

Briefing Paper

Proposal to Change Waiting Time Criteria for Kidney-Pancreas Candidates

OPTN/UNOS Pancreas Transplantation Committee

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Proposal to Change Waiting Time Criteria for Kidney-Pancreas Candidates

<i>Affected Policies:</i>	<i>11.3.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old; 11.3.D Waiting Time Assignments for Kidney, Kidney-Pancreas, Pancreas, and Islet Candidates</i>
<i>Sponsoring Committee:</i>	<i>Pancreas Transplantation Committee</i>
<i>Public Comment Period:</i>	<i>January 22, 2018 – March 23, 2018</i>
<i>Board of Director's Date:</i>	<i>June 11-12, 2018</i>

Executive Summary

A section of the kidney-pancreas (KP) waiting time criteria limits waiting time accrual to candidates on insulin that have either a C-peptide ≤ 2 ng/mL or a C-peptide > 2 ng/mL and a body mass index (BMI) below or equal to the maximum (30 kg/m²). Pancreas Committee (Committee) analysis and review of current evidence indicates that this waiting time criterion unnecessarily limits certain candidates' ability to accrue waiting time. Because waiting time is an important part of pancreas allocation, it may also limit these candidates' access to transplantation.

The waiting time criterion was included in the 2014 Pancreas Allocation System (PAS) because of concerns about outcomes for high BMI Type 2 candidates (who are identified by having a high C-peptide). However, evidence gathered by the Committee suggests this restriction for Type 2 candidates is unnecessary because Type 1 and Type 2 diabetic KP recipients may have comparable outcomes.¹ Additionally, well-selected Type 2 high BMI simultaneous pancreas-kidney (SPK) recipients may have comparable outcomes to other SPK recipients.^{2,3} The KP waiting time criterion restricts waiting time accrual for Type 2 high BMI candidates while allowing Type 1 high BMI candidates to accrue waiting time and have greater access to transplant. Asians, African Americans and Hispanic populations comprise a higher proportion of Type 2 candidates and recipients with a high BMI (> 30), indicating that the current policy may create an inequity in restricting minority KP candidate access to waiting time accrual.⁴

Changing KP waiting time criteria aligns with the first OPTN strategic goal to increase the number of transplants. In 2015, 25% of pancreata recovered for transplant were discarded.⁵ By enhancing access for candidates currently prevented from accruing waiting time, this proposal may reduce the pancreas discard rate and increase the total number of KP transplants. By removing a barrier to waiting time accrual for minority populations, this proposal may also reduce an inequity in access to transplant, which aligns with the second OPTN strategic goal. Ultimately, removing the KP waiting time criterion and maximum allowable BMI would provide certain candidates access to kidney and pancreas transplantation based on center best practices and clinical evidence rather than an unnecessary and inequitable waiting time criterion.

¹ Sampaio, M. S., et al. "Outcomes of Simultaneous Pancreas-Kidney Transplantation in Type 2 Diabetic Recipients." *Clinical Journal of the American Society of Nephrology*, vol. 6, no. 5, 2011, pp. 1198–1206., doi:10.2215/cjn.06860810.

² Forbes, R., et al. "Obesity was not associated with worse outcomes for type 2 diabetic simultaneous pancreas kidney transplant recipients." ATC-submitted: 2018.

³ Laftavi, M., et al. "Access to simultaneous pancreas and kidney transplant (SPK) should not be restricted to BMI > 28 ." American Transplant Congress, 2017: 178.

⁴ Urban, Read. UNOS Research, 2017 OPTN data.

What problem will this proposal address?

Kidney-pancreas (KP) candidates can only accrue waiting time if:

- They are on insulin and have a C-peptide ≤ 2 ng/mL, or
- They are on insulin and have a C-peptide > 2 ng/mL but have a BMI less than or equal to the maximum allowable BMI (currently 30 kg/m²)

Waiting time accrual is critical for KP candidates because it impacts allocation. Within each allocation classification, pancreas, kidney-pancreas, and islet candidates are sorted based on waiting time (longest to shortest) in accordance with *Policy 11.4.E Sorting Within Each Classification*. UNOS data analyses show that 50 candidates listed for a kidney-pancreas between 2014 and 2016 (post-PAS implementation) did not meet the waiting time criteria, thus limiting access to transplant for these candidates.⁶ Furthermore, the data does not capture candidates who are not even being listed because they did not meet the waiting time criteria.

Impact on Type 2 Candidates & Minority Populations

The level of fasting C-peptide is sometimes considered to be an approximation of diabetes status. For example, Type 2 diabetes is often associated with higher C-peptide values compared to Type 1 diabetes, but it is not an absolute sine qua non. When PAS was first developed in 2009, there were concerns about Type 2 recipient outcomes.⁷ The KP waiting time criterion restricts Type 2 candidate access to transplant, since Type 1 candidates may have high BMIs but still qualify to accrue waiting time because of a low C-peptide. However, numerous OPTN and single center analyses indicate that outcomes of KP transplantation for Type 2 recipients may be comparable to Type 1 recipients, negating the need to limit their access to transplant.^{8,9,10,11}

Not only is the policy unfair because Type 2 diabetics with high BMIs may have comparable outcomes to Type 1 KP recipients,¹² the policy limits access to transplant for Type 2 candidates, which includes a greater proportion of minority candidates.¹³ Asians, African Americans and Hispanics represent a greater proportion of Type 2 high BMI KP candidates and SPK recipients.¹⁴

Minimal Impact on Kidney-Along

Including KP waiting time criterion and maximum allowable BMI in PAS also reflected concerns regarding the impact of PAS on kidney-alone candidates. Before any restriction was in place for Type 2 KP candidates, however, there were on average less than 9 transplants of high BMI Type 2 KP recipients every year over the course of a decade, or 87 in total.¹⁵ Review of Type 2 candidates registered for a KP transplant indicates that the number of Type 2 candidates from 2014 to 2016 has not increased greatly.¹⁶ While there is concern from the kidney community about an increase in Type 2 high BMI KP transplants negatively affecting access to transplant for kidney-alone candidates, all available data suggests the

⁶ Curry, Michael. UNOS Research, 2016 OPTN data

⁷ "Proposal to Develop an Efficient, Uniform National Pancreas Allocation System." OPTN/UNOS Briefing Paper, 2010

⁸ Curry, 2016

⁹ Wong, K., et al. "Simultaneous pancreas and kidney transplantation for type 2 diabetics." American Transplant Congress, 2016: 302

¹⁰ Forbes, 2018

¹¹ Light, J.A., & Barhyte, D.Y. "Simultaneous pancreas-kidney transplants in type I and type II diabetic patients with end-stage renal disease: similar 10-year outcomes." *Transplant Proc.* 2005 Mar;37(2):1283-4

¹² Forbes, 2018

¹³ Urban, 2017

¹⁴ Ibid

¹⁵ Redfield, 2017

¹⁶ Urban, 2017

impact on kidney-alone candidates would be minimal.¹⁷ The evidence suggests that concerns over Type 2 KP recipient outcomes and impact on kidney-alone candidates, which led to including the KP waiting time criterion and maximum allowable BMI in PAS, are no longer applicable.

Removing this barrier to transplant would increase the number of kidney-pancreas transplants (fulfilling the first OPTN strategic goal), reverse an inequitable policy and provide access to transplant for an underserved population of candidates.

Why should you support this proposal?

OPTN data analyses and review of relevant publications indicate that one of the current KP waiting time criteria limits access to waiting time accrual for candidates who may be appropriate for transplant. Substantial evidence indicates that Type 2 candidates can be successfully transplanted,^{18,19} even when these recipients have a BMI above 30.^{20,21} Additionally, minority populations represent a greater proportion of Type 2 candidates, who are disparately impacted by the inclusion in policy of this criterion compared to Type 1 candidates.²² Because the current KP waiting time criterion restricts waiting time accrual for high BMI Type 2 candidates, and non-Caucasian candidates represent a greater proportion of high BMI Type 2 candidates, the current policy may have a disproportionate impact on minority populations.²³

Eliminating the KP waiting time criterion and references to maximum allowable BMI would likely increase the number of KP transplants by allowing potential candidates greater access to transplant by virtue of being able to accrue waiting time. The solution would support a program's autonomous decision either to list or not list a patient and leaves the discretion to the physician/center in assessing whether a candidate is appropriate for transplantation. The available evidence suggests the best solution to address the problem is to eliminate the restriction preventing high BMI Type 2 candidates from accruing waiting time.

