

Briefing to the OPTN Board of Directors on
**Eliminate the Use of DSA and Region in
Pancreas Allocation Policy**

OPTN Pancreas Transplantation Committee

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Eliminate the Use of DSA and Region in Pancreas Allocation Policy

<i>Affected Policies:</i>	<p>1.2: Definitions</p> <p>11.4.A: Kidney-Pancreas Allocation Order</p> <p>11.4.B: Pancreas Allocation When a Kidney is Unavailable</p> <p>11.4.C: Organ Offer Limits</p> <p>11.4.D: Blood Type for Kidney-Pancreas Allocation</p> <p>11.4.E: Sorting Within Each Classification</p> <p>11.4.F: Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m²</p> <p>11.4.G: Deceased Donors More than 50 Years Old or with a BMI Greater than 30 kg/m²</p> <p>11.5: Reallocation of Unsuitable Islets</p> <p>11.6.A: Transplant Program Qualifications</p> <p>11.6.B: Facilitated Pancreas Offers</p>
<i>Sponsoring Committee:</i>	OPTN Pancreas Transplantation Committee
<i>Public Comment Period:</i>	August 2, 2019 – October 2, 2019
<i>Board of Director's Date:</i>	December 3, 2019

Executive Summary

The Final Rule sets requirements for allocation policies developed by the Organ Procurement and Transplantation Network (OPTN), including the use of sound medical judgement, achieving the best use of organs, preserving the ability for transplant programs to decide whether to accept an organ offer, avoiding wasting organs, avoiding futile transplants, promoting patient access to transplantation and promoting efficient management of organ placement.¹ The Final Rule also includes a requirement that allocation policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by the other requirements.²

OPTN Policy 11: Allocation of Pancreas, Kidney-Pancreas and Islets currently uses donation service area (DSA) and region as geographic units of distribution. DSAs and regions are poor units of distribution between donors and transplant candidates due to variation in size and shape, resulting in an inconsistent application for all candidates. As a result, the use of DSAs and regions in pancreas distribution presents a conflict with the Final Rule.

The OPTN Pancreas Transplantation Committee (hereafter, “Committee”) proposes removing DSA within pancreas allocation policy in favor of a single fixed distance circle of 250 nautical miles (NM) around the donor hospital. Region as currently defined would be removed as a unit of distribution. The 250 NM circle would include proximity points that provide candidates inside the fixed circle a maximum of two points and provide candidates outside of the fixed circle a maximum of four points based on their distance from the donor hospital. These points would be added to a candidate’s total allocation score

¹ 42 C.F.R. § 121.8(a).

² 42 C.F.R. § 121.8(a)(8).

based on the proximity of the candidate's hospital of listing to the donor hospital. Also included in this policy proposal are changes regarding facilitated placement of pancreata that require amendment due to the removal of DSA from allocation policy. The goal of these changes is to make pancreas allocation policy more consistent with the Final Rule while increasing the opportunity for pancreas utilization with broader distribution and preserving increased equity in access for certain vulnerable populations.

The Committee remains committed to the advancement of allocation policies towards the OPTN Board of Directors' vision of continuous distribution. Members see the following proposal as forward progress and innovation towards that goal while achieving the overall purpose of removing DSA and region from allocation policies in alignment with the Final Rule.

Purpose of Proposal

The OPTN is required to develop policies for the equitable distribution of cadaveric organs in potential transplant recipients. This proposal address the problem that “the use of DSAs and Regions in...organ allocation policies has not and cannot be justified under the OPTN Final Rule.”³ This proposal seeks to remove DSA and region from pancreas allocation policy and allocate using geographic units that are consistently applied and that remove inconsistent artificial barriers that can exist within a very short distance between donors and recipients, in accordance with Final Rule requirements that organ allocation not be based on a candidate’s residence or place of listing except to the extent required by other regulatory requirements.⁴

Utilization of pancreata is a significant problem in the pancreas community.⁵ In 2017, 23.6% of pancreata were discarded overall, and the rate of discard varied from 0% to 54.5% depending on DSA.⁶ The Committee considers that broader distribution could spur programs to be more aggressive in their acceptance practices of viable pancreata and increase pancreas utilization, due to the fact that more programs will have access to offers in their area.⁷ As an added benefit, the proposal is projected to increase access to transplant for certain vulnerable populations including minority candidates, candidates on Medicare and highly sensitized candidates.

The proposal serves as a transitional step from current policy towards the direction of continuous distribution.

Background

DSAs and Regions Not Optimized as Geographic Units of Allocation

DSAs and regional boundaries were not optimized as geographic units for the purposes of organ allocation. The DSA is the geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one Organ Procurement Organization (OPO), one or more transplant programs, and one or more donor hospitals (defined in OPTN *Policy 1.2: Definitions* as “The hospital where the deceased or living donor is admitted”). DSA borders were drawn to define the boundaries in which an OPO is obligated to recover organs, not for equitable organ distribution purposes.

Allocation circles were developed based on the sound medical judgement of the Committee, and validated in modeling for intended and unintended consequences.⁸ Furthermore, circles were deemed compliant with the Final Rule by the Ad Hoc Geography Committee.⁹

³ Letter from HRSA Administrator to Yolanda Becker, MD, President of the OPTN. November 21, 2017.

⁴ 42 C.F.R. § 121.8(a)(8).

⁵ 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.

⁶ Urban, Read. UNOS Research, 2017 OPTN data.

⁷ Pancreas Committee, Meeting Summary June 25, 2019, available at: <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

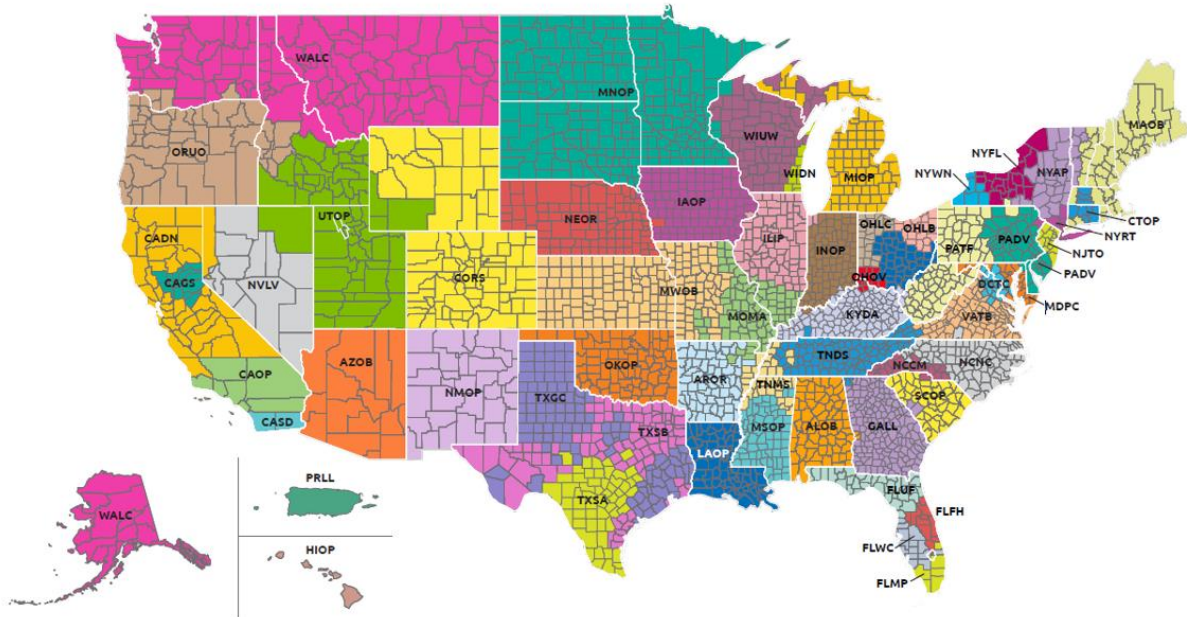
⁸ Meeting Summary for October 21, 2019 meeting, OPTN Kidney Transplantation Committee.

⁹ Geographic Organ Distribution Principles and Models Recommendations Report, OPTN Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed October 31, 2019).

Regions are administrative boundaries used to facilitate OPTN governance activities. Each region is a collection of DSAs in which there were historical relationships between the OPOs and transplant hospitals. Regions vary in size and shape. These regions are used for multiple purposes (collecting public comment, Board and committee representation, etc.) but were not designed to optimize organ distribution.¹⁰ **Figure 1** and **Figure 2**¹¹ below illustrate the current geographic layout of DSAs and OPTN regions across the country.

Figure 1: Geographic Layout of DSAs across the United States

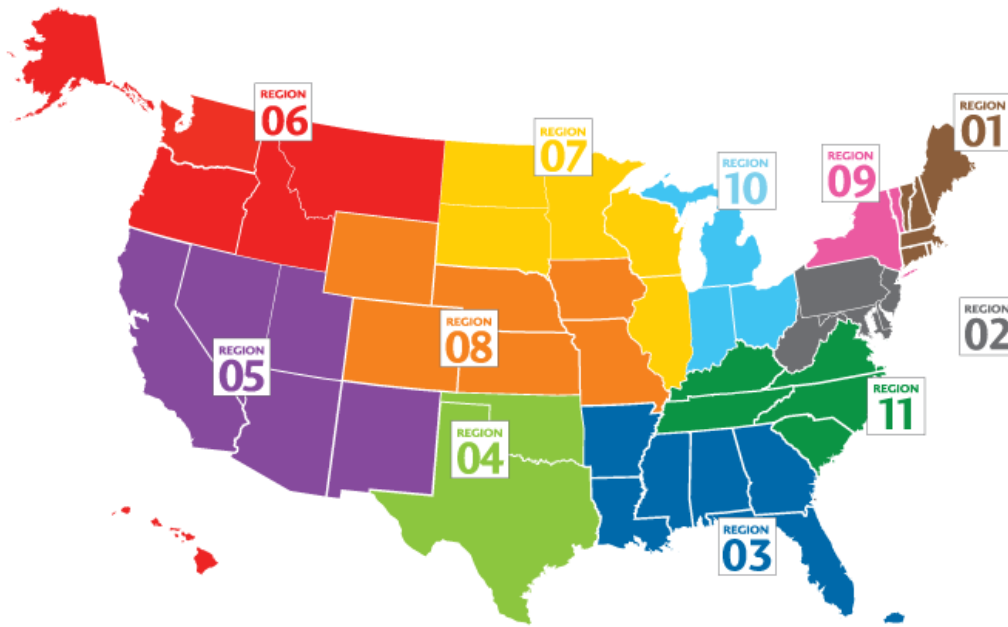
Donation Service Areas



¹⁰ OPTN Bylaws Article IX: Regions. https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Article_09 (accessed July 9, 2019).

¹¹ "Regions." Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/members/regions/>. (accessed July 3, 2019).

Figure 2: Map of OPTN Regions across the United States



The Final Rule sets requirements for allocation policies developed by the OPTN, including: sound medical judgement, best use of organs, preserving the ability for transplant programs to decide whether to accept an organ offer, avoiding wasting organs, promoting patient access to transplant, avoiding futile transplants, and promoting efficiency.¹² The Final Rule also stipulates that allocation policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by the other requirements of Section 121.8 of the Final Rule.¹³ Finally, the Final Rule includes a performance goal for allocation policies of “distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency.”¹⁴

The requirement to distribute over a broad geographic area reflects professional consensus that organs are a national resource meant to be allocated based on patients’ medical need. In, 1984, the Task Force on Organ Transplantation was formed within the U.S. Department of Health and Human Services to “conduct a comprehensive assessment of organ donation and procurement.”¹⁵ The final report of the Task Force stated that:

“The principle that donated cadaveric organs are a national resource implies that, in principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where

¹² 42 C.F.R. §121.8(a)(1)-(5).

