for programs to qualify for facilitated pancreas allocation were also revised. The new facilitated pancreas allocation system allows transplant programs to qualify for facilitated pancreas offers if they have transplanted a minimum of two pancreata within two previous years that were recovered from deceased donors located at donor hospitals over 250 NM away from the transplant hospital. This includes pancreata transplanted as part of a multi-organ transplant. Facilitated pancreas offers are permitted by the OPO and OPTN contractor if no pancreas offers are accepted three hours prior to organ procurement. The offers must be made in the order of the match run. The OPO may only switch to facilitated pancreas allocation once all KP and PA offer within the 250 NM of the donor hospital have been declined [13].

There were also modifications to the reallocation of kidney, KP, PA, and pancreas islets when an organ allocated is unable to be transplanted in the intended recipient. This includes the use of a 250-NM reallocation circle around the hospital where the intended transplant was to occur. In regard to the allocation

of released kidneys and pancreata, the donor hospital's OPO has the option to continue allocation using the original match run or to contact the OPTN for assistance. If they split the organs, they must allocate the kidney following the released kidney policy but the pancreas may be allocated to a potential recipient at the accepting hospital. For released kidneys, the OPO may run a new match utilizing the 250 NM around the intended recipient hospital. Also, for the pancreas, the OPO may allocate the organ to a potential recipient at the current accepting transplant center. For released KP, the OPO may decide to keep the organs together or separate them. If they remain together, they may continue the original match or allocate it to a potential kidney-pancreas transplant recipient at the accepting center. If they decide to split the kidney-pancreas, the host OPO may allocate the kidney according to the released kidney policy and then may allocate the pancreas to a potential transplant recipient at the accepting center. In either of these situations, the host OPO has the option to contact the OPTN for assistance [14].

Post-implementation Monitoring

Following the implementation of the elimination of the use of DSA and region for KP, PA, and kidney allocation, a 3-month and a 6-month post-implementation monitoring

report most recently was released which was an analysis based on OPTN data as of October 15, 2021. The policy eras were defined as pre-policy (December 01, 2020, to March 14, 2021) and post-policy (March 15, 2021, to June 30, 2021). The OPTN plans to evaluate again at 1 year and 2 years post-implementation. The report evaluates the waiting list, transplant rates, and volumes, as well as other factors including subpopulations characteristics related to HLA, race/ethnicity, and gender as well as CIT and discard rates.

Kidney-Pancreas (KP) and Pancreas (PA)

Waiting List

The waiting list volume for both KP and PA changed minimally following the policy implementation. However, the proportion of candidates listed in “active” status increased slightly after policy implementation for the pancreas alone. While the overall volume on the waitlist was stable, the registrations added to that waitlist slightly increased for KP post-implementation, but slightly decreased for PA. Overall the KP transplant rate increased from 102 to 119 transplants per 100 patient-years and the PA transplant rate increased from 64 to 74 transplants per 100 patient-years after policy implementation, which aligns with KPSAM modeling predictions. For KP registrations, there was an increase in rates of registration for ages 35–49 years, Hispanic race/ethnicity (from 13.3 to 17.7%), with little change in the distribution of CPRA in listing after policy implementation, approximately 68% of adults having CPRA 0%. For PA registration, there was an increase in registration rates for ages 0–17 and 18–34, Asian and Hispanic race/ethnicity, and those with CPRA 0% and 20–79%.

The overall KP transplantation rate increased from 102.5 to 119.4 transplants per 100 patient-years, with the directionality as predicted by the KPSAM. The rates for 18–34 years, 35–49 and 50–64 years age groups had increased transplant rates from 109.7 to 112.5, 91.5 to 110.1, and 108.9 to 143.7 transplants per 100 patient-years respectively. The rates of transplantation increased for all minority races/ethnicities, specifically Asian (84.8 to 161.9), Black (103.9 to 112.3), and Hispanic candidates (116.4 to 144.9) for transplants per 100 patient-years. The overall transplantation rate for PA transplants also increased from 63.5 to 73.7 transplants per 100 patient-years.