KP transplants generally have a higher LYFT (life years from transplant) score than kidney-alone transplants.²⁴ By removing a barrier to transplant, the Committee projects an increase in the total number of transplants and an increase in LYFT.

How was this proposal developed?

In 2010, the Board of Directors approved the Pancreas Allocation System (PAS) policy to bring consistency to how pancreata are allocated across the country. The 2010 PAS policy included new criteria that KP candidates would be required to meet in order to accrue waiting time. The PAS policy was implemented in 2014.

The KP waiting time criteria included a requirement that candidates be on insulin and have a C-peptide \leq 2 ng/mL, or if they are on insulin and have a C-peptide $>$ 2 ng/mL they must have a BMI below the maximum allowable BMI. The determination to either increase or lower the maximum allowable BMI is based on the percentage of active KP candidates that meet the waiting time criteria. This criterion was included because of concerns that Type 2 candidates with high BMIs would have worse outcomes.

¹⁷ Ibid

¹⁸ Sampaio, M. S., et al. "Obesity was associated with inferior outcomes in simultaneous pancreas kidney transplant." *Transplantation*. 2010 May 15; 89 (9): 1117-25. doi: 10.1097/TP.0b013e3181d2bfb2

¹⁹ Chakkerla, H., et al. "Comparison of Insulin Resistance Post Transplant among Type 2 Diabetics Receiving SPK Transplant to Type 1 Diabetics Receiving SPK and to Non Diabetics Receiving Kidney alone." *IPITA 2013 Abstracts Supplement: Transplantation: 2013*; 96: 1–155. doi: 10.1097/TP.0b013e3182a7ab68

²⁰ Bry, W., et al. "Elevated BMI does not affect outcome in Type II diabetics undergoing whole organ pancreas transplantation." *International Pancreas and Islet Transplant Association: 2013*

²¹ Laftavi, 2017

²² Urban, 2017

²³ Ibid

²⁴ OPTN/UNOS Briefing Paper, 2010

In the PAS public comment, a substantial number of pancreas professionals raised concerns that the maximum allowable BMI would restrict appropriate candidates' access to transplant.²⁵ As part of PAS implementation, the Committee was tasked to review the maximum allowable BMI every 6 months to determine if the maximum should be adjusted. The determination to either increase or lower the maximum allowable BMI is based on the following:

- If less than 10% of active KP candidates have a C-peptide > 2 ng/mL and BMI ≤ maximum, the maximum BMI is increased by 2 kg/m²
- If more than 15% of active KP candidates have a C-peptide > 2 ng/mL and BMI ≤ maximum, the maximum BMI is lowered by 2 kg/m²
- If 10% to 15% of active KP candidates have a C-peptide > 2 ng/mL and BMI ≤ maximum, the maximum BMI is not changed

After the first 6 month analysis of active KP candidates in 2014, the maximum allowable BMI was raised from 28 kg/m² to 30 kg/m². Subsequent 6 month analyses indicated the maximum BMI should be raised further because candidates with a C-peptide > 2 and BMI ≤ maximum still comprised less than 10% of the total number of active KP candidates. However, current policy states that the maximum allowable BMI cannot be modified to exceed 30 kg/m². The PAS included this cap because 30 kg/m² is the standard definition of obesity.²⁶

Modification of the BMI threshold indicated to the Committee that it needed to re-evaluate the qualifying criteria. The Committee reviewed data on the number of KP candidates by qualification status for accruing waiting time (not qualified, qualified after listing, qualified at listing), and the number of candidates who listed for a KP but are not accruing waiting time due to having a C-peptide > 2 ng/mL and BMI above the maximum. The Committee also analyzed the relationship between BMI and patient and graft survival for KP transplants (see "How well does this proposal address the problem statement" section for more detailed discussion of the data analysis).

Options Considered

The Committee discussed three options to modify policy:

1. Remove the maximum allowable BMI and the KP wait time criterion that requires candidates to be on insulin and have a BMI below the maximum if their C-peptide levels are > 2
2. Change the maximum allowable BMI to another number, or
3. Remove the maximum allowable BMI but keep or modify the table in policy limiting transplantation of high BMI Type 2 candidates

1. Remove the maximum allowable BMI and the KP wait time criterion, including insulin use

This solution would remove the KP waiting time criterion that restricts access for candidates with C-peptide levels > 2 and high BMIs, as well as for candidates not on insulin. The previous sections have demonstrated the need to remove the maximum allowable BMI and restrictions for certain candidates with C-peptide levels > 2. However, the Committee found the insulin requirement in the KP waiting time criterion follows some of the same arguments for removal of the BMI maximum: there are a few SPK candidates not currently on insulin (25 candidates from 2014 to 2016 did not meet waiting time criteria because of insulin or kidney waiting time criteria).²⁷ Removing the insulin restriction would restore transplant program discretion but be unlikely to negatively impact kidney-alone candidates because of the low number of pancreas candidates that would meet the insulin criterion. The Pancreas Committee has received several requests for exceptions for waiting time for patients not currently on insulin. These

²⁵ OPTN/UNOS Briefing Paper, 2010.

²⁶ Ibid.

²⁷ Curry, 2016.

patients typically have a history of insulin use but were taken off because of clinical complications, yet still need a transplant. Removing the insulin requirement would allow these candidates to accrue waiting time.

Removing the KP waiting time criterion restricting access based on C-peptide, BMI and insulin usage directly addresses the problems identified by the Committee. It would support a program's decision to list a patient by allowing these candidates to accrue waiting time. Available evidence suggests that the impact on kidney-alone transplants would be minimal, and review of the literature indicates certain candidates currently unable to accrue waiting time could be suitable for transplant.

2. Change the maximum allowable BMI to another number

The Committee considered raising the BMI threshold, which would allow more candidates currently restricted to accrue waiting time. However, this option does not fully address the problem, which is that having a BMI threshold and a KP waiting time criterion together unfairly restricts Type 2 candidate access to waiting time accrual and transplant without a medical basis for the exclusion.^{28,29,30} Research and evaluation of current literature indicates that Type 2 and Type 1 outcomes for high BMI recipients are comparable, and restrictions on Type 2 candidates disproportionately affect minority populations.³¹ Raising the maximum allowable BMI would alleviate part of the problem by allowing more candidates to be transplanted, but would still be unfair and leave an inequitable policy in place.

3. Remove the maximum allowable BMI and keep the table in policy that limits transplanting high BMI Type 2 candidates

The third option would limit Type 2 transplantation based on the proportion of active KP candidates with C-Peptide > 2 ng/mL and BMI ≤ 30 kg/m². This option would continue to unfairly limit transplantation for Type 2 candidates with a high BMI, and was rejected by the Committee.

Kidney Committee Feedback

In October 2017 the Committee presented the proposal to the Kidney Committee and received feedback. The Kidney Committee offered general support for the efforts of the Pancreas Committee to modify the KP waiting time criteria by raising the maximum BMI, but was concerned about the potential impact on kidney-alone candidates if removing the restriction would lead to a high number of Type 2 SPK candidates being transplanted and a negative impact for kidney-alone candidates. Because of concerns about significantly increasing transplantation of Type 2 diabetic candidates, the Kidney Committee issued a formal recommendation to increase the maximum allowable BMI to an alternative number, but not remove it.

The Committee appreciates this feedback and the concerns of the Kidney Committee. However, substantial review of the literature and data analysis indicate that impact on kidney-alone candidates would be minimal (see sections "How well does this proposal address the problem statement?" and "Which populations are impacted by this proposal?"). The Committee feels strongly that the proposed changes should make KP waiting time criteria more equitable and less arbitrary, and the proposed solution best accomplishes this goal.

Proposed Solution

The Committee supported removing the KP waiting time criterion, including the insulin use requirement and maximum allowable BMI cap for candidates with a C-peptide > 2. By removing the KP waiting time criterion, Type 1 and Type 2 diabetic candidates with high BMIs will be treated equally in their access to waiting time. SPK candidates not currently on insulin may accrue waiting time. The number of KP

²⁸ Redfield, 2017.

²⁹ Sampaio, 2010.

³⁰ Forbes, 2017.

³¹ Urban, 2017.

transplants may increase as this restriction to transplant is removed. Finally, transplant surgeons and their teams would be supported in their discretion to decide which candidates are appropriate to transplant.