¹³ 42 C.F.R. §121.8(a)(8).

¹⁴ 42 C.F.R. §121.8(b)(3).

¹⁵ U.S. Dept. of Health & Human Services, Public Health Service, Health Resources and Services Administration, Office of Organ Transplantation, “Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Transplantation.” Rockville, MD., p. 91, 1987

the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography.”¹⁶

The Institute of Medicine made this same conclusion in 1999.¹⁷ In 2012, the American Medical Association’s Code of Medical Ethics stated that, “[o]rgans should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.”¹⁸ Additionally, a national survey conducted by the U.S. Department of Health and Human Services in 2012 showed that 81.7% of respondents would prefer for their “organs to go to more medically urgent patients regardless of where they live in the U.S.”¹⁹ The Advisory Committee on Transplantation (ACOT) recommended, “that the Secretary take steps to ensure the OPTN develops evidence-based allocation policies which are not determined by arbitrary administrative boundaries such as OPO service areas, OPTN regions and state boundaries.”²⁰

The OPTN Board of Directors has also concluded that organs are a national resource, as evidenced by the Principles of Geography composed and affirmed by a Board vote in December 2017.²¹

Proposal for Board Consideration

The purpose of this proposal is to remove DSA and region from pancreas allocation, and replace them with units of distribution that will be applied consistently nationwide.

The proposal represents a removal of DSA and region from pancreas allocation policy in alignment with the Final Rule as well as a transitional step from current policy towards the goal of implementing a framework of continuous distribution.

The proposal the Committee is recommending for approval by the OPTN Board of Directors includes the following:

1. A single fixed-distance circle of 250 NM around the donor hospital.
2. Proximity points added to a candidate’s allocation score based on the distance between their center of listing and the donor hospital. Candidates listed inside of the circle can receive a maximum of two (2) proximity points. Candidates listed outside of the circle can receive a maximum of four (4) proximity points.
3. Program qualification for facilitated placement of transplanting two pancreata procured 250 NM or further from the program in the previous two years

¹⁶ U.S. Dept. of Health & Human Services, Public Health Service, Health Resources and Services Administration, Office of Organ Transplantation, “Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Transplantation.” Rockville, MD., p. 91, 1987, quoting Hunsicker, LG.

¹⁷ National Academies Press, “Organ Procurement and Transplantation.” (1999).

¹⁸ American Medical Association. “Opinion 2.16 – Organ Transplantation Guidelines.” *AMA Journal of Ethics* 14(3) (2012); 204-214, available at <https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-organ-transplantation/2012-03> (accessed December 26, 2018).

¹⁹ U.S. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, 2012 National Survey of Organ Donation Attitudes and Behaviors. Rockville, Maryland: U.S. Department of Health and Human Services, 2013.

²⁰ Advisory Committee on Organ Transplantation Recommendation 51, August 2010, available at <https://www.organdonor.gov/about-dot/acot/acotreccs51.html> (accessed July 9, 2019).

²¹ OPTN Board of Directors, Meeting Summary December 3-4, 2018, available at: https://optn.transplant.hrsa.gov/media/2787/board_executivesummary_201812.pdf (accessed October 31, 2019).

The proposal being submitted to the Board (also known as the 250.2.4 variation) was considered by the Committee prior to public comment and included in the public comment proposal in discussion of modeled variations and alternative solutions. The Committee proposed a 500 NM solution for public comment because it accomplished the objective of replacing DSA and region in pancreas allocation with a consistently applied distribution unit while broadening distribution and providing the opportunity to increase pancreas utilization by allowing more aggressive programs access at to organs farther away at the initial distribution level. However, public comment feedback reflected significant concerns with the 500 NM solution implications for pancreas utilization and Final Rule considerations of unnecessary organ loss, efficient management of organ placement, and best use of organs.

The Committee recognized that the proposal distributed for public comment may weigh the factor of distributing organs as far as feasible too heavily, perhaps at the expense of other required considerations such as achieving the best use of organs, avoiding unnecessary organ loss, and promoting efficient management of organ placement. The Committee agreed that increased travel and logistical complexity may have the effect of increasing ischemic time, which could negatively impact pancreas utilization with potential for increased organ loss or a negative impact on patient graft outcomes.²² Therefore the Committee modified the proposal from a 500 NM fixed-distance circle to a 250 NM fixed-distance circle to mitigate the concerns raised in public comment related to ischemic time impacting organ loss, patient outcomes, and pancreas utilization. The Committee supported fewer proximity points (up to two inside the circle; up to four outside) to better balance proximity and waiting time in pancreas allocation.

The public comment solution for facilitated placement would define facilitated placement qualifying criteria for pancreas programs as transplanting two pancreata procured from 500 NM or further from the transplant program in the previous two years; the Committee modified this solution post-public comment to define the criteria as transplanting two pancreata procured from 250 NM or further from the program in the previous two years. The change directly reflects public comment feedback that the facilitated placement criteria be more inclusive and accessible to pancreas programs looking to grow in volume and experience. The Committee agreed that a more inclusive definition would be more appropriate, also considering that current data to assess future facilitated placement program participation may overestimate the number of pancreas programs that qualify. The change reflects consistency with the modification from 500 NM to 250 NM in circle size around the donor hospital, and provides more inclusivity through less stringent qualifying criteria in response to public comment feedback.

1. Fixed-Distance Circle

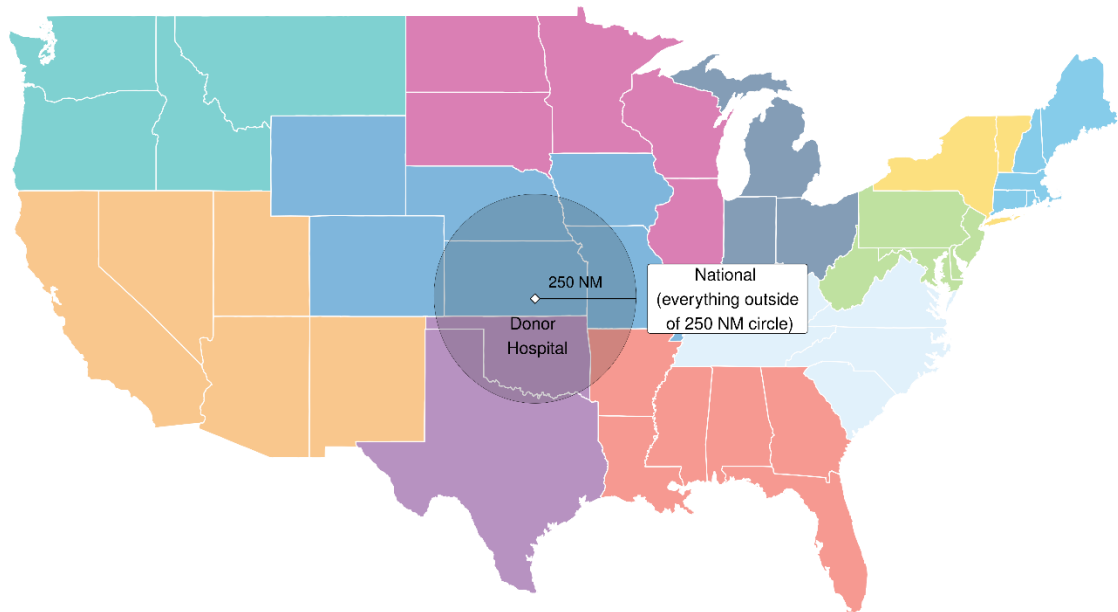
The hybrid framework utilizes a single fixed-distance circle to replace DSA in allocation policies. The circle is a fixed geographic unit based on the distance from the donor hospital to the candidate's place of listing and is consistently applied across the country.²³ The hybrid framework removes regional distribution, so any organs that move beyond the single fixed-distance circle would be considered "national" organ offers. This method²⁴ is illustrated in **Figure 3** below, utilizing a 250 NM circle:

²² Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

²³ *Frameworks for Organ Distribution*, OPTN Ad Hoc Geography Committee, December 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf

²⁴ *Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution*, OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, available at https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (accessed July 3, 2019).

Figure 3: Visualization of Single Fixed-Distance 250 NM Circle



2. Proximity Points

The hybrid framework adds proximity points to candidates' allocation scores based on the distance between the program where a candidate is registered and the donor hospital.²⁵ The intent of proximity points is to promote the efficient management of organ placement and avoid organ loss by reducing unnecessary transportation time, cold ischemic time, cost, and the potential for higher offer refusal rates. Proximity points are also intended to avoid sending a pancreas further away for a candidate with only slightly higher waiting time compared to a nearby candidate.²⁶

Candidates listed at centers closer to the donor hospital will receive more proximity points than those listed at centers further away. The current pancreas allocation system is still utilized to determine the order these candidates appear within each classification to receive organ offers on the match run. Therefore, total allocation points would include both proximity points and candidate waiting time. Based on the current pancreas allocation tables, one proximity point can be thought of as equivalent to one year of waiting time. Importantly, candidates in classifications at the top remain at the top, and cannot be surpassed by candidates below them on the match classifications even with the inclusion of proximity points. In other words, proximity points only affect rank-ordering of candidates within classifications; they cannot cause candidates in a lower classification to be prioritized over candidates in a higher

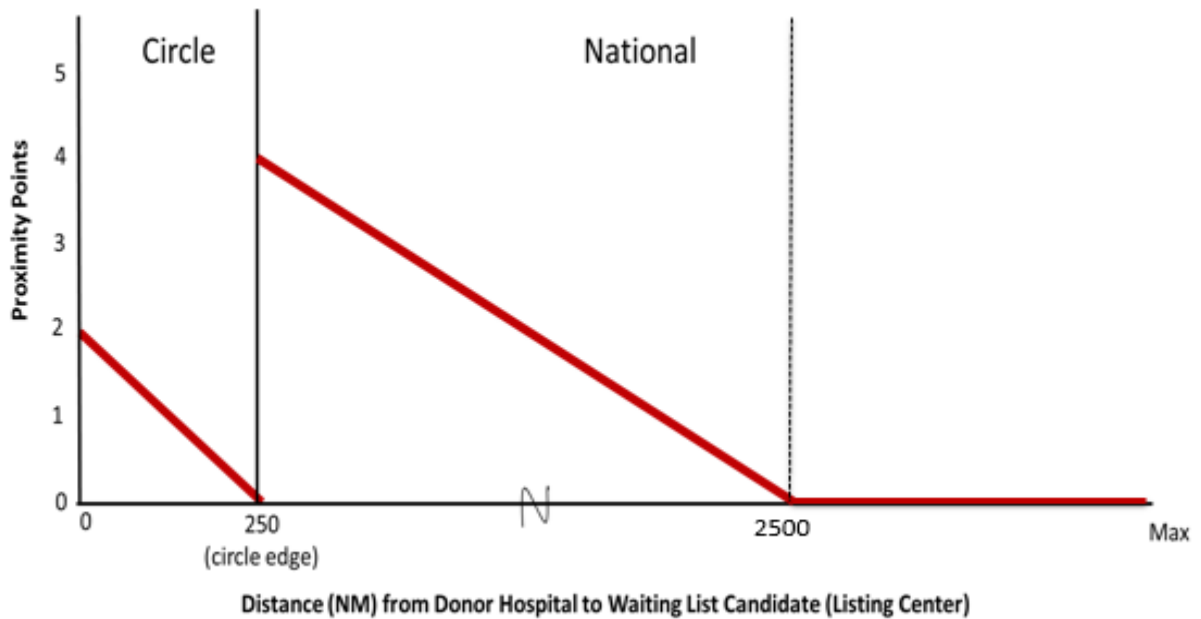
²⁵ *Frameworks for Organ Distribution*, OPTN Ad Hoc Geography Committee, December 2018, available at https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf

²⁶ *Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution*, OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee, January 2019, available at https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (accessed July 3, 2019).

classification. Pancreas allocation also accounts for candidate blood type and sensitization, as well as donor age and BMI.²⁷

Points are awarded in a linear fashion, so a candidate listed at the donor hospital at the center of the fixed-distance circle would receive the maximum number of points. If no candidate within the fixed-distance circle accepts the organ offer, allocation then moves outside of the fixed-distance circle. Points continue to be awarded linearly out to an endpoint of 2500 NM. Beyond 2500 NM, no proximity points are awarded. **Figure 4** illustrates the linear nature in which proximity points would be awarded first inside of the fixed-distance circle and then subsequently outside the fixed-distance circle according to the original solution.