Transplants

Prior to policy implementation, there were a total of 227 KP and 23 PA transplants performed. Despite a slightly shorter post-policy implementation timeframe, both increased to

281 KP and 50 PA after policy implementation, with average weekly KP transplants increasing to 15 KP transplants/week from 18 KP transplants/week and 4 PA transplants/week from 3 PA transplants/week pre-policy. For KP, the transplant volume was increased for the age groups 18–34, 35–49, and 50–64, and was decreased for the 65+ age group. For PA the proportion of transplants post-policy increased from 35 to 49 and 65+ age groups (Table 1). For KP, the proportion of transplants in Hispanics and Asian recipients increased from 15.4 to 17.4% and 4.0 to 6.4% respectively. Simultaneously, there was a relative decrease in White and Black recipients, but in the setting of an overall increase in transplantation. Comparably, PA transplants saw an increase in the proportion of Black recipients (13.5 to 16.0%) and decrease in Hispanic recipients (16.2 to 14.0%). The median time on the waiting list for KP and PA slightly decreased from 0.44 to 0.35 years and PA slightly increased from 0.40 to 0.79 years, suggesting that those that have been on the waiting listing longer are getting transplanted.

With the implementation of the 250-NM circle, the median distance from donor hospital to transplant center increased from 72 to 98 NM for KP and decreased from 199 to 146.5 NM for PA. Also corresponding with the KPSAM analysis for both KP and PA, more transplants occurred at centers outside the recovering organ procurement organization (OPO)’s DSA. The proportion of transplants using organs recovered in the same DSA as the transplant hospital decreased for KP (67.8 to 41.99%) and for PA (43.2 to 30.0%). The proportion of national sharing increased for KP (16.3 to 29.5%) and for PA (37.8 to 46.0%) as well. For KP, there was a notable increase in transplants in regions 4, 5, and 7, and a decrease in regions 6, 10, and 11. For PA, the majority of regions saw an increase in transplants. Of the 27 DSAs with at least one pancreas transplant during the cohort, 16 DSAs saw an increase in transplantation following implementation, and 8 DSAs saw a decrease. Of the 95 transplant centers with at least one kidney-pancreas transplant during the cohort, 47 saw an increase and 35 saw a decrease in pancreas transplants post-policy implementation. Of the 35 states that have kidney-pancreas transplant programs, 16 saw an increase and 15 saw a decrease in the number of transplants.

Utilization

Following the implementation of the new policy, the number of PA donors increased from 365 to 434 with a decrease in discard rate from 26.6 to 23.27%. This was accompanied by an increase in the acceptance rate for organs recovered outside the same DSA as the potential transplant recipient from 23 to 34 per 1000 offers with a decrease in acceptance rate for organs recovered from the same DSA from 282 to 173 per 1000 offers after policy implementation (Table 1) [3].

Table 1 Pre- and post-policy implementation outcomes [3]

	Kidney		Kidney-pancreas		Pancreas	
	Pre-policy	Post-policy	Pre-policy	Post-policy	Pre-policy	Post-policy
Transplants	4926	3402	227	281	37	50
Age						
0–17	144 (2.92%)	212 (3.51%)	0	0	8 (21.62%)	5 (10.00%)
18–34	491 (9.97%)	654 (10.85%)	54 (23.79%)	61 (21.71%)	11 (29.73%)	8 (16.00%)
35–49	1181 (23.97%)	1422 (23.60%)	114 (50.22%)	142 (50.53%)	7 (18.92%)	25 (50.00%)
50–64	1927 (24.02%)	2423 (40.22%)	56 (24.67%)	77 (27.40%)	10 (27.03%)	10 (20.00%)
65+	1183 (24.02%)	1314 (21.81%)	3 (1.32%)	1 (0.36%)	1 (2.70%)	2 (4.00%)
Ethnicity						
White	1886 (38.29%)	2108 (34.99%)	107 (47.14%)	124 (44.13%)	25 (67.57%)	34 (68.00%)
Black	1649 (33.48%)	2075 (34.44%)	72 (31.72%)	85 (30.25%)	5 (13.51%)	8 (16.00%)
Hispanic	926 (18.80%)	1266 (21.01%)	35 (15.42%)	49 (17.44%)	6 (16.22%)	7 (14.00%)
Asia	341 (6.92%)	434 (7.20%)	9 (3.96%)	18 (6.41%)	1 (2.70%)	1 (2.00%)
Other	124 (2.52%)	142 (2.36%)	4 (1.76%)	5 (1.78%)	0	0
CPRA %						
0	2993 (60.76%)	3447 (57.21%)	153 (67.40%)	188 (66.90%)	28 (75.68%)	36 (72.00%)
1–19	438 (8.89%)	469 (7.78%)	24 (10.57%)	32 (11.39%)	4 (10.81%)	3 (6.00%)
20–79	851 (17.28%)	950 (15.77%)	39 (17.18%)	45 (16.01%)	2 (5.41%)	4 (10.00%)
80–97	307 (6.23%)	701 (11.63%)	9 (3.96%)	14 (4.98%)	2 (5.41%)	4 (8.00%)
98–100	337 (6.84%)	458 (7.60%)	2 (0.88%)	2 (0.71%)	1 (2.70%)	2 (4.00%)
CIT (median, hours)	17.32	19.64	8.97	10.26	*Not included in PA outcomes data	
Discard rate	24.25%	21.91%	*Not included in KP outcomes data		26.58%	23.27%
Distance to donor hospital						
0–250 NM	3938 (79.94%)	5136 (85.24%)	186 (81.94%)	241 (85.77%)	21 (56.76%)	30 (60.00%)
> 250 NM	988 (20.06%)	889 (14.76%)	41 (18.06%)	40 (14.23%)	16 (43.24%)	20 (40.00%)
Median distance traveled (NM)	70	125	72	98	199	146.5