How well does this proposal address the problem statement?

The problem addressed by the Committee is whether it is appropriate to restrict access to KP transplant by restricting waiting time accrual for candidates based on their BMI, insulin usage or C-peptide. The Committee reviewed evidence and performed data analyses relevant to evaluating how to modify KP waiting time criterion and whether to remove references to maximum allowable BMI.

High BMI Recipient Outcomes

Substantial evidence supports removing the maximum allowable BMI for Type 2 KP candidates to accrue waiting time. A retrospective analysis of Type 2 SPK transplants from 2004 to 2014 found that BMI did not reach significance as a risk factor for poor post-transplant outcomes.³² Comparable outcomes were achieved in patients with a BMI ≥ 30 to those with a BMI < 30 in Type 2 recipients.³³ A single center study of 44 Type 2 recipients, 9 of which had BMIs above 30, also found higher BMIs do not impact outcomes.³⁴ An abstract accepted for the American Transplant Congress (ATC) 2018 based on analysis of OPTN data performed by the Pancreas Committee reviewed patient, pancreas graft and kidney graft survivals for Type 1 and Type 2 recipients by BMI category. The 2006-2013 cohort showed no significant differences in kidney graft survival by diabetes type and BMI, although there was lower reported graft survival for Type 1 recipients with BMI > 30 compared to Type 1 recipients with overweight or normal BMIs.³⁵ The analysis indicated Type 2 SPK recipients with BMIs > 30 have similar outcomes and a maximum allowable BMI “may be an unwarranted limitation” of access to transplant for certain Type 2 recipients.³⁶

Figures 1 and 2 show graft survival out to three years for Type 1 and Type 2 recipients stratified by BMI categories from this analysis. These figures highlight that Type 2 recipients with higher BMIs may have comparable outcomes to those of Type 1 recipients in general. In fact, the analysis indicates that outcomes for Type 1 recipients with higher BMIs may be worse than Type 2 recipients with BMIs > 30 or other Type 1 recipients.

³² Redfield, 2017

³³ Ibid

³⁴ Bry, 2013

³⁵ Forbes, 2017

³⁶ Ibid

Figure 1: KI Graft Survival in SPK recipients stratified by recipient category and by BMI

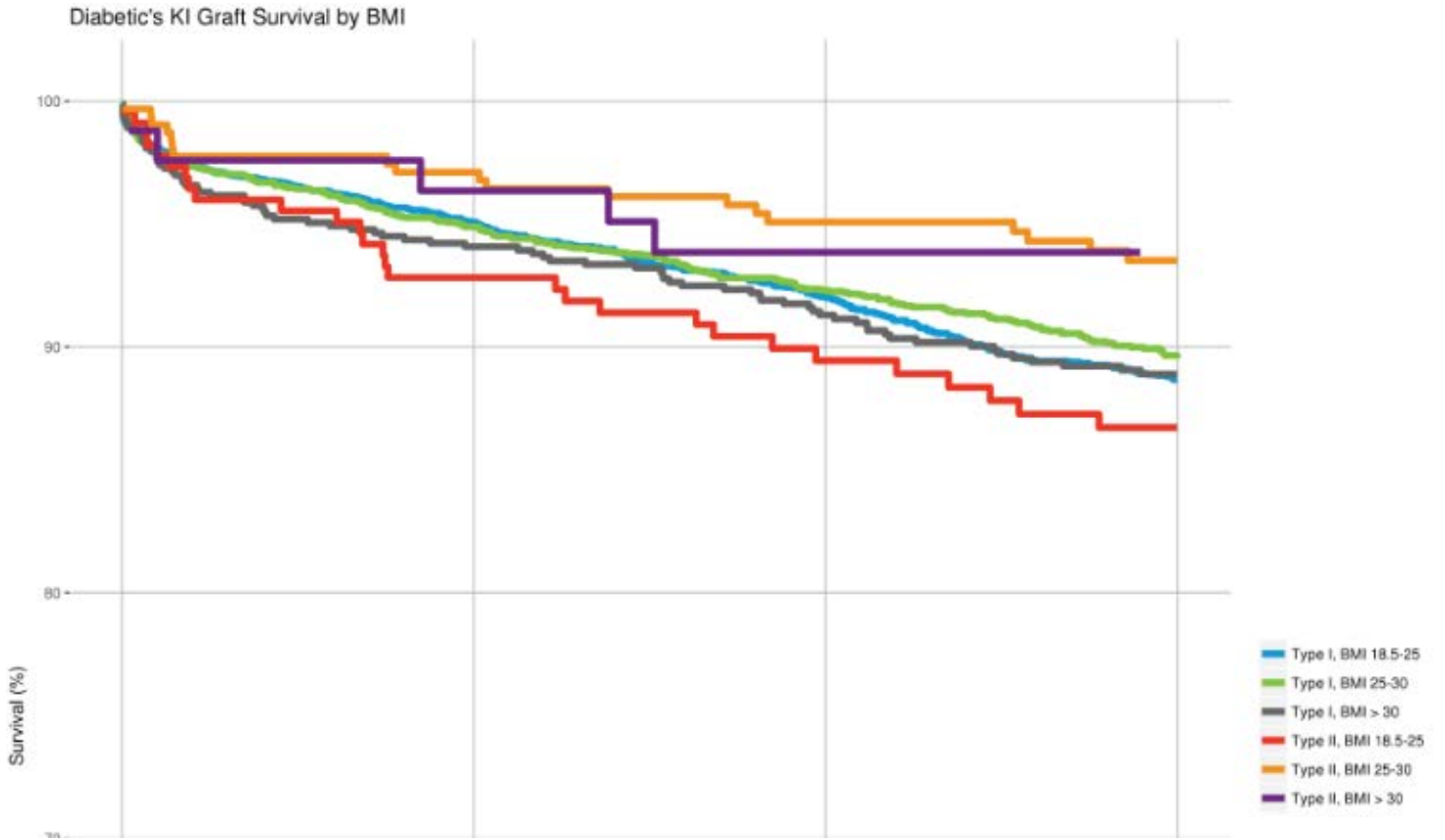
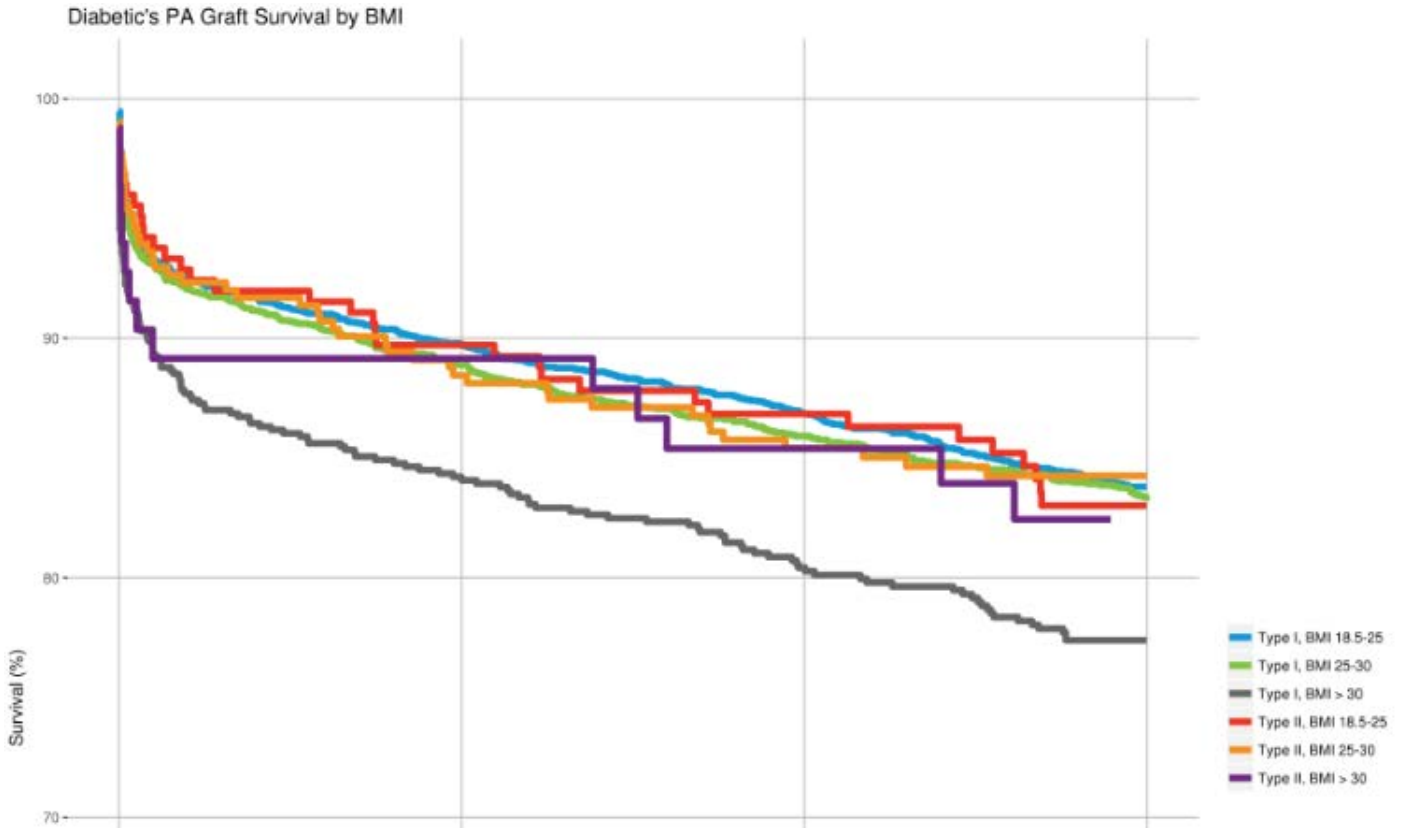