Figure 4: Illustration of Proximity Points Allocation



The higher the maximum number of proximity points awarded, the more geography weighs when determining a candidate's position on a match run. Therefore, if the maximum number of points awarded is high, then points awarded for these candidate characteristics will have relatively less effect on candidate match run placement.

Regardless of the maximum number of proximity points utilized, a candidate cannot move from one classification to another on the match run. Therefore, candidates cannot cross the line representing the circle edge in **Figure 4** within pancreas allocation classifications. Proximity points simply “reorder” candidates against each other, in terms of identified characteristics as well as geography *within* their classification.

3. Facilitated Pancreas Allocation

Current facilitated placement in pancreas allocation policy allows OPOs and the UNOS Organ Center to offer organs to a list of pancreas programs that transplant a certain number of pancreata procured

²⁷ OPTN Policy 11.4: Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings (Accessed November 1, 2019).

outside the program's DSA (five pancreata in a two year period) when the OPO is within three hours of procurement and has already offered the organ to candidates in the OPO's DSA.²⁸ This aspect of pancreas allocation provides the opportunity for increased efficiency and potentially more utilization of pancreata by offering imported pancreata to those programs most likely to use them. The facilitated placement policy needs to be updated because the facilitated pancreas programs are defined using pancreata imported from outside of a program's DSA, which is no longer applicable with a circle based distribution system around donor hospitals. The policy also needs to be changed to indicate that the facilitated placement list is only used after exhausting offers to candidates within a certain NM distance instead of within the DSA.

Proposal Submitted for Public Comment

The original proposal submitted by the OPTN Pancreas Transplantation Committee for OPTN Public Comment contained four key components:

1. A single fixed-distance circle of 500 NM around the donor hospital.
2. Proximity points added to a candidate's allocation score based on the distance of their center of listing from the donor hospital. Points are assigned linearly both inside and outside of the circle. Candidates listed inside of the circle could receive a maximum of four (4) proximity points. Candidates listed outside of the circle could receive a maximum of eight (8) proximity points.
3. A modified facilitated placement policy changing the qualification for a facilitated placement program to transplanting two (2) pancreata recovered 500 NM or further from the pancreas program in the previous 2 years.
4. A new import backup policy to address instances when a pancreas or kidney-pancreas cannot be transplanted into its original intended recipient.

The allocation framework containing the single fixed distance circle at 500 NM and the addition of proximity points was referred to in the proposal as a "hybrid" framework, as it contained elements of two of the frameworks proposed to the OPTN Board of Directors by the Ad Hoc Geography Committee: a fixed-distance circle framework and the framework of continuous distribution.^{29,30} In this proposal, the public comment solution is also referred to the 500.4.8 variation.

Community Feedback and Committee Response

The Committee seriously considered a 250.2.4 variation as an alternative before the Committee ultimately supported a 500 NM for public comment. Given the strong support for 250 as an alternative to the 500 NM solution, the Committee included discussion of the 250 NM alternative in the public comment proposal to inform the public comment and solicit feedback. The 250.2.4 alternative was clearly listed as an option the public could consider, and public comment feedback indicated that a majority of commenters supported an alternative to the 500 NM solution because of concerns about the impact on ischemic time, organ loss and efficient placement. Of the alternatives listed in public comment feedback, the 250.2.4 solution received the most support.

²⁸ OPTN Policy 11.6: *Facilitated Pancreas Allocation* (Accessed July 9, 2019).

²⁹ *Eliminate the Use of DSA and Region in Pancreas Allocation Policy*, OPTN Pancreas Transplantation Committee, August 2019. https://optn.transplant.hrsa.gov/media/3108/pancreas_publiccomment_201908.pdf (Accessed November 1, 2019).

³⁰ *Frameworks for Organ Distribution*, OPTN Ad Hoc Geography Committee, July 2018.

https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf (Accessed November 1, 2019).

The OPTN Fall 2019 Public Comment period opened on August 2, 2019 and closed on October 2, 2019. During the span of those two months, Committee representatives presented the proposal at 11 OPTN Regional meetings and reported regional sentiment as well as comprehensive feedback to the Committee, which continued to meet in order to receive and consider feedback incrementally as the comment period progressed.

In addition, Committee leadership presented the proposal and sought feedback from 11 OPTN Committees. Sentiment from each of these key stakeholder committees as well as their area-specific feedback and expertise were reported back to the greater Committee for consideration as policy development progressed.

Furthermore, the Committee publicized, organized, and conducted 6 informational webinars during the OPTN Fall Public Comment Period. Some of these webinars were customized for the purposes of educating and receiving feedback from a diverse group of stakeholders, including webinars focused specifically on the patient community, program directors, and the media. Other webinars were open to the public, recorded for those who could not attend, and posted to the OPTN website. Each of these webinars provided the committee with insightful feedback for the committee's consideration.

Each of these mechanisms for educating the community and soliciting constructive feedback was essential to the committee's policy development process and informed their deliberation as they developed a final proposal for OPTN Board consideration. Specifically, the feedback received in public comment and evidence reviewed directly led to the Committee's modification of the proposed solution in circle size (from 500 NM to 250 NM) and proximity points (from four inside the circle/eight outside the circle to two inside the circle/four outside the circle). The community sentiment, key themes presented within the collective feedback, and the resulting proposal modification in compliance with the Final Rule are highlighted in the sections to follow.

Community Sentiment

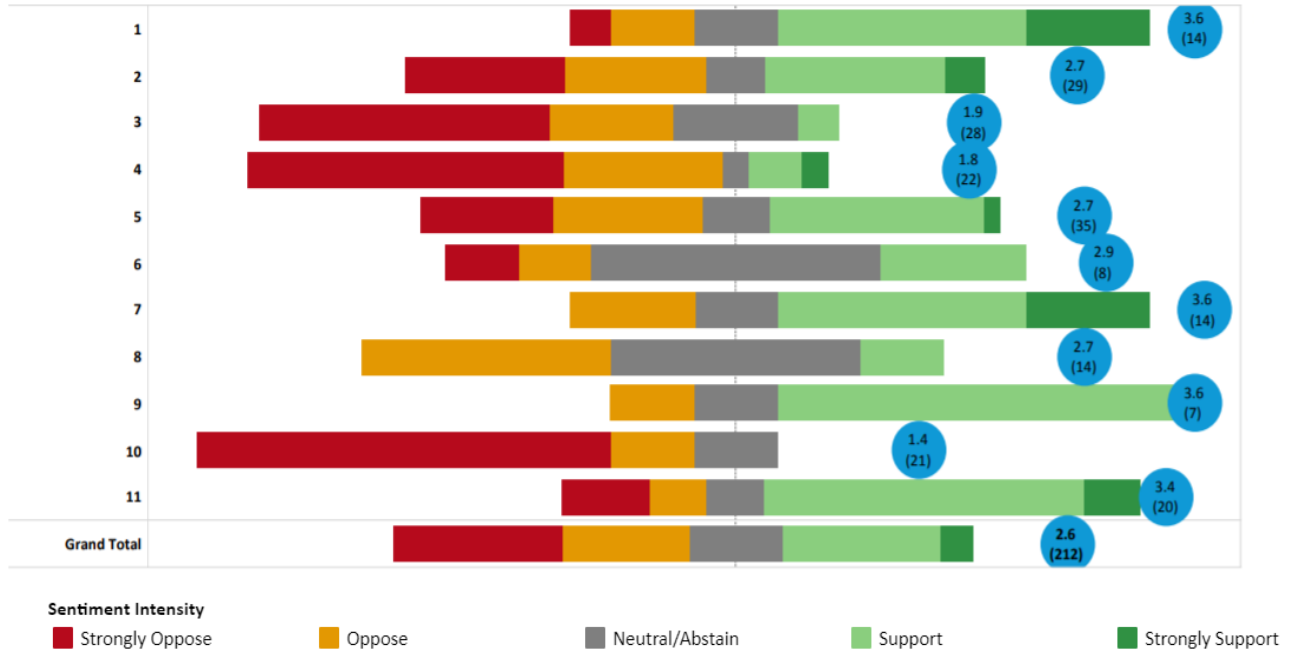
The proposal received mixed sentiment throughout the community, and feedback varied depending on region, member type, and stakeholder focus.

Sentiment Among OPTN Regions

A majority (6 of 11) regions did not support the proposal outright. At several OPTN Regional meetings, community members and stakeholders recognized the need to remove DSA and region from allocation policy, but disagreed with the Committee's proposed approach, and offered alternative measures (specifically, the 250 NM solution being proposed by the Committee to send to the Board).

Figure 5 illustrates the sentiment for the Committee's proposal received at the OPTN Fall 2019 Regional Meetings. Red indicates strong opposition, yellow indicates general opposition, gray represents neutral sentiment or abstentions, light green represents general support, and dark green represents strong support.

Figure 5: Regional Sentiment at OPTN Fall 2019 Regional Meetings



Two regions that did not support the kidney proposal did support the pancreas proposal: regions six and 11. Two of the six regions that opposed the proposal expressed a majority positive sentiment for the 250.2.4 variation.

Region 5 expressed negative sentiment for the proposal on the basis of proximity points alone, accepting that a 500 NM circle as the first unit of allocation would be appropriate, but disagreeing with the principle of awarding candidates priority for proximity to the donor hospital.

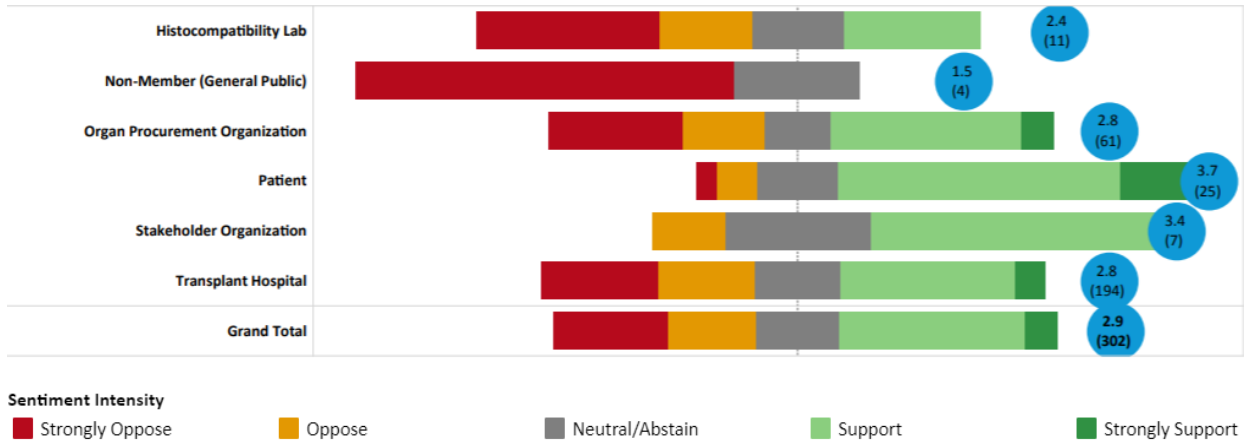
Five OPTN regions expressed a majority positive sentiment for the proposal as written, though these meetings did elicit insightful conversation around similar feedback themes expressed in other regions, highlighted in the section below.