Kidney

As mentioned, since KP allocation is integral to kidney allocation, it is important to consider the impact on the kidney alone. The number of transplants from deceased kidney donors also increased (from 4926 to 6025) after policy implementation (Table 1). There was an overall increase in kidney transplant volume across all age groups and for all ethnicities with the largest increase in Black recipients. There was a decrease in the number of kidney transplants for CPRA values 0% and 20–79% with little change in the distribution of KDPI or EPTS at transplant after policy implementation. As predicted by the KPSAM, the median distance from the donor hospital to the transplant center increased from 70 to 125 NM with an increase in the proportion of transplants occurring within 250 NM of the donor hospital, from 80 to 85%. The median cold ischemia time for kidneys increased from 17.3 to 19.3 h after the implementation of the new policy. With an increase in the number of deceased kidney donors, the overall discard rate decreased from 24

to 22%, with the largest decrease observed for high KDPI kidneys.

Next steps, Continuous Distribution

The initial post-implementation data show increased transplant rates for all organs KP, PA, and kidney which is due in part to overall increases in total transplant volume during the post-policy period. Additionally, broader sharing of KP is occurring without significant increases in CIT and with overall increases in pancreata procured and decreases in the discard. Another positive aspect is that with broader sharing, the highly sensitized KP candidates (80–98%) are seeing an increase in transplant rates. None of the kidney transplant populations, including pediatrics, was adversely affected by either the new allocation or by increases in KP and PA transplant volumes post-implementation. Although this data analysis aimed to minimize the effect of the COVID-19 pandemic by selecting only the 3 months prior to the

allocation date of March 15, 2021, and 6 months after, more widespread access to vaccination and increasing numbers of fully vaccinated candidates for KP and PA may have led to increased pancreas transplants numbers. Furthermore, this could be a delayed compensation for periods of relative inactivity during the third peak of the COVID-19 pandemic in January and February of 2021. Future post-implementation reports evaluating longer timeframes will be helpful to better understand long-term effects and if any early bolus effects are occurring.

The OPTN is continuously working to improve the equitable allocation of deceased donor organs and desires to remove hard boundaries, such as geography, that exist within a classification-based system. This has led to a proposal for a more flexible system that can be applied to all organ donation systems and has been termed continuous distribution. In the most recent allocation system, candidates are awarded points for different reasons at various points in a fixed sequence. In addition, candidates are then awarded a certain number of points based on the distance of their transplant center to the donor hospital. If their transplant center does not lie within that “hard” boundary of the 250-NM circle, candidates are no longer prioritized in the match run. Continuous distribution aims to change the system of rank-ordered classification to consider all candidates at once while continuing to be consistent with the OPTN Final Rule. Within continuous distribution, all candidates would be ranked by an overall score that is based on an assessment of multiple attributes with the intention to weigh all factors together: medical urgency, post-transplant survival, candidate biology, patient access, and placement efficiency. It will be important to be mindful of the effects of the 250-NM fixed circle with 2:4 proximity points in the upcoming months and years. Furthermore, as the OPTN is moving toward a continuous distribution system, it will be important for everyone in the pancreas transplant community to understand and engage in upcoming changes. Active engagement and involvement will be particularly crucial as there may be changes to multi-organ transplant priority, including KP. Removal of the 250-NM circle may affect pancreas transplant candidates and transplant volumes [15].

Conclusions

The goal for the removal of DSAs and implementation of 250-NM fixed-circle allocation policy was to eliminate the artificial geographic boundaries and in so doing improve access for key groups of transplant candidates. Preliminary data from 6 months post-implementation demonstrate that there has been an overall increase in transplantation and for various subpopulations of KP, PA, and kidney which is in alignment with the KPSAM modeling used to inform

the policy. The OPTN Pancreas Committee will continue to monitor the policy and evaluate the changes in registration, donation, and allocation. Implementation of this policy appears to improve equity and access for pancreas transplantation across the country.

Declarations

Conflict of Interest The authors declare no competing interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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