Figure 2: PA Graft Survival in SPK recipients stratified by recipient category and by BMI



The Committee also requested data on waitlist and post-transplant mortality by BMI and diabetes. The analysis showed similar waitlist mortality across BMI and diabetes type, using a cohort from 2006-2016 with two year follow up.³⁷ Figure 3 shows Type 2 recipient survival over two years, segmented by BMI.

³⁷ Curry, 2016

Figure 3: Type 2 recipient survival by BMI

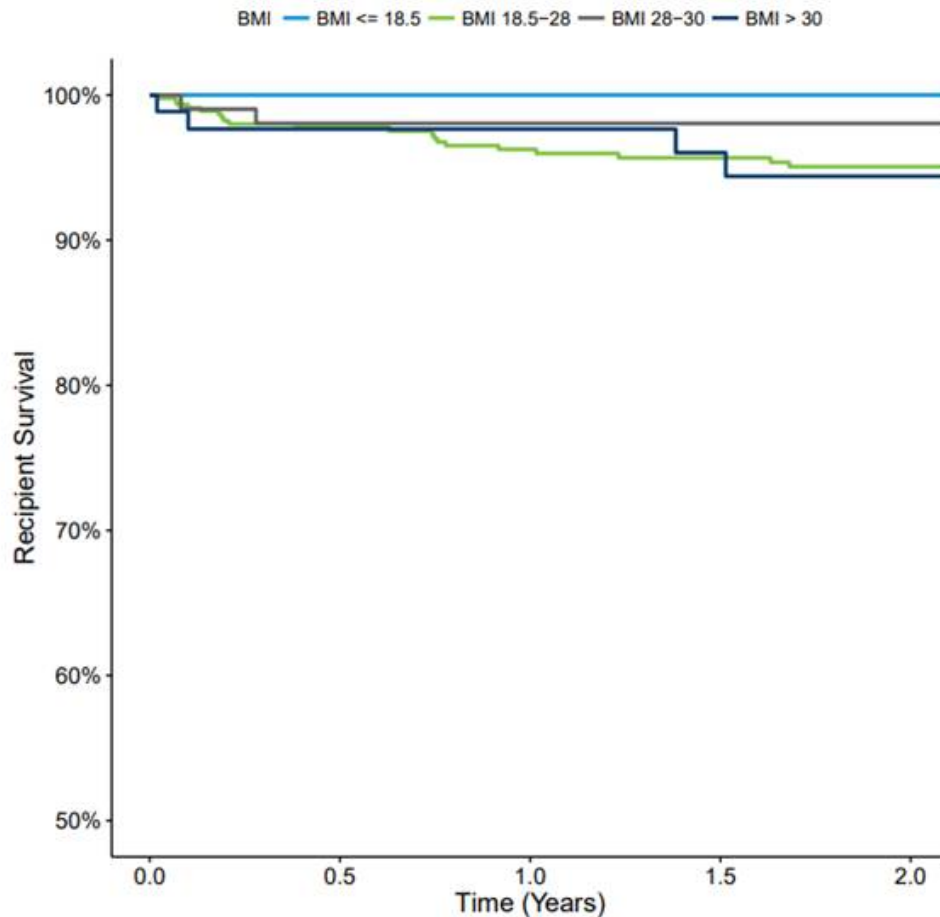


Figure 3 highlights that candidates with BMIs above 30 (n=92) and those with BMIs from 28-30 (n=114) did comparably well post-transplant as the normal BMI group (BMI 18.5-28, n=504). Type 1 post-transplant survival stratified by BMI also showed similar outcomes for candidates with BMIs > 30 or 28-30.

In a related analysis, the Committee found that 50 candidates (2%) registered for a KP transplant did not qualify for waiting time from the time PAS was implemented to October 31, 2016.³⁸ The data analysis performed at the Committee's request indicates that transplants could be increased by removing the restriction on waiting time since two percent of the KP waiting list would be able to accrue waiting time. The data also shows that Type 2 recipients with higher BMIs, whose access to transplant is currently restricted by the KP waiting time criteria, showed comparable outcomes to other SPK recipients.³⁹

Disagreement in the existing literature on the impact of BMI on transplant outcomes for both Type 1 and Type 2 patients does not provide a strong scientific foundation to actively restrict high BMI patients from receiving transplants. Certain analyses found comparable outcomes among overweight (BMI=25-30) or obese (BMI > 30) recipients and those recipients with normal BMIs (typically defined as BMI=18.5-25). An analysis by Laftavi et al. found BMI did not represent a significant risk factor for 4,465 SPK Type 1 recipients from 2009 and 2015 with follow up of at least one year.⁴⁰ The analysis indicated a correlation between age and BMI, finding the "most influential risk factors for technical failures...were increased

³⁸ Ibid

³⁹ Ibid

⁴⁰ Laftavi, 2017

donor age (over 30 years), no induction therapy and PRA level > 20%.”⁴¹ On the other hand, Sampaio et al. did find increased risk of post-transplant complications, pancreas and kidney graft loss, and patient death for higher BMI Type 1 recipients.⁴² It is important to note that although there remains concern over outcomes for high BMI Type 1 SPK recipients, Type 1 candidates with high BMIs are able to accrue waiting time, without restriction, in current policy.

Type 2 Recipient Outcomes

Since new, defined KP wait time criteria were included in PAS in part because of concerns about Type 2 recipient outcomes, the Committee reviewed the relevant literature to determine whether Type 2 recipient outcomes are inferior to those of Type 1 recipients for KP transplants. If the literature showed similar outcomes for both Type 1 and Type 2 recipients, that would indicate that there is an unfounded concern about worse outcomes in Type 2 recipients and reduced organ utility.

Emerging data from several single center studies over the last decade support the notion that having Type 2 diabetes is not an absolute contraindication for an SPK transplant.^{43,44,45,46} A single center study from 2002 to 2015 found 73 Type 2 SPK recipients “maintained long-term euglycemia and stable renal function.”⁴⁷ A retrospective analysis from 2000 to 2007 comparing 582 Type 2 recipients and 6,141 Type 1 recipients found similar patient and graft survival.⁴⁸ Another retrospective analysis found that the time period in which the transplant was performed was significant in correlation to patient and graft survival: Type 2 SPK transplants from 2009-2015 performed significantly better than 2002-2008.⁴⁹ The paper concluded that patient and graft outcomes after SPK for Type 2 recipients significantly improved over time.⁵⁰

Substantial review of the literature and evidence gathered by the Committee indicates that the KP waiting time criterion is arbitrary in targeting only Type 2 recipients with higher BMIs and should be removed. The solution being pursued by the Committee is in accordance with current literature indicating comparable outcomes may be achieved in Type 2 diabetic SPK recipients. Although there are still concerns about transplanting both Type 1 and Type 2 high BMI candidates, policy should not restrict access for one group without compelling evidence to do so; instead, discretion should lie with the transplant surgeon and transplant team.