Sentiment Among Different Member Types

Sentiment for the proposal was mixed among different member types during the OPTN Fall 2019 Public Comment period, with more support among patients and stakeholder organizations than the general public or histocompatibility labs.

Figure 6 illustrates sentiment for the Committee’s proposal by member type.

Figure 6: Proposal Sentiment by Member Type

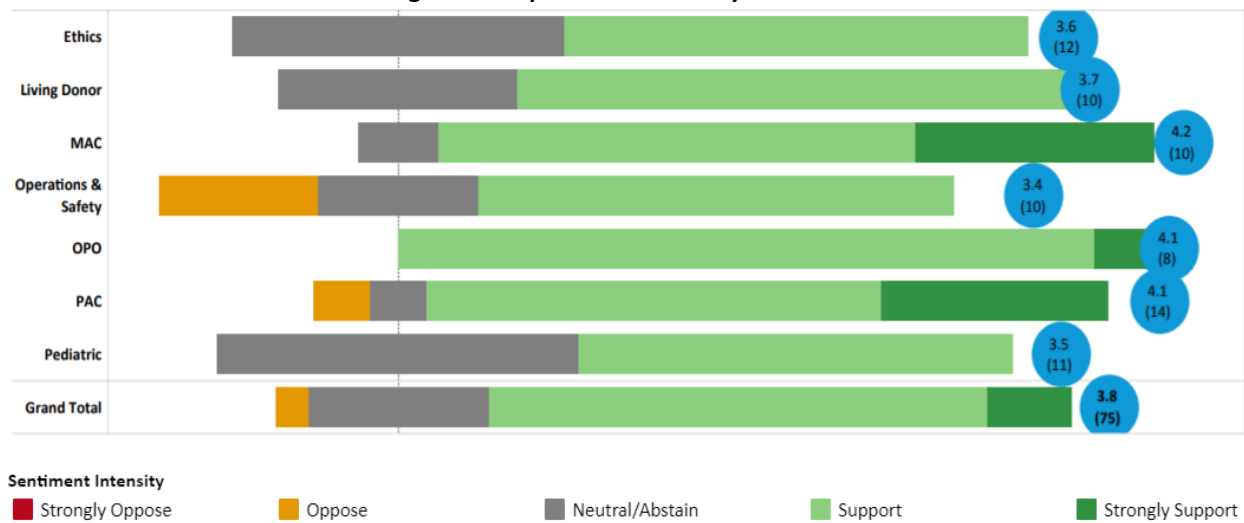


Sentiment Among OPTN Committees

During the OPTN Fall 2019 Public Comment period, leadership of the Committee presented the proposal to 11 OPTN Committees to receive sentiment and feedback for consideration.

Figure 7 represents the sentiment registered by OPTN Committees for the proposal.

Figure 7: Proposal Sentiment by Committee



The majority of OPTN Committees responded positively to the proposal as written. The Pediatric Committee, Minority Affairs Committee, Ethics Committee and Patient Affairs Committee expressed concern about the potential impact of KP allocation on kidney-alone candidates, and pediatric candidates in particular.

Major stakeholders such as AST and NATCO focused on logistical challenges related to the proposal. APOO, ASTS, ANNA, the Transplant Coordinator Committee and two other commenters indicated support for a 250 NM circle with up to two points inside the circle and up to four points outside the circle.

Public Comment Feedback Themes

Several themes emerged from public comment related to patient access to transplant, logistical implications of a 500 NM circle, and feedback on the Committee's import back up and facilitated placement solutions. The Committee reviewed feedback both during and after public comment to evaluate the community's response to elements of the proposal and its implications.

The Committee seriously considered the feedback from the community. The purpose of OPTN public comment is to engage the community and listen to their feedback, concerns and suggestions.

Access to Transplant

One major theme from public comment identified the potential increase in kidney-pancreas (KP) transplants as adversely affecting access to transplant for kidney-alone groups, including pediatric and minority populations. This issue goes beyond KPs: several commenters indicated that multi-organ prioritization overall should be re-evaluated. The Committee appreciates the concerns about the impact on kidney alone candidates and the focused feedback on pediatric kidney-alone candidates. KP candidates were prioritized as part of the Pancreas Allocation System policy changes approved in 2010 and implemented in 2014 to address that KP candidates need both a kidney and a pancreas since they have both diabetes and renal failure.³¹ The changes also promoted the utilization of pancreata, which could otherwise may not be transplanted, and brought consistency to how OPOs distributed KPs nationwide.

The modified proposal, which projects less of an increase for KP transplants, should help mitigate some of the concerns about a negative impact on pediatric kidney-alone. The Committee also considers that not all KP programs will take advantage of the 250 NM circle because of conservative acceptance practices, and the projected increase may be less than initially modeled.³² Regarding the overall prioritization of multi-organ, the Committee appreciates the feedback from the Pediatric Committee and others that this prioritization should be discussed. The Committee agrees that changing KP prioritization as part of a project to remove DSA and region from pancreas allocation is out of scope.³³ The OPTN Executive Committee has established looking at multi-organ transplantation and its impact on single organ transplant candidates as a priority for the OPTN.³⁴ The work on this project directly relates to the concerns of the Pediatric Committee and others, and will be addressed in a separate project that addresses all of multi-organ allocation. Additionally, the implementation monitoring plan has been updated to emphasize the plan should review the potential impact of KP on pediatric kidney-alone.

³¹ *Proposal to Develop an Efficient, Uniform National Pancreas Allocation System*, OPTN Pancreas Transplantation Committee, November 2010. https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf (Accessed November 1, 2019).

³² Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

³³ Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

³⁴ Executive Committee, Meeting Summary October 8, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/board-of-directors-executive-committee/>.

Pediatric Priority in KP Allocation

Some public comments questioned why pediatric candidates don't receive priority in KP transplantation and encouraged the Pancreas Committee to consider such a prioritization. This is a current project of the Pancreas Committee. The Committee discussed potential modifications to allocation regarding pediatric access to transplant in KP and pancreas-alone transplantation at their October 23, 2019 meeting.³⁵ The Committee appreciates the public feedback emphasizing that this is a priority for the community. However, it is out of scope to change the prioritization for pediatric candidates for this project, which seeks to remove DSA and region from pancreas allocation.

Logistics Challenges, Efficiency in Placement and Pancreas Utilization

During public comment, the Committee received feedback from the community on their concerns about the proposal. The implied impact of logistical challenges and travel distance on utilization, outcomes, and ischemic time were themes of public comment that the community raised in relation to an initial distribution distance of 500 NM. A majority of commenters at regional meetings and on the OPTN public comment site indicated that logistical challenges associated with a 500 NM circle would negatively impact ischemic time and outcomes in a way that hurts patients, even with the proposed proximity points of four inside the circle and eight outside. The concerns focused on logistical challenges of a 500 NM circle leading to more ischemic time and organ loss and potentially decreased utilization. Because 500 NM is a much further distance than most programs are willing to drive to procure organs, they contend, more pancreata will be flown.

Community members noted in public comment that there are a number of existing issues with flying pancreata that would be exacerbated with a 500 NM circle. Some OPOs handle travel logistics solely through ground transportation, which would increase the challenge of an allocation system utilizing a 500 NM circle because the percent of kidney-pancreas that travel more than 250 NM is projected to be 20% more than the baseline.³⁶ For commercial flights, organs may wait overnight in a baggage hold that is inaccessible, increasing ischemic time. Community members noted experiences of losing organs on commercial flights.

Public comment feedback also suggested the potential for organ loss and longer ischemic time is increased with the use of connecting flights. Rural OPOs and transplant programs would face more opportunities for increased ischemic time and lost pancreata because of not being close to major transplant hubs, due to the increased need to put organs on planes and experience either layovers or a requirement to transfer them from one plane to another. Other issues include that commercial flights often don't fly overnight. Longer ischemic time may lead to increased organ loss or to decreased patient graft outcomes. The Committee discussed that since the pancreas can handle less ischemic time, a 500 NM circle and the associated distribution challenges could lead to increased organ loss and impact on patient outcomes.

It is important to note that while a majority of comments focused on 500 NM not being an acceptable option, there were a minority of regions and comments that supported a 500 NM circle or one even larger. However, most comments focused on 500 NM being an unacceptably large circle for the logistical concerns already discussed. A majority of the alternative solutions proposed a smaller distribution unit

³⁵ Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

³⁶ Scientific Registry of Transplant Recipients, SRTR KI2019_01, June 21, 2019. https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (accessed October 31, 2019).

of 250 NM with up to two points inside the circle and up to four points outside the circle. Commenters specifically cited 250 NM as a “drivable distance” that would allow OPOs and transplant programs to utilize ground transportation as an alternative more than a 500 NM circle, which would in the commenters’ view necessitate air travel. Commenters also preferred options that preserved proximity points overall, since it preserved the priority for programs that may be lower volume to receive pancreas offers. Of the options modeled by the Committee, only one includes proximity points inside the circle and utilizes a circle of 250: the 250.2.4 variation. Thus commenters identified this variation as a viable alternative based on it alleviating some of the logistical concerns with the 500.4.8 variation. Two regions independently proposed and supported this alternate proposal, as did AOPO and ASTS.

In their post-public comment discussions, the Committee agreed that the logistical challenges associated with a 500 NM circle may impact ischemic time in a way that negatively affects utilization of pancreata or patient outcomes.³⁷ The Committee considered the 250.2.4 option supported by ASTS and AOPO (among others) to be a good step forward in addressing the logistical concerns by creating a distribution unit that would be easier to use ground transportation than a 500 NM circle. The Committee noted that the KP transplant rate overall was still projected to increase with a 250.2.4 variation. The OPO representative to the Committee noted the variability in OPO resources and volume in handling such a large distance of distribution from a logistical standpoint, and how that can affect patients through the impact on ischemic time. The Committee agreed it could be logistically challenging to have different solutions for kidney and pancreas as well. By including proximity points with the single fixed distance circle, the Committee considered the modified proposal would still represent a step towards continuous distribution.³⁸

Proximity Points

Within current pancreas allocation classifications, pancreas candidates are only sorted by waiting time (as compared with kidney allocation, which prioritizes candidates within a classification based on multiple factors including waiting time, sensitization, blood type, etc.). Some commenters expressed concern about the proposed value of proximity points in relation to waiting time: one proximity point is equivalent to one year of waiting time, and the original proposal indicated up to four proximity points would be allocated to candidates at the same location as the donor hospital. Since most KP and pancreas-alone candidates wait about a year before receiving a transplant, proximity could be the major determinant regarding who receives allocation offers.³⁹ Contrast with kidney allocation, in which candidates typically wait longer, and have other items such as cPRA that are valued more highly in allocation than proximity points would be. Members suggested either bringing in points for other factors such as sensitization, or decreasing the proposed value of the proximity points. The Committee’s proposed solution does limit the use of proximity points to up to two inside the 250 NM circle and up to four outside the circle. However, the Committee considers it important to preserve the use of proximity points to allow candidates at pancreas programs in closer proximity to the donor hospital more access, given the concerns in the community and the Committee to limit pancreas ischemic time.⁴⁰ The Committee also considers the inclusion of proximity points a step towards continuous distribution.

³⁷ Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

³⁸ Id.

³⁹ Urban, Read. UNOS Research, 2017 OPTN data.

⁴⁰ Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

Import Backup

There was mixed feedback on the Committee's import backup solution. Some members supported the proposed changes, but there was also some support for either a smaller import back up circle or center back up (letting the originally accepting program transplant the pancreas into another of their candidates). Members cited that the pancreas can withstand less ischemic time than the kidney, and also that there are the fewer pancreas candidates and programs available. Some commenters also expressed support for keeping responsibility for import back up with the host OPO that originally allocated the organ. Commenters noted the importance of monitoring the impact of the import back up policy. Commenters also indicated the importance of avoiding situations in which programs accept a KP then transplant the kidney into a different candidate at the hospital. Current policy and the proposed changes both stipulate that the transplant program must let the host OPO know when the organs are unable to be transplanted into the intended recipient, and it is up to the host OPO whether to grant import back up. The OPTN monitors instances in which organs are transplanted into someone other than the intended recipient.

The Committee considered the concerns regarding ischemic time and pancreas reallocation valid and important. The Committee considered that center back up may be too limiting and back up that includes other close-by centers would be appropriate. Given that the Committee proposes a different solution for removing DSA and region (a 250 instead of a 500 NM circle around the donor hospital), the Committee needs to have further discussions regarding the appropriate size and characteristics of import back up for pancreata.⁴¹ Accordingly, the Committee will work with the Kidney Committee, OPO Committee and Operations and Safety Committee to discuss options for modifying import back up policy to be consistent with the removal of DSA and region and avoid inefficiencies.

Facilitated Pancreas

The Committee seriously considered the implication of removing DSA and region on facilitated placement of pancreata prior to public comment. The Committee recognized the necessity of modifying this section of policy because DSA is part of facilitated placement qualifying criteria and because policy currently specifies that the facilitated placement list can only be used after exhausting offers to candidates within the DSA, instead of within a certain nautical mile distance. The Committee proposed a public comment solution that changed the facilitated pancreas criteria based on pancreata procured 500 NM from the transplant program. In discussing different options before public comment, and looking at what the implication would be for the number of qualifying pancreas programs, the Committee agreed to a more inclusive criteria (two pancreata procured 500 NM from the transplant program in the previous two years) instead of more stringent criteria. The Committee asked for public comment feedback on the proposed solution, and directly changed the proposed solution based on that feedback.

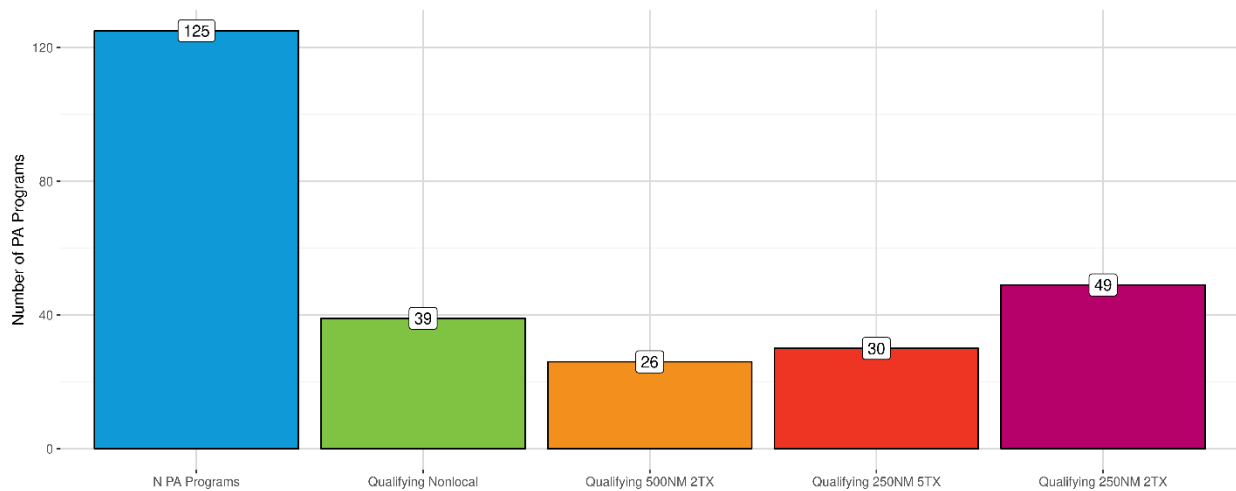
Public comment feedback indicated additional inclusivity for facilitated pancreas criteria may be appropriate. Commenters supporting more inclusive criteria questioned whether the qualifying criteria would limit participation in facilitated placement and access for pancreas programs looking to grow in volume and experience. Given the other changes to allocation happening concurrently, commenters urged use of criteria that would not limit use of facilitated placement to a few programs but be more widely available. Feedback suggested criteria should be less stringent or eliminated altogether. One comment suggested an opt-in system instead. The facilitated pancreas program previously did have an

⁴¹ Id.

opt-in system, and it did not increase any efficiencies in the allocation system, which is why it was modified to require meeting criteria.⁴² However, the Committee agreed that increasing experience in transplanting pancreata procured from farther away may be beneficial for programs looking to grow in volume. The Committee also recognized that changes to the allocation system could impact how many programs qualify for facilitated placement in the future, and should be considered in the context of whether the proposed qualifying criteria is appropriate.

Some commenters rightly noted that if the circle distance of 500 NM around the donor hospital was modified, the facilitated placement criteria may need to be modified as well for consistency with the proposed solution. These comments anticipate the Committee's modified solution with facilitated placement criteria of two pancreata procured outside 250 NM, which is both more inclusive and reflects consistency with the proposed circle of 250 NM around the donor hospital in allocation. Although the number of pancreata to qualify (2) is the same as compared to the public comment proposed criteria, the distance from which the program must procure has decreased with the proposed solution from 500 NM to 250 NM. The Committee reviewed facilitated pancreas program data indicating that 49 programs would qualify under the modified criteria of transplanting two pancreata procured 250 NM from the program in the previous two years (**Figure 8**). This is significantly more than the number of programs that would meet the proposed public comment criteria (26), as well as the current number of qualifying programs (39).

Figure 8: Number of Qualifying Facilitated Placement Programs



At their October 23, 2019 meeting, the Committee discussed that the projected number of qualifying programs seen in **Figure 8** is estimated using available data.⁴³ These data reflect the number of programs that have imported farther than 250 NM or 500 NM currently. However, the Committee noted that the change from DSA and region to a 250 NM circle may imply that fewer programs qualify for facilitated placement, because these programs may accept fewer organs from beyond 250 NM in the new system. The Committee reviewed public comment indicating support for an inclusive definition and

⁴² Proposal to Revise Facilitated Pancreas Allocation Policy. OPTN Pancreas Transplantation Committee, August 2015. https://optn.transplant.hrsa.gov/media/1191/0815-11_Facilitated_Pancreas_Allocation.pdf (Accessed November 1, 2019).

⁴³ Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

also considered the limitations of current data before agreeing to change the qualifying criteria to transplanting two pancreata procured 250 NM from the transplant program. While current data would suggest that nearly 50 programs would have access to using facilitated placement, the Committee considers this number may be lower given that the new system will be using 250 NM as an allocation unit instead of DSA, so the number of programs that can qualify by importing pancreata outside of the 250 NM distance may be fewer. At the same time, the change in facilitated placement qualifying criteria allows pancreas programs more opportunity to participate in facilitated placement opportunities compared to the public comment solution, directly addressing public comment concerns. The Committee is consistent in its approach to broaden access to facilitated placement and in accord with public comment support for allowing more programs to participate, while also accounting for limitations in assessing how many future programs may qualify. The Committee appreciates the comments suggesting that the impact of the facilitated pancreas changes be monitored; it is a part of the post-implementation monitoring plan for this project.

OPO Performance

One of the criticisms expressed about the Committee's proposal is the sentiment that the presence of DSAs and regions in allocation policy is not the largest determinant factor in determining a candidate's access to transplant, but rather the performance and the practices of the OPO facilitating their transplantation. This criticism is grounded in the variation in transplant rate by DSA that exists in the current allocation system and that one of the effects of removing DSA and region from those allocation policies would reduce that variation.

Community desire for improved performance monitoring metrics for OPOs and transplant systems alike is well-documented. Most recently, the OPTN's Ad Hoc Systems Performance Committee (SPC) delivered a report to the Board of Directors in June 2019 making several specific recommendations for improving both OPO and transplant program performance monitoring metrics.⁴⁴ In September 2019, the OPTN Board President utilized the SPC's report in part to issue a response to an August 2019 request for public comment on OPO performance monitoring metrics from the Centers for Medicare & Medicaid (CMS). The OPTN's submission offered specific recommendations for data collection and analytical methodologies in support of enhanced OPO performance monitoring.⁴⁵ As the SPC recognized in its work, OPO performance is but one of several variables impacting system operations and equity in access. The OPTN is committed to continuing the work of improving transplantation systems performance as a whole.

Because DSAs and regions have been determined to be non-compliant with the Final Rule⁴⁶, the Committee must address how pancreata will be allocated in their absence. Based on their sound medical judgement and collective experience, while using the KPSAM modeling as a tool, the Committee believes that a hybrid framework with a single allocation circle and proximity points is best approach to immediately eliminate DSA and region in compliance with the Final Rule. Members of the Committee understand that greater gains in equity can be achieved as the allocation system evolves and moves

⁴⁴ Neil, Heather, Overacre, B., Rabold M., Haynes C.R. PDF file. 10 June 2019. "Table 9: OPO Metrics Beyond Organ Yield." *OPTN Ad Hoc Systems Performance Committee Report to the OPTN Board*, p. 9.

https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf

⁴⁵ Johnson, Maryl R. to Alpha-Banu Wilson and Diane Corning, Centers for Medicare & Medicaid (CMS), U.S. Department of Health & Human Services. *Copy of the OPTN Response to Proposed Revisions of Organ Procurement Organizations Conditions of Coverage (Section XVIII) as submitted via the Federal Register*. 17 Sept. 2019.

⁴⁶ Letter from HRSA Administrator to Yolanda Becker, MD, President of the OPTN. November 21, 2017.

⁴⁶ 42 C.F.R. § 121.8(a)(8).

towards the OPTN Board-endorsed continuous distribution framework, including more comprehensive OPO performance monitoring, but the stated goal of this project remains unchanged.

Limitations of and Modifications to the KPSAM Modeling

While limitations exist within the KPSAM acceptance model, it is important to keep in mind that the KPSAM can be very useful in estimating the relative direction of possible effect for policy changes. Previous experience with the SAMs suggests that they typically predict the direction of subgroup changes, but under-predict the number of transplants that would occur in reality if a given policy scenario were adopted.⁴⁷

Both the SRTR and the Committee have been transparent about the limitations of the KPSAM modeling in evaluating the move from DSA/Region to circles, both in the concept paper published in December 2018 concept paper as well as the proposal published for the OPTN Fall 2019 Public Comment period. Specifically, the Committee has been oriented to the fact that the KPSAM modeling is a tool to be used in combination with their collective experience and that that KPSAM cannot model changes in program behaviors under new allocation policies. Furthermore, concerning offer acceptance, one aspect of the simulation results strongly affected by acceptance probability is the number of projected transplants. KPSAM uses a simple model of organ discard: if an organ is offered 200 times without an acceptance, it is marked as discarded.⁴⁸

Comments at OPTN Regional meetings as well as on the OPTN Public Comment website took issue with some of the metrics, limitations, and structure of the KPSAM modeling and analysis. These included criticisms about the use of transplant rate by DSA as a measure of equity in access and the Committee's decision to adopt SRTR-proposed changes to the KPSAM accept/decline model to more accurately predict the effects of changes in allocation by removing DSA as a determinant factor in modeled acceptance behavior.