Impact on Kidney-Along Candidates

The Kidney Committee expressed concern about whether a potential increase in KP transplants resulting from this policy change would impact access for kidney-alone candidates, particularly pediatric kidney-alone candidates. The main concern of the Kidney Committee is that there could be a substantial increase in the number of Type 2 recipients after removal of the KP waiting time criterion and maximum allowable BMI. This could decrease organ offers for pediatric kidney-alone candidates because SPK candidates receive offers prior to pediatric kidney-alone candidates. Instead of removing the KP waiting time criterion and accompanying references to the maximum BMI, the Kidney Committee recommended raising the threshold to a fixed BMI.

⁴¹ Ibid

⁴² Sampaio, 2010

⁴³ Weems, P., & Cooper, M. “Pancreas transplantation in type ii diabetes mellitus.” *World J Transplant.* 2014 Dec 24; 4(4): 216–221. doi: 10.5500/wjt.v4.i4.216

⁴⁴ Bry, 2013

⁴⁵ Chakkerla. 2013

⁴⁶ Nath, et al. “Outcomes of Pancreas Transplants for Patients with Type 2 Diabetes Mellitus.” *Clin Transplant.* 2005 Dec;19(6):792-7

⁴⁷ Wong, 2016

⁴⁸ Samaio, 2011

⁴⁹ Laftavi, 2017

⁵⁰ Ibid

The Pancreas Committee appreciates the Kidney Committee's feedback and their concerns. However, available evidence indicates that transplantation of Type 2 candidates would remain a small number of pancreas transplants performed each year. Figure 4 shows monthly KP registrations and recipients from 2006 to 2016, stratified by diabetes type.

Figure 4: Adult KP Registrations and Recipients by Year and Diabetes Type, 2006-2016

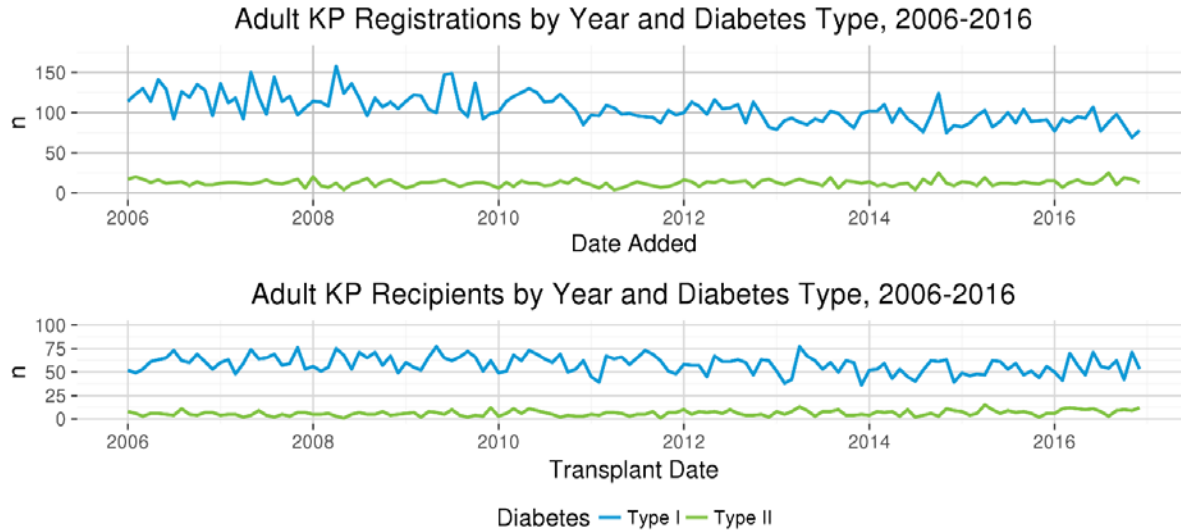


Figure 4 shows no increasing trends in the number of monthly Type 2 registrations and Type 2 recipients, even before there was a BMI restriction for Type 2 candidates. Meanwhile, Type 1 registrations have decreased over time. It is important to reiterate that until PAS was implemented in 2014, there was no restriction on any candidates accruing waiting time, yet programs did not perform many KP transplants in Type 2 candidates and the number of high BMI candidates with Type 2 diabetes that were transplanted remained on average less than 9 transplants a year.⁵¹ Thus, the concern regarding a trend in the number of Type 2 KP candidates increasingly being transplanted is not borne out by the data.

Another important point to consider regarding the concern that Type 2 KP transplantation could increase significantly is the behavior of programs in choosing which candidates to list for KP transplants. Based on the new pancreas graft failure definition that was implemented in February 2018, programs will be reviewed in the future for pancreas graft outcomes in addition to kidney graft outcomes and patient outcomes, which form the basis of current program specific reports (PSRs).⁵² Choosing inappropriate candidates for KP transplantation resulting in substandard outcomes, regardless of diabetes type, could reflect poorly on a program and may not be in the program's best interest. As the data before PAS was implemented indicates, removing this restriction is not likely to lead to abuse by centers choosing to transplant inappropriate candidates or to a significant increase in transplanting Type 2 diabetics with KPs.

After reviewing these data, the Committee determined that removing the KP waiting time criterion and maximum allowable BMI is the appropriate solution for achieving its goal to increase KP transplantation by removing a barrier to accruing waiting time for candidates who may be appropriate for transplantation.

Was this proposal changed in response to public comment?

This proposal was distributed for public comment during a 60-day period from January 22 through March 23, 2018. Overall, a majority of commenters supported the proposal. Eight regions supported the

⁵¹ Redfield, 2017

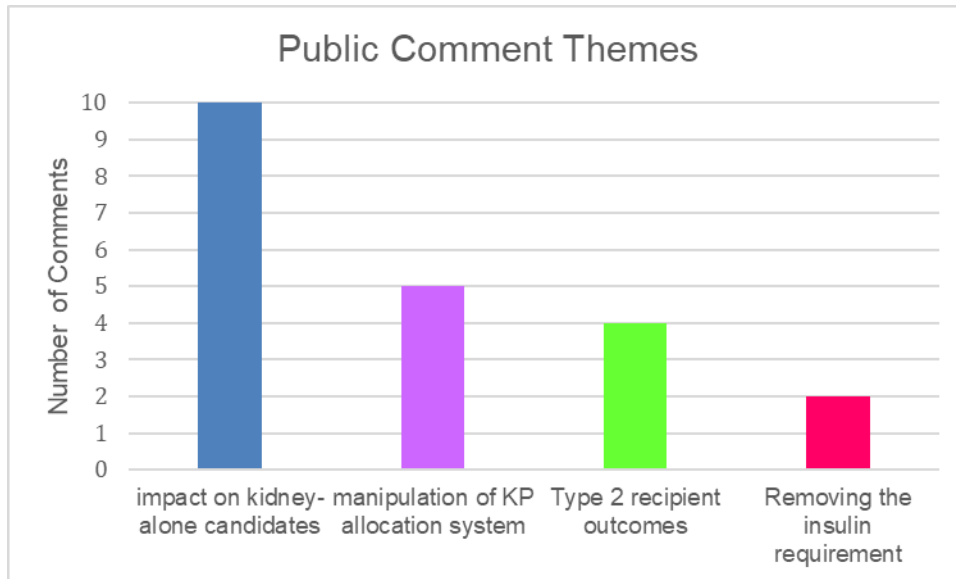
⁵² OPTN/UNOS, Proposal for the Definition of Pancreas Graft Failure, 2014

proposal and three opposed it. The OPTN/UNOS Operations and Safety Committee supported the proposal, as did the OPTN/UNOS Minority Affairs Committee (MAC). The Kidney Committee did not support the proposal. All of the professional organizations that reviewed the proposal – American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), American Society for Histocompatibility and Immunogenetics (ASHI), The Organization for Transplant Professionals (NATCO), International Pancreas and Islet Transplant Association (IPITA) – supported it. AST and NATCO, in their comments, noted that the Committee should closely monitor the impact of the change. The Committee carefully considered each theme and concern from public comment. Besides the concerns that the Committee responds to below, the proposal also received positive feedback indicating support for the solution offered by the Committee: in particular, support for removing a clinically unnecessary limitation on waiting time accrual.