The acceptance models are the components of KPSAM least aligned with the underlying data, and are therefore the most difficult to implement. Specifically, the acceptance models use offer data only for eventually accepted pancreata, but KPSAM uses the acceptance models to determine not only who accepts the pancreas but whether a pancreas is discarded. However, the acceptance models, by definition, contain no information on when a pancreas is discarded. Additionally, the acceptance models in KPSAM are based on offer data from 2017, and therefore assume that acceptance behavior under alternative allocation systems will be similar to acceptance behavior under the previous allocation system in 2017. Together, these issues represent significant limitations to KPSAM in evaluating transplants in a totally new allocation schema.

KPSAM discards pancreata offered 200 times without acceptance. Historically, this mechanism of pancreas discard is used for convenience, but it has important consequences. When the distribution of factors that predict acceptance changes across different allocation systems, the acceptance models will predict that pancreata will require more or fewer offers before being accepted. However, the acceptance models cannot determine whether pancreata requiring more offers will be discarded,

⁴⁷ Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? *Transplantation*. 2018;102(5):769-774; Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. *J Am Soc Nephrol*. 2014;25(8):1842-8.

⁴⁸ Scientific Registry of Transplant Recipients, SRTR KI2019_01, June 21, 2019.

https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (accessed October 31, 2019).

because they include no information on the mechanism causing discard. Instead, they indicate only that such pancreata will require more offers before being accepted. Thus, for the second KPSAM request, factors were excluded from the acceptance models if their distribution within a match run was likely to change across different allocation systems. The SRTR believes excluding such factors allows KPSAM to more accurately predict the potential distribution of transplants.

The acceptance models in the first round of KPSAM modeling included donor factors (e.g., age or offer number), candidate factors (e.g., dialysis time at offer), and donor/candidate interactions (e.g., a “local indicator” for whether a candidate was listed in the same DSA as the donor). The distributions of candidate factors and donor/candidate interactions within match runs are likely to change across different allocation systems, because they largely determine candidates’ relative allocation priority (i.e., how candidates are ordered within the same tier of allocation). This is particularly true for the current KPSAM modeling requests because broader sharing ensures that candidates with high relative allocation priority (e.g., longer times on dialysis) will be closer to the beginning of the match run than they would be under current allocation policy. Additionally, broader sharing will obviously reduce the proportion of local offers at the beginning of the match run. Thus, the acceptance model for the second KPSAM request included only donor factors because their distributions within a match run are unlikely to change across different allocation systems.

The KPSAM acceptance models also assume that acceptance behavior under the alternative allocation system will be the same as under the current allocation system. However, acceptance behavior related to factors correlated with the current allocation system may change under alternative allocation systems in which the role and/or importance of the factor changes. The “local indicator” is an obvious example. This factor is highly important in the current allocation system but is less meaningful in allocation systems without DSAs. Thus, local offers are currently associated with more ideal offers (i.e., closer to the beginning of the match run), while non-local offers are currently associated with less than ideal offers (i.e., later in the match run). It is not clear that this preference for local offers will remain in an alternative allocation scheme that does not include DSAs.

SRTR began a detailed investigation of the acceptance model component of KPSAM in December 2018, almost immediately after submitting the first request to the OPTN Kidney and Pancreas Committees. The SRTR determined that the local indicator was significantly reducing the number of transplants in the first request, but that candidate characteristics, e.g., dialysis duration at offer, were also reducing the number of transplants, although at a lower magnitude than the local indicator. However, as detailed above, the investigation also revealed the limitations of using the acceptance models to determine discard, i.e., their lack of data on the actual discard process. For these reasons, estimating the number of transplants from KPSAM is difficult and fraught. Instead, a lower number of transplants in KPSAM indicates that the alternative allocation systems would require more offers to place such pancreata. Because KPSAM cannot determine whether alternative allocation systems that require more offers before a pancreas is accepted would cause fewer transplants, the acceptance model for the second KPSAM modeling request included only donor factors.

It is important to reiterate the usefulness of the KPSAM in indicating the potential direction of effect for policy changes. Specific limitations do not invalidate the benefit the KPSAM can provide to Committees in considering possible paths forward in modifying policy, in conjunction with stakeholder input, public feedback, and Committee member experience and expertise.

Evaluation of Key Factors

This section details the most relevant factors related to the Committee’s decision to modify the proposal from a 500 NM circle with proximity points to a 250 NM circle with proximity points, an alternative considered by the Committee prior to public comment and again in response to public comment feedback.

Transplant Rate

Figure 9 shows the projected KP transplant rate per patient year for the different scenarios. In the KPSAM, 10 iterations of each model was run to provide some measure of variability. Averages and the range of results (minimum – maximum) for the 10 iterations were provided. While the public comment proposal of 500.500.4.8 has a projected average transplant rate of 0.631, the Committee’s solution of 250.250.2.4 shows a projected average transplant rate of 0.583. While the projected transplant rate is lower for the 250.250.2.4 solution, an increase compared to the baseline is still preserved. The Committee believes that the 250 solution avoids potential negative impacts associated with the 500 NM solution regarding pancreas ischemic time, organ loss and patient outcomes, while preserving a projected overall increase in pancreas transplant rate.

Figure 9: KP Transplant Rate

Scenario	Transplant Rate per Patient- Year
BL	0.422 (0.412,0.432)
500.500.0.8	0.623 (0.613,0.63)
500.500.4.8	0.631 (0.621,0.638)
500.150.0.8	0.501 (0.488,0.511)
250.250.2.4	0.583 (0.576,0.59)
250.250.0.8	0.581 (0.566,0.592)
250.150.0.8	0.507 (0.497,0.517)
150.150.0.8	0.523 (0.512,0.539)
150.150.0.20	0.521 (0.504,0.536)
500.500.step150	0.626 (0.616,0.636)
500.500.step250	0.63 (0.619,0.643)

Review of Travel Distance Data

The Committee considered that a solution that represents a more incremental change and avoids a potential decrease in utilizing pancreata would be a better solution. The Committee therefore re-considered KPSAM modeling on distribution of travel distance to ascertain if the alternative proposal of 250 NM would result in most pancreata traveling a distance that can be covered by ground transportation. **Figure 10** shows violin plots to project the shape of distribution across the modeled KPSAM variations.

**Figure 10: Distribution of Organ Travel Distance, Kidney-Pancreas
Averaged Results from 10 Iterations per Scenario**

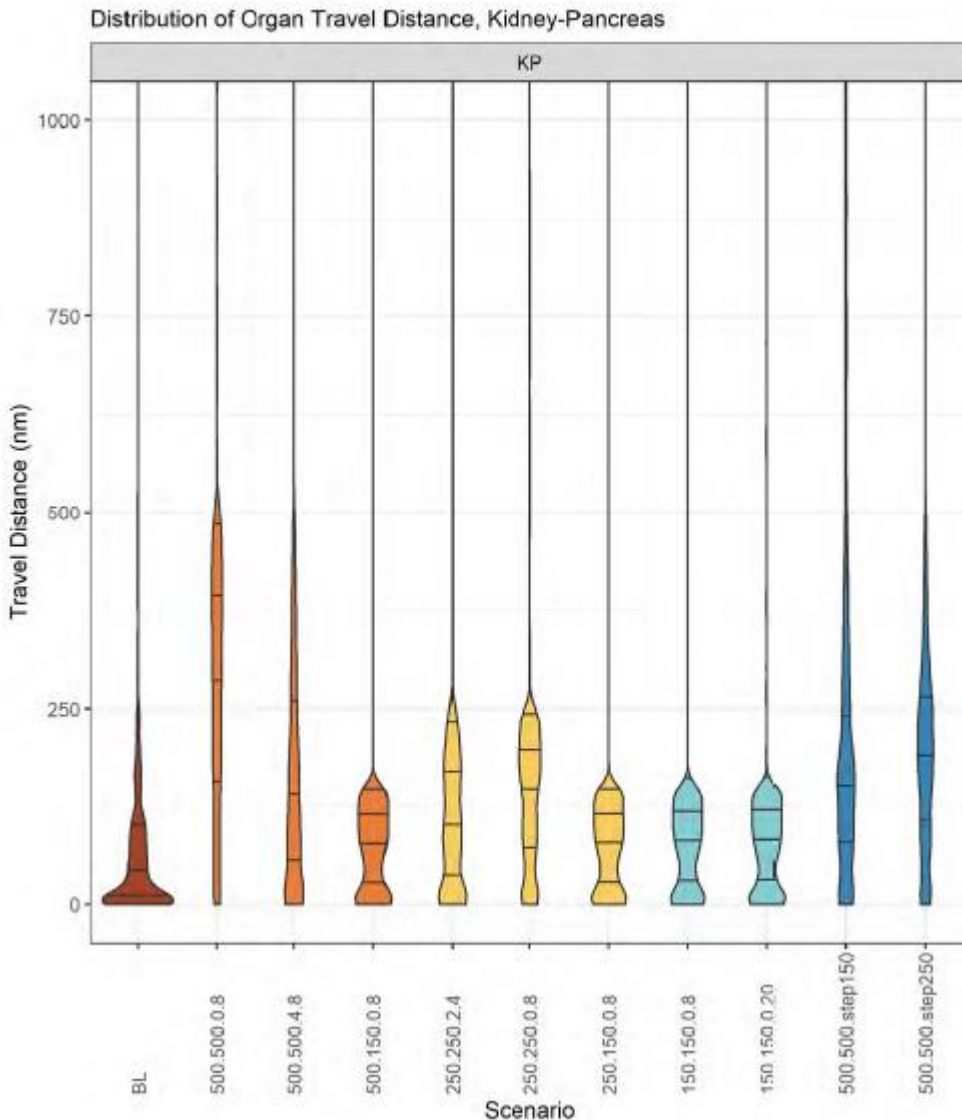


Figure 10 illustrates the projected differences in the shape of distribution that results from differently sized fixed distance circles among the modeled variations as well as the projected effects of proximity points. Overall, this figure shows how the circle size limits the projected travel distance – in general, travel tapers off sharply outside the size of the circle. The figure also demonstrates the impact of

proximity points. The 250.250.2.4 model shows more transplants occurring within shorter distances as depicted wider bands in the shorter distances and corresponding lower quartiles in comparison to the 250.250.0.8 model. The 250 NM solution limits geographic distribution more than the 500 NM, reflecting public comment concerns regarding the logistical challenges of a 500 NM circle with proximity points. Specifically, Figure 10 demonstrates how travel is projected to be limited to a more feasibly drivable distance (250 NM) with a 250 NM circle, thereby addressing the concerns of the community regarding travel logistics and the potential decrease in utilization, increase in organ loss and loss of efficient placement that could result from a 500 NM circle. The inclusion of proximity points is expected to help avoid unnecessary organ loss and to also promote efficient management of organ placement, while not providing an imbalance of allocation points with waiting time and proximity that may result from the 500.4.8 public comment solution.

Preserved Increase in Equitable Access for Vulnerable Populations

Overall, the gains in equity in access to transplant for certain vulnerable populations projected with the 500 NM solution are preserved with the 250 NM solution. This is true for projected increases in equity in access for highly sensitized, African American, and candidates on Medicare. Figures 11 through 13 illustrate the projected increase in transplant rates for these populations. Within the graphics, “BL” represents a baseline scenario without further prioritization for pediatric patients and “BL_PedsPrior” represents a baseline scenario when pediatric patients receive increased priority in allocation tables. The graphics also show the projected changes across the public comment proposal of 500 NM with proximity points (500.500.4.8) and the option the Committee voted to send to the Board of 250 NM circle with lower proximity points (250.250.2.4).

Figure 11: Transplant Rates by cPRA, Kidney-Pancreas



Figure 12: Transplant Rates by Payment Status: Kidney-Pancreas

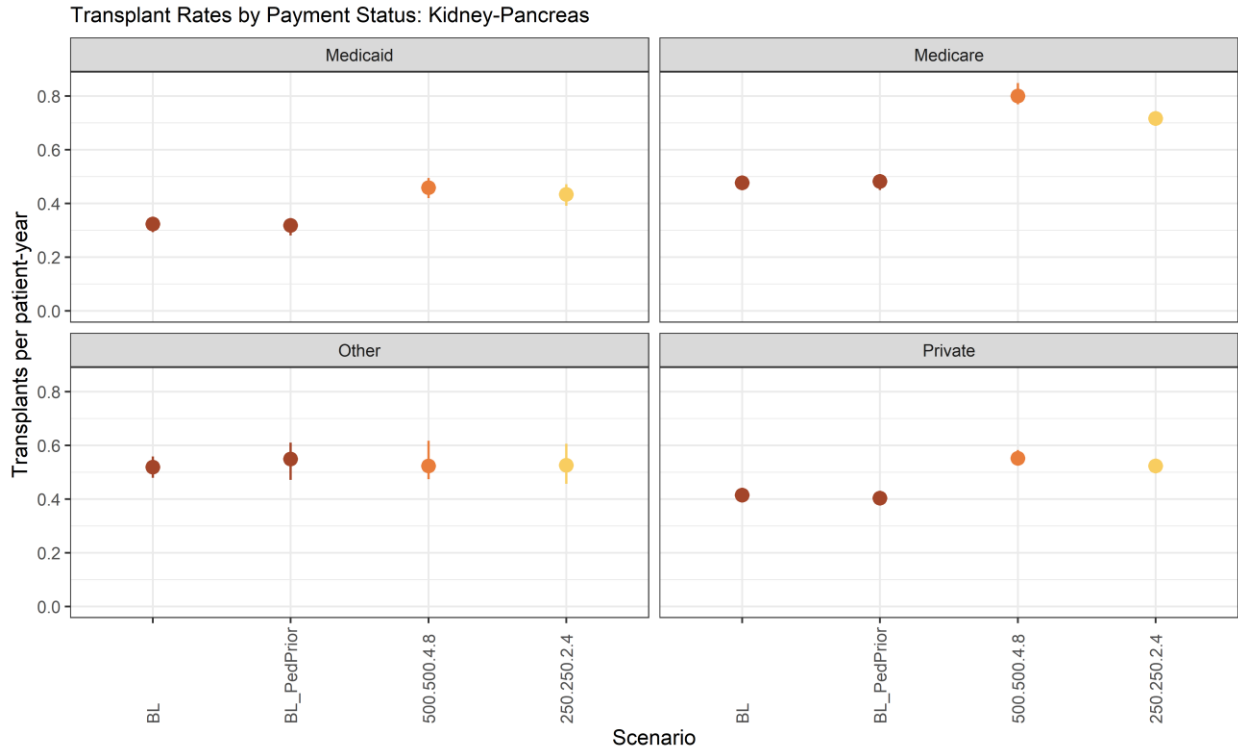
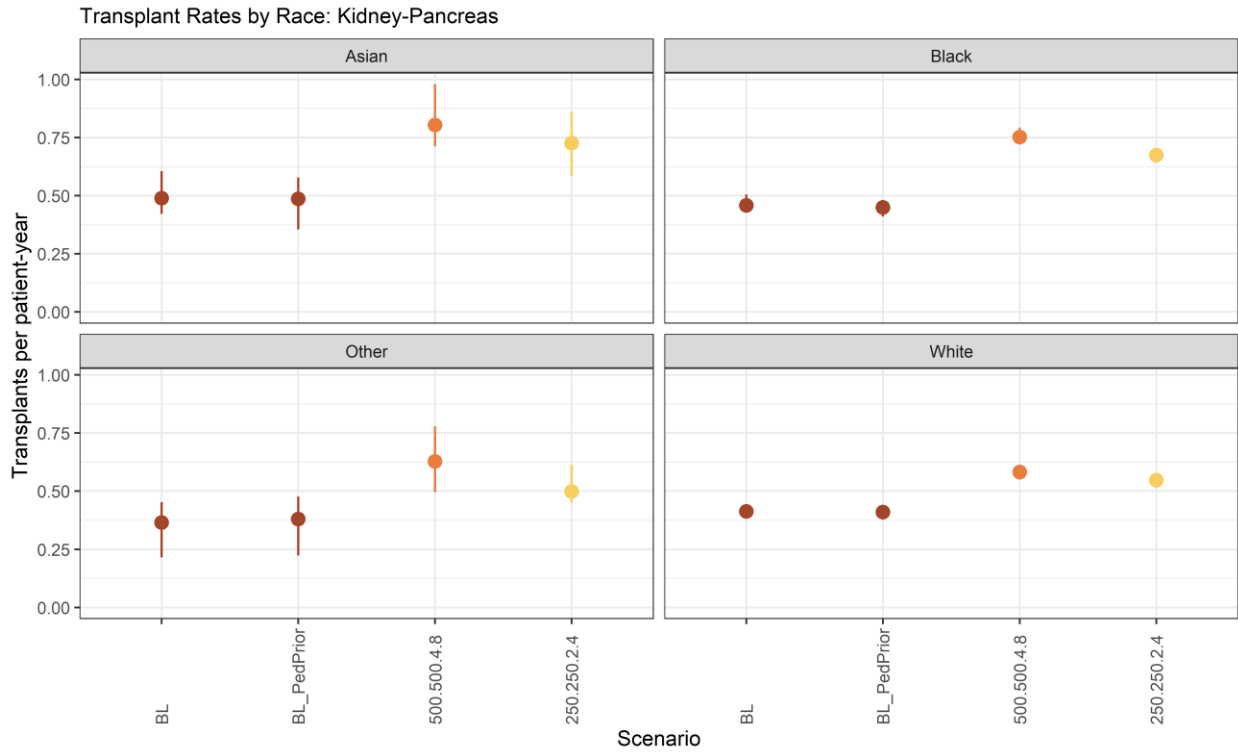


Figure 13: Transplant Rates by Race: Kidney-Pancreas



The Committee considers that the 250 NM option keeps the significant gain in equity for these vulnerable populations without the potential negative impact on utilization that the 500 NM solution may incur.⁴⁹ The Committee considers that the projected decrease in logistical challenges of flying pancreata, along with the preserved increase in equity, indicate that 250 NM is a better incremental change that distributes pancreata as broadly as feasible while achieving the best use of organs, avoiding organ loss and promoting efficient placement of organs.

Alignment of Modified Proposal with OPTN Strategic Plan

1. *Increase the number of transplants:* Broader distribution for pancreas could allow more aggressive programs to access organs that would otherwise be lost, and therefore a 250 NM circle may positively impact utilization and increasing the number of transplants overall.
2. *Improve equity in access to transplants:* The Final Rule requires that allocation policies “shall not be based on the candidate’s place of residence or place of listing.” This proposal aims to implement a unit for geographic distribution that is consistently applied and removes artificial barriers that can exist within short distances between donor hospitals and candidates. It seeks to improve equity in transplant opportunities for certain vulnerable populations, including highly sensitized candidates, minority candidates, and candidates on Medicare.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Increased travel could impact ischemic time and transplant recipient outcomes. By modifying the proposal to a 250 NM circle instead of a 500 NM circle, the Committee seeks to avoid a negative impact on patient graft outcomes and to avoid organ loss.
4. *Promote living donor and transplant recipient safety:* There is no impact on this goal.
5. *Promote the efficient management of the OPTN:* The proposal could impact the percentage of pancreas transplants that require air transportation and thereby impact costs and affect recovery team safety. It is important to note, however, that the OPTN currently does not collect transportation mode nor can the KPSAM simulate it.

Final Rule and National Organ Transplantation Act (NOTA) Compliance of Modified Proposal

The OPTN Final Rule says that organ allocation “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by other elements of the Final Rule.⁵⁰ The elements that may constrain organ distribution include sound medical judgment, the best use of donated organs, avoiding unnecessary organ loss, avoiding futile transplants, promoting patient access to transplantation, and promoting the efficient management of organ placement. The best use of organs, avoiding unnecessary organ loss, and promoting the efficient management of organ placement may provide justification for constraining geographic distribution of organs through the impact on ischemic time, travel logistics, utilization and outcomes.⁵¹

⁴⁹ Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

⁵⁰ 42 C.F.R. § 121.8

⁵¹ 42 C.F.R. § 121.8

The Committee considered these constraints when evaluating how to remove DSA and region from pancreas allocation. In particular, these constraints led to the Committee supporting a 500 NM circle with proximity points for public comment. Members considered that a 500 NM circle size would improve equity in access to transplant, while proximity points would mitigate the impact of the size of the circle on ischemic time, outcomes, utilization and travel logistics.⁵² Since one proximity point has been aligned to one year of waiting time, candidates closer to the donor hospital would receive what would equate to four years of waiting time for their proximity. This, the Committee considered, would limit the median travel distance, which could reduce logistical hurdles and the likelihood that long ischemic time could negatively impact patient outcomes, result in futile transplants, or negatively impact utilization of the donated organs. The Committee also considered a 250 nautical mile circle with proximity points as an alternative solution⁵³ throughout both rounds of modeling and the various committee and KP Work Group meetings, because some members had concerns about logistical impact and utilization of the 500 NM solution even with the proximity points.

While the Committee previously considered that the inclusion of proximity points with a 500 NM circle mitigated the potential impact on travel logistics, the detailed concerns from public comment made the Committee reconsider whether the 500 NM would be an appropriate distribution unit. Specifically, the Committee considered that the significant logistical challenge of flying more pancreata may negatively impact outcomes and utilization and how those challenges could affect efficiency of placement and increased risk for organ loss or graft failure.⁵⁴ This in turn raises potential concerns about the Final Rule requirements to achieve the best use of organs, avoid unnecessary organ loss, and promote efficient management of organ placement. Ultimately, the Committee believes that the 250 NM proposal still makes significant steps towards achieving more equity in access to transplant, while the proposed proximity points help to minimize the risk of poor utilization of donated organs, futile transplants by way of poor post-transplant outcomes, and logistical challenges associated with transporting organs further distances.

Implementation and Operational Considerations

OPTN actions

Programming changes will be required for this proposal. This will be an “Enterprise” size effort in terms of IT implementation.

Changes will be made to the kidney allocation and combined kidney/pancreas & pancreas match allocation to remove DSA and Region and allocate using a nautical mile circle. In addition to that, classification titles in the pancreas and combined KP/PA allocations will also be changed to remove references to “local” and “regional.”

UNOS will follow established protocols to inform members and educate them on any policy changes through Policy Notices. UNOS Professional Education will monitor for additional educational needs throughout the development of this proposal.

⁵² Pancreas Committee, Meeting Summary June 25, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

⁵³ Id.

⁵⁴ Pancreas Committee, Meeting Summary October 23, 2019, available at <https://optn.transplant.hrsa.gov/members/committees/pancreas-committee/>.

Member actions

Transplant Hospitals

As a result of the increased distance, some transplant hospitals will receive offers from OPOs with whom they have not worked previously with. Transplant hospitals will need to develop relationships with all OPOs in a certain travel distance for obtaining an organ. Furthermore, under the broadened relationships, transplant hospitals may need to adjust their operations to account for the practices of their new OPO partners, including how they communicate with one another.

The changes to pancreas distribution may also impact overall transplantation program costs, as broader distribution may increase the number, distance, and time of additional pancreas fly outs. Some programs may need to hire more staff to assist with recoveries to travel further to recover pancreata from donors. Transplant hospitals may want to establish a process for sharing organ acquisition cost information as part of their outreach to new OPOs.