Figure 5 shows the most common concerns and comments raised during public comment:

1. Impact on kidney-alone candidates
2. Manipulating the KP allocation system
3. Type 2 recipient outcomes
4. Removing the insulin requirement

Figure 5: Public Comment Themes



Below is a review of each public comment theme.

1. Impact on kidney-alone candidates

The Kidney Committee, MAC, and several regions expressed concern that removing the restriction for C-peptide > 2, high BMI candidates could lead to an increase in Type 2 SPK transplants that decreases the number of offers to local kidney-alone candidates. In particular, concern was expressed about the potential impact on pediatric candidates and kidney-alone candidates with an EPTS < 20. If Type 2 high BMI KP candidates receive more kidney offers, healthier kidney-alone candidates may wait longer for a transplant. Given the large Type 2 diabetic population, several commenters suggested raising the maximum BMI instead of eliminating it, then monitoring the impact of this change before removing the maximum altogether. Some commenters felt that eliminating the maximum BMI was too drastic given the potential impact on the kidney-alone population.

Committee Response:

The Committee carefully considered the potential impact on the kidney-alone population by looking at the number of Type 2 high BMI candidates that were transplanted before the waiting time criterion restricting their access was put into place in 2014. On average, there were less than 9 transplants each year of Type 2 SPK recipients with BMIs > 30.53 After public comment, the Committee requested data on the distribution of BMIs for both Type 1 and Type 2 SPK recipients in the pre-PAS era (Figure 6).

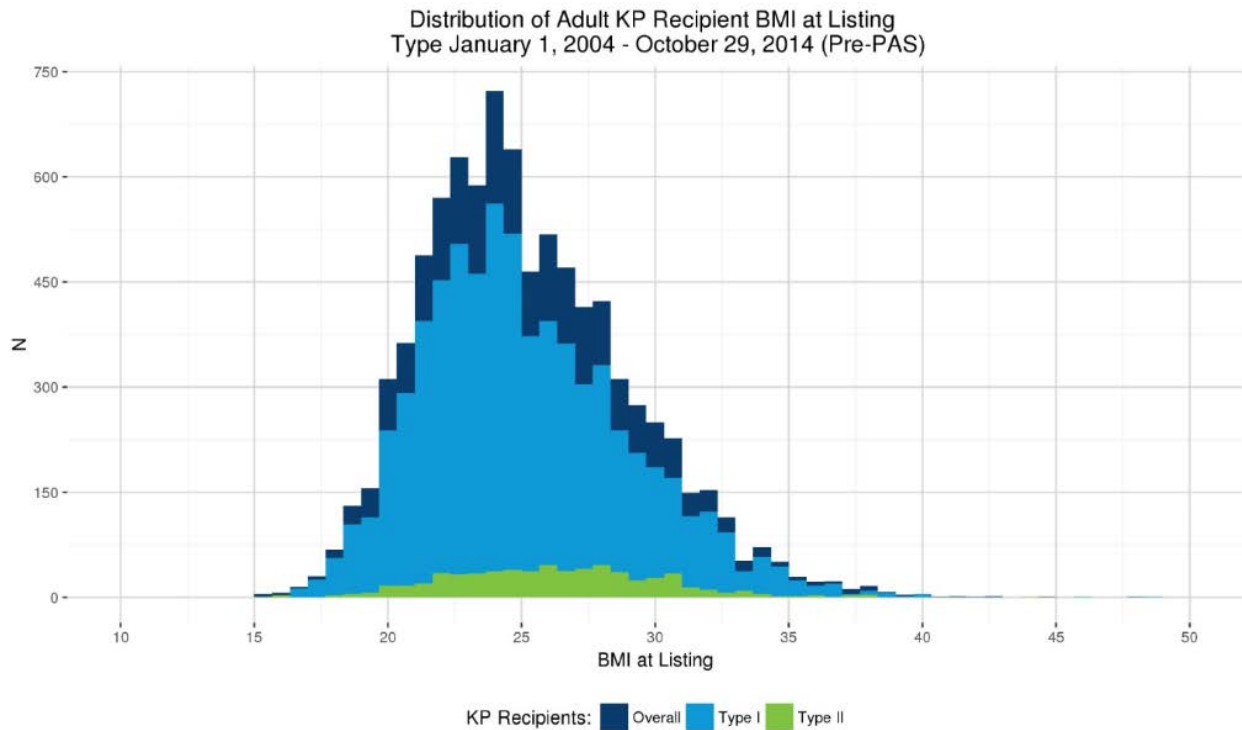
Figure 6: Adult KP Recipient BMI at Listing, 2004-2014

Figure 6 shows that the Type 2 transplanted SPK population is not significantly different than the distribution of the Type 1 transplanted SPK population from 2004 to 2014. The graph shows that there were very few Type 2 diabetic patients transplanted who had a BMI > 30 before there were any restrictions on waiting time accrual. The graph also shows, however, that there are many more high BMI Type 1 patients getting SPK transplants than Type 2 patients getting SPKs at all. This highlights that most high BMI candidates can get transplanted without any restriction on their waiting time, and the low number of high BMI Type 2 candidates getting transplanted pre-PAS supports the Committee's position that the change to KP waiting time is unlikely to have a significant impact on kidney-alone populations.

The Committee also considered that the proposed solution to eliminate the BMI restriction received the support of 8 of 11 regions, all organizations that considered the proposal (AST, ASTS, NATCO, IPITA, ASHI), and two of three OPTN/UNOS committees. The Committee agreed that the few Type 2 high BMI SPK candidates should be able to accrue waiting time if considered suitable for transplant by their programs. In response to the concerns that were raised, the Committee supports monitoring kidney-alone post-transplant outcomes for patient and graft survival, as well as pre vs. post-policy trends in organ offers to pediatric kidney-alone candidates as part of the implementation of this proposal.

2. Concern about manipulating the KP allocation system

Some commenters expressed concern that programs could manipulate the KP transplant allocation system by accepting a KP for a Type 2 high BMI KP candidate, decline the pancreas but keep the kidney and transplant it into the candidate. Kidney-alone candidates have longer waiting times, so Type 2 high BMI candidates on the kidney waiting list could be listed for a KP to get a kidney sooner.

Committee Response:

The Committee carefully considered this concern and has requested data to examine whether this type of manipulation may occur. However, the method of KP and kidney allocation indicates that this behavior is extremely unlikely. If a program accepts a KP for a candidate, then discovers the pancreas is not viable for transplant, the program must alert the OPO. The OPO decides whether the kidney stays at the center or not. Depending on the cold ischemia time, the OPO may ask that the program send the kidney back. If the cold ischemia time is too long such that additional travel would make the organ unviable, the OPO may accept the program transplanting it into the original candidate. Thus, the program risks damaging its relationship with its local OPO if it repeatedly accepts a kidney-pancreas only to reject the pancreas very late in the process. Also, a program attempting to game the system does not get to decide what to do with the kidney; it is up to the host OPO to further allocate the organ according to Policy 5.9 Released Organs.

There is no evidence the Committee is aware of indicating this type of manipulation occurs now. The Committee will examine many programs actually transplant just the kidney after accepting both the kidney and pancreas to see how widespread the opportunity for gaming is. However, the Committee recognizes and affirms that KP programs often have legitimate clinical reasons for determining a pancreas is not viable upon examination. Therefore, data indicating that programs sometimes reject the pancreas is in itself not evidence of gaming. The Committee looks forward to sharing the analysis currently being performed with the Board once it is completed in May.

The risk incurred by the program by this type of behavior, in potentially damaging its relationship with its local OPO, other transplant programs, the OPTN and the broader transplant community, indicates this behavior is unlikely to occur. However, the Committee considered these concerns in its decision to reinstate insulin usage as a requirement for KP waiting time criteria. See Public Comment Theme 3 – Require insulin usage – for further discussion.

3. Type 2 recipient outcomes

Although the Committee identified substantial evidence indicating that Type 2 recipients with higher BMIs can have similarly positive outcomes to other SPK recipients, certain commenters still felt concern that transplanting organs in Type 2 high BMI candidates would not be the best utilization of the organs.

Committee Response:

The Committee reviewed substantial literature and performed data analyses to determine whether Type 2 outcomes or high BMI outcomes suffer compared to other SPK recipients. Figures 2 and 3 in this proposal indicate that Type 2 candidates with a BMI above 30 can have comparable kidney and pancreas graft outcomes. The Committee acknowledges that a candidate's BMI is certainly a factor in determining whether the transplant would be successful, but this is true for candidates with C-peptide < 2 as well. Many factors affect whether a candidate would be appropriate for transplant, including BMI, but BMI does not serve as an absolute contraindication for transplant. Factors such as age can be a more significant factor than BMI for predicting technical failures,⁵⁴ yet KP waiting time provides no restriction on age to accrue waiting time (nor would that be appropriate).

⁵⁴ Laftavi, 2017.

In addition, implementation of the pancreas graft failure definition on February 28, 2018 will ensure that programs are reviewed on their pancreas graft outcomes going forward.⁵⁵ This serves as a disincentive for programs to transplant candidates that may be clinically more susceptible to post-transplant complications or poor graft outcomes.

4. Require insulin usage

Certain reviewers of the KP waiting time proposal questioned the public comment proposal's change to remove the requirement for a candidate to be on insulin in order to accrue waiting time. For these commenters, being on insulin represented a baseline requirement for a candidate receiving KP offers, and should be reinstated in the waiting time criteria.

Committee Response:

The Committee originally considered whether to remove the insulin usage requirement before public comment, and concluded it was appropriate to remove it because certain candidates may not currently be on insulin but still require a KP transplant. These cases are rare but do occur.⁵⁶ Post-public comment, however, the Committee considered adding insulin usage back in as a requirement for KP waiting time. The Committee acknowledged the concerns about having candidates not on insulin accruing waiting time. The Committee also recognized that adding insulin usage to the KP waiting time criteria may address concerns with manipulation as well.

Public comment themes included concerns about removing insulin usage as a requirement and concerns about manipulating the allocation system. If the Committee reinstated insulin as a requirement in the KP waiting time criteria, it would be responding to both of these themes. Demonstrating that candidates are on insulin would provide evidence that the candidate does indeed need the pancreas as well as the kidney, lessening fears of manipulation. Including this criteria increases the evidence that the patient needs an SPK transplant. The Committee agreed that adding insulin back in as a requirement for KP waiting time accrual would be appropriate.

The Committee thanks all commenters for their thoughtful feedback and consideration of this proposal.

Modifications Considered

Change Table 11-1

In addition to the original proposal to remove the 3rd KP waiting time criterion, the Committee considered modifying the table in policy to change the percent of active KP candidate. See Figure 7 for the table:

Figure 7: Table 11-1

Table 11-1: Maximum Allowable BMI

If the percent of active kidney-pancreas candidates that meet criterion 3.b:	Then the OPTN Contractor will:
Is greater than 15% nationally	Reduce the maximum allowable BMI by 2 kg/m ²
Is less than 10% nationally	Increase the maximum allowable BMI by 2 kg/m ²

⁵⁵ OPTN/UNOS, Proposal for the Definition of Pancreas Graft Failure, 2014.

⁵⁶ Curry, 2016.

The Committee discussed increasing the percentage of active KP candidates that can meet criterion 3.b (on insulin and having a C-peptide level > 2 but a BMI < 30) before the maximum allowable BMI is reduced. However, no Committee members supported keeping the adjustable BMI and modifying the table to change the percentage of KP candidates that meet the criteria. This option was considered confusing and perpetuating a complicated and non-transparent policy.

Fixed BMI

Some commenters felt that a more cautious approach would be to gradually raise the maximum BMI instead of removing the requirement altogether. The Committee considered raising the maximum allowable BMI instead of eliminating it before sending the proposal out for public comment in January. The Committee decided against this option since it would have less of an impact and would still leave in place a policy that, in the Committee's opinion, was arbitrary and unfair by allowing Type 1 and not Type 2 high BMI candidates to accrue waiting time.

After public comment, the Committee reconsidered modifying the maximum allowable BMI instead of eliminating it altogether. In particular, the Committee considered making the BMI a fixed number. Currently, the BMI may fluctuate every 6 months depending on the percentage of active KP candidates that have C-peptide levels > 2 and BMI below or equal to the maximum according to *Policy 11.3.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old*. The Committee discussed how this system is very confusing for the community in that members of the community may not know what the current BMI is, since policy does not specify the value. There could be scenarios where eligible candidates may not realize they are able to accrue waiting time, and their programs do not list them for a KP transplant.

The Committee felt a fixed BMI would be an improvement on the current system, in which the BMI can fluctuate and programs may not know what constitutes current eligibility for high C-peptide candidates. However, a significant portion of the Committee agreed that a fixed BMI would not adequately address the issues identified by the Committee of inequity and fairness. Raising the maximum BMI to a fixed number would leave an unfair restriction on waiting time accrual for certain candidates, a restriction that is not based on scientific consensus or equity considerations. As Figure 6 shows, the number of high BMI Type 1 recipients greatly outnumbered high BMI Type 2 recipients from 2004 to 2014.

After careful review and discussion, the Committee agreed that a BMI restriction on Type 2 candidates accruing waiting time would be inappropriate to include in policy.

Reinstate Insulin Requirement

The Committee acknowledged the concerns expressed during public comment regarding candidates not on insulin accruing waiting time. Most Committee members supported at least having a history of insulin use as a requirement in the KP waiting time criteria. However, doing so might mean modification to TIEDI® forms, which often requires additional administrative steps prior to implementation. In a straw poll to assess support for either keeping or removing the insulin requirement, a large majority of Committee members supported keeping the requirement as a helpful compromise that may address several concerns raised in the public comment themes.

Post-Public Comment Changes

Given the near-unanimous support for adding back in the insulin requirement, the Committee discussed two main options for modifying the KP waiting time criteria:

1. Require insulin but remove the BMI requirement and references to the maximum BMI. This alternative is identical to the original proposal except it puts insulin usage back as a requirement for KP waiting time accrual.
2. Require insulin and change the BMI requirement so candidates with C-peptide levels > 2 would have to meet a fixed BMI threshold. The BMI would no longer fluctuate, and all candidates with C-peptide levels > 2 would have to meet this BMI requirement.

Ultimately, Committee members unanimously agreed to send option 1 to the Board. Committee members agreed that it would be appropriate to require KP candidates to be on insulin in order to accrue waiting time, since this would demonstrate the candidate’s need for a pancreas transplant and lessen any perception of manipulation of the KP allocation system by programs that wanted the kidney but not the pancreas. Committee members felt that any number chosen for the fixed BMI threshold would still be arbitrary, and agreed that it was inappropriate to require a certain BMI just for candidates with C-peptide levels > 2. This alternative is closest to the solution that went out for public comment, which received support from all of the organizations that reviewed it, as well as 8 of 11 regions.

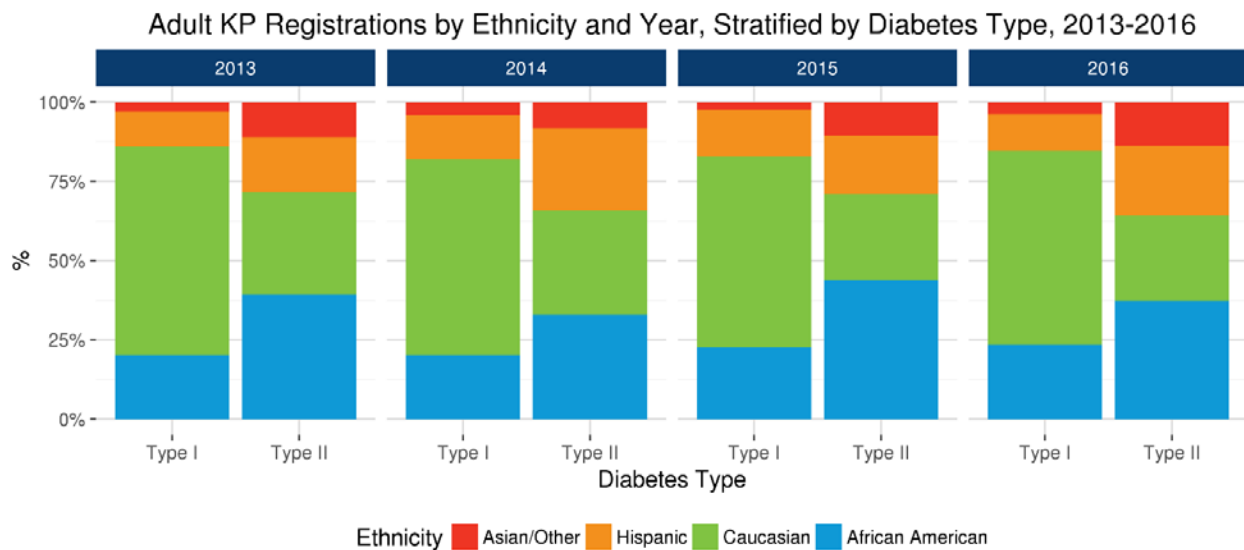
Which populations are impacted by this proposal?

Minority KP Candidates

This proposal would increase access for minority populations who represent a larger proportion of Type 2 diabetic KP candidates and recipients. African Americans represented 37.3% of Type 2 adult KP candidates but only 23.4% of Type 1 adult KP candidates in 2016.⁵⁷ Latinos represented 21.8% of Type 2 adult KP candidates and 11.6% of Type 1 adult KP candidates. Asian and other ethnicities represented 13.8% of Type 2 adult KP candidates and only 3.8% of Type 1 adult KP candidates for 2016. By contrast, Caucasians were over-represented as Type 1 KP candidates: in 2016, Caucasians represented 27% of the Type 2 KP candidates and 61.2% of the Type 1 candidates. These trends are seen for adult KP recipients as well.⁵⁸

Figure 8 shows that minority populations represent a greater proportion of Type 2 candidates when compared to Type 1 candidates for KP, and that these proportions have not substantially changed over a recent four year period. Similarly, Figure 9 shows that the proportion of minority KP Type 2 recipients is greater than minority KP Type 1 recipients from 2013 to 2016.

Figure 8: Adult KP Registrations by Ethnicity and Year, Stratified by Diabetes Type, 2013-2016



⁵⁷ Urban, 2017.

⁵⁸ Ibid.

Figure 9: Adult KP Recipients by Ethnicity and Year, Stratified by Diabetes Type, 2013-2016

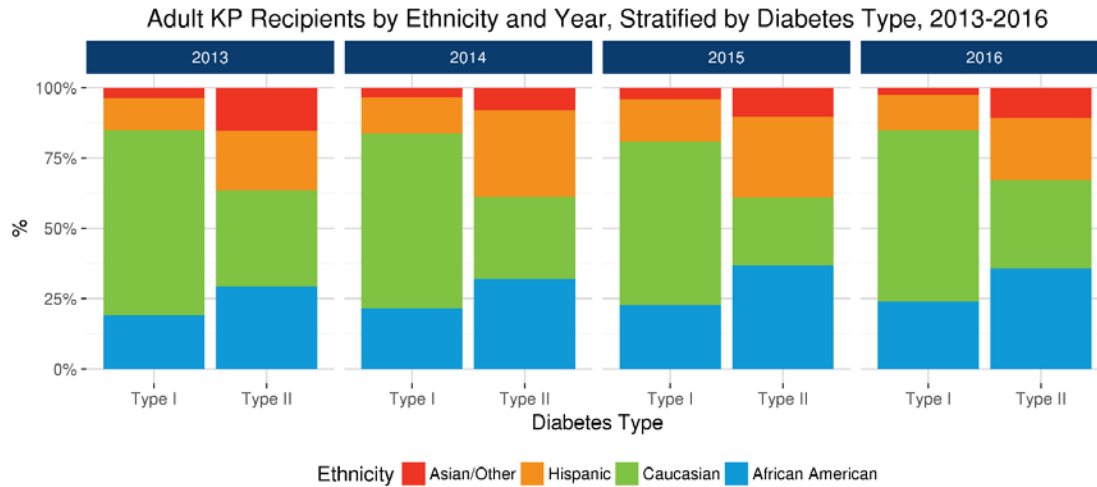
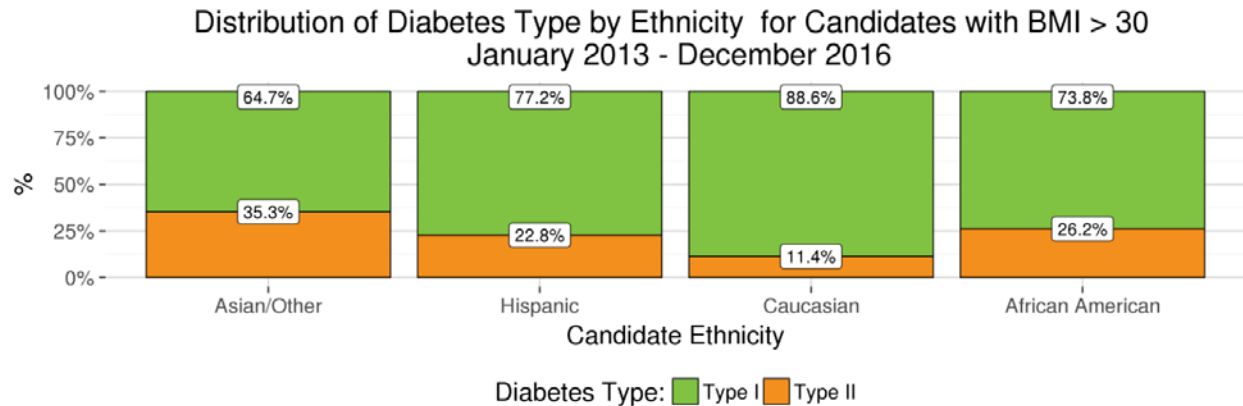


Figure 10 shows that the proportion of minority populations who would benefit from removing the KP waiting time criterion limiting waiting time accrual for Type 2 candidates with a BMI > 30 kg/m² may be greater than the proportion of Caucasian candidates who would benefit. This graph shows that a higher percentage of Asian, Hispanic and African American candidates with BMI > 30 kg/m² are Type 2 diabetics, and are thus directly impacted by the current KP waiting time criterion. Eliminating this restriction for candidates with Type 2 diabetes may increase relative access to pancreas transplantation for certain minority patients, by allowing them to accrue waiting time.

Figure 10: Distribution of Diabetes Type by Ethnicity for Candidates with BMI > 30, 2013-2016



Because the KP waiting time criterion limits access to transplant for Type 2 candidates with BMI > 30 kg/m², a population that is more highly represented by minority populations, removing this restriction would improve equity in access to transplant by ethnicity. The proposed solution aligns with evidence suggesting that race and C-peptide should not be barriers to SPK transplantation.^{59,60}

Kidney-Along and Pediatric Candidates

The Kidney Committee expressed concern that modifying KP waiting time criteria could have a negative impact on the kidney-alone population, particularly pediatric candidates. The Kidney Committee

⁵⁹ Light, J.A., et al. "Successful long-term kidney-pancreas transplants regardless of C-peptide status or race." *Transplantation*. 2001 Jan 15;71(1):152-4.

⁶⁰ Light, 2005.

suggested the Pancreas Committee examine whether the data showed a trend in increasing transplantation of Type 2 candidates, which could indicate that there could be an impact on kidney-alone candidates. However, OPTN data indicates that trend was not seen in the analysis of Type 2 and Type 1 candidates and recipients over the last decade (see Figure 4: Adult KP Registrations/Recipients by Year and Diabetes Type, 2006-2016). Instead, the data shows some monthly and quarterly fluctuation but an overall consistent low number of Type 2 SPK candidates and recipients.⁶¹

The Committee does not foresee that this proposal would negatively impact pediatric kidney-alone candidates based on the available data that indicates low transplantation numbers for Type 2 candidates with high BMIs. Before PAS was implemented in 2014, the community chose appropriate candidates for transplant despite no restriction on BMI, C-peptide or insulin usage. There were only 87 Type 2 KP recipients transplanted with BMIs ≥ 30 from 2004-2014,⁶² which averages to 9 transplants per year *nationally*, when there was no limitation on candidate waiting time criterion.

All available information indicates the impact on kidney-alone candidates, including pediatric kidney-alone candidates, would be minimal.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* Removing the maximum allowable BMI and modifying the KP waiting time criterion is expected to increase the number of candidates who currently are not listed because they do not meet criteria for accumulating waiting time. In 2015, 25% of pancreata recovered for transplant were discarded. By enhancing access for candidates currently prevented from accruing waiting time, this proposal may reduce the pancreas discard rate and increase the total number of KP transplants.
2. *Improve equity in access to transplants:* Removing the maximum allowable BMI from the KP waiting time criterion for accumulating waiting time would increase access to transplant for a population of candidates