OPOs

OPOs will continue allocating donor organs through the match runs. OPOs that will be working with transplant hospitals for the first time may want to consider developing working relationships to address issues such as sharing donor information and coordinating recoveries.

Potential Fiscal Impact of Proposal

Members

Allocation change detailed in this proposal will affect the costs incurred by most transplant centers, but is directly the result of volume, geography, and current contractual agreements.

Some centers may experience loss in volume, while others may see an increase. Currently, single pancreas allocated often requires greater travel compared to single kidney or kidney-pancreas allocation. Increase in travel cost may not be as drastic compared to potential travel distance and cost changes associated with the proposed kidney or kidney-pancreas changes. Kidney-pancreas programs can range from very conservative to very aggressive in accepting offers. Even if the programs are receiving more offers from farther away, not all of them would necessarily accept offers, thereby not changing costs.

Loss in volume may cause a decrease in program revenue or even closure of the pancreas program. Increase in volume may result in greater revenue, but also greater cost per transplant. Increase in flight cost (travel time) and recovery team procurement costs are possible. It is not clear if procurement would be performed locally or by the transplant hospital. If flying to procure or needing flights to transport pancreata increases, more rural areas with limited direct flights may bear a disproportionate cost burden-to transport kidneys (pancreas) and/or conduct perfusion.

While additional costs associated with an increase in travel time and procurement efforts may be covered by Medicare via the Cost Report, it is possible that additional costs may *not* be covered by non-Medicare payers unless existing contractual agreements are renegotiated.

Both Transplant Program and OPO staff would require training and communication about new policies. Transplant Programs would likely implement the new allocation in 3-6 months, while OPOs would be able to train and adjust more quickly. Additional staff or staff hours may be necessary, dependent on change on volume.

OPTN

The pancreas team in the Policy and Community Relations (PCR) department accounts for an estimated 2,500 hours in development of the proposal, including meetings, analysis, policy development, writing, outreach, and travel. Additionally, Research worked closely with the PCR team to develop, review, and monitor data reports and consult in internal and committee meetings.

An effort estimated at 3,888 hours will be required to program the proposed allocation changes to remove Designated Service Areas (DSA) and change organ offer notification limits. Communications will create a robust campaign, including directed outreach to media, patients, and members, to disseminate changes associated with any allocation changes (kidney and/or pancreas) through multiple platforms and points in time. Communications estimates up to 310 hours to execute this effort.

Significant ongoing monitoring (IT and Research) annually is estimated to create reports and status updates to evaluate outcomes. Both departments estimate several hours per week will be required.

Post-implementation Monitoring

Member compliance

This proposal will not change the current routine monitoring of members. All policy requirements, as well as any data entered in UNetSM, may be subject to OPTN review, and members are required to provide documentation as requested. OPTN contractor staff will continue to review deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and staff will continue to investigate potential policy violations.

Policy evaluation

This policy will be formally evaluated approximately 3 months, 6 months, 1 year, and 2 years post-implementation. The following metrics, and any subsequently requested by the Committee, will be evaluated as data become available (Appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNet) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy. To assess the policy's impact on pediatric populations as well as the geographic variation in pediatric populations, when feasible, metrics will be stratified by pediatric age groupings, DSA and OPTN Region:

Waitlist

1. Total kidney-pancreas and pancreas registrations on the waitlist (snapshot by month)
2. Kidney-pancreas and pancreas registrations added to the list, overall and by age, gender, ethnicity, cPRA, blood type, and insurance status at time of listing
3. % of candidates in active status

4. Waitlist mortality per 100 patient years, overall and by candidate age, gender, ethnicity, cPRA, blood type

Transplants

1. Donor, recipient and transplant characteristics: # and % of transplants by recipient age, ethnicity, waiting time (days on the waiting list), ABO, cPRA, HLA-ABDR mismatch level, diagnosis, DCD, inside/outside fixed circle, preservation time and cold ischemic time (CIT).
 - a. Distribution of kidney-pancreas and pancreas travel distance (NM), overall and by inside/outside fixed circle
2. Change in access by location: N and % of transplants by
 - a. Distribution type (local/regional/national)
 - b. OPTN region
 - c. DSA
 - d. (de-identified) transplant center
 - e. State
3. Deceased donor transplants per 100 patient years by recipient age, ethnicity, ABO, cPRA, HLA-ABDR mismatch level, and DSA
4. Variance in deceased donor transplant rate across DSA
5. Rates of receiving kidney-pancreas and pancreas offers per 100 patient years by recipient age, ethnicity, ABO, cPRA, and HLA-ABDR mismatch level

Utilization and Efficiency of Allocation

1. # pancreas donors recovered for transplantation
2. # and % of pancreata recovered but not utilized (discarded), overall
3. # and % of pancreata discarded by discard reason
4. # and % pancreata with a final acceptance
5. Offer acceptance per 100 patient years by recipient age, ethnicity, waiting time (days on the waiting list), ABO, cPRA, and inside/outside fixed circle among organs with a final acceptance.
6. Distribution of sequence number of final acceptor
7. Distribution of time between electronic offer and cross-clamp
8. # and % by cPRA, of kidney-pancreas and pancreas offers refused due to a positive cross-match

Outcomes

The following analyses are reserved for future (1-year, 2-year) reports as enough data become available:

1. Post-transplant graft and patient survival rates, overall and stratified by recipient age, gender, ethnicity, cPRA, blood type, HLA-ABDR mismatch, CIT and preservation time.

Facilitated Pancreas Allocation

1. # and % of programs that qualify for facilitated pancreas allocation
2. Frequency of facilitated allocation use by OPOs
3. Transplant volumes that laced with facilitated pancreas allocation

4. Criteria for qualification, specifically whether distance from donor hospital or volume of transplants within two years is an acceptable threshold to qualify

Conclusion

The Committee determined that the 250 NM fixed circle with a maximum of two points inside the circle and a maximum of four points outside the circle would provide a consistent foundation for pancreas distribution while improving equity in access to transplant for certain vulnerable populations and potentially furthering competition between pancreas programs that could decrease variance in offer acceptance and increase utilization, thus avoiding unnecessary organ loss. The Committee considered feedback about logistical challenges impacting pancreas ischemic time, graft outcomes, and potential for organ loss. These concerns largely informed the Committee's decision to reduce the allocation circle size from 500 NM to 250 NM, as they believed that increasing these risks and potentially decreasing the efficiency of organ placement justified a distribution shape less broad than initially proposed. The inclusion of proximity points is expected to help avoid unnecessary organ loss and to also promote efficient management of organ placement. The Committee concluded the modified proposal is compliant with the Final Rule. The Committee unanimously supported removing DSA and region in pancreas allocation and using instead a 250 NM circle around the donor hospital, with up to two proximity points inside the circle and up to four proximity points outside the circle. The Committee also unanimously supported modifying the facilitated pancreas criteria to transplanting two pancreata procured 250 NM or further from the transplant program in the previous two years. The Committee agreed import back up needed further consideration.

The Committee remains committed to the advancement of allocation policies towards the OPTN Board of Directors' vision of continuous distribution. Members see the following proposal as forward progress and innovation towards that goal while achieving the overall purpose of removing DSA and region from allocation policies in alignment with the Final Rule.

Policy Language

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

1 1.2 Definitions

2 ~~Zero antigen~~ 0-ABDR mismatch

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

- 5
- 6 1. At least one donor antigen is identified for each of the A, B, and DR loci
- 7 2. At least one candidate antigen is identified for each of the A, B, and DR loci
- 8 3. The donor has zero non-equivalent A, B, or DR antigens with the candidate’s antigens
- 9 4. The donor and the candidate have compatible or permissible blood types

10
11 In cases where a candidate or donor has only one antigen identified at an HLA locus (A, B, or DR), the
12 antigens are considered to be identical at that locus. A ~~zero antigen~~ 0-ABDR mismatch may also be
13 referred to as a zero mismatch or ~~0-ABDR~~ zero antigen mismatch.
14

15 **Policy 11: Allocation of Pancreas, Kidney-Pancreas, and** 16 **Islets**

17 11.2 Pancreas Allocation Score

18 Candidates receive an allocation score according to the total of all points assigned in Table 11-1.
19

20 **Table 11-1: Allocation Points**

21

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

22

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

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

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

11.4.A Kidney-Pancreas Allocation Order

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

1. The host OPO must offer the kidney and pancreas according to classifications 1–54 in *Tables 11-45: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m²* and *Table 11-56: Allocation of Kidneys and Pancreas from Donors more than 50 Years Old or with a BMI greater than 30 kg/m²*.
2. Then, the host OPO may do either:
 - a. Continue to offer the kidney and pancreas according to the remaining classifications in *Table 11-45* and *Table 11-56*.
 - b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas candidates, according to the remaining classifications in *Table 11-45* and *Table 11-56* and offer the kidney to kidney candidates according to *Policy 8: Allocation of Kidneys*.

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

11.4.B Pancreas Allocation When a Kidney is Unavailable

If a host OPO only has a pancreas, but not a kidney to offer for allocation, then the host OPO must offer the pancreas to pancreas and islet candidates but not kidney-pancreas candidates according to *Tables 11-45: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m²* and *Table 11-56: Allocation of Kidneys and Pancreas from Deceased Donors more than 50 Years Old or with a BMI Greater than 30 kg/m²*.

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

57

11.4.C Organ Offer Limits

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

61

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

66

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

68

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

73

11.4.D Blood Type for Kidney-Pancreas Allocation

Within each classification, kidney-pancreas will be allocated to candidates according to the blood type matching requirements in *Table 11-34* below:

77

78

11-34: Allocation of Kidney-Pancreas by Blood Type

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

79

11.4.E Sorting Within Each Classification

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

83

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

86

87 **11.4.F Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30**
 88 **kg/m²**

89 Pancreas, kidney-pancreas, and islets from donors 50 years old or less and who have a BMI less than
 90 or equal to 30 kg/m² will be allocated to candidates according to *Table 11-45* based on waiting time.

91
 92 **Table 11-4: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI**
 93 **Less Than or Equal To 30 kg/m²**

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

Classification	Candidates that are within the:	And are:
12	Nation	Islet candidates

94
95
96

Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m²

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

97
98

11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m²

99
100
101

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/m² are allocated to candidates according to Table 11-56 based on waiting time below.

102
103
104

Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m²

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

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

105
106
107

Table 11-6: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m²

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

<u>Classification</u>	<u>Candidates that are:</u>	<u>And registered at a transplant program that is at or within this distance from the donor hospital:</u>
<u>7</u>	<u>Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%</u>	<u>Nation</u>
<u>8</u>	<u>Pancreas or kidney-pancreas candidates</u>	<u>Nation</u>

108

109 11.5 Reallocation of Unsuitable Islets

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

114

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

119

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

122

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

125

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

130

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

132

133 11.6 Facilitated Pancreas Allocation

134 11.6.A Transplant Program Qualifications

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

139

140 11.6.B Facilitated Pancreas Offers

141 OPOs and the ~~Organ-Center~~ OPTN Contractor are permitted to make facilitated pancreas offers if no
 142 pancreas offer has been accepted three hours prior to the scheduled donor organ recovery. The
 143 OPO or ~~Organ-Center~~ OPTN Contractor must offer the pancreas only to potential transplant
 144 recipients registered at a transplant program that participates in facilitated pancreas allocation.

145 Facilitated pancreas offers must be made in the order of the match run, and OPOs will only have
146 access to facilitated allocation after all local pancreas and kidney-pancreas offers made to
147 candidates registered at transplant programs within 250 nautical miles of the donor hospital have
148 been declined.

149 #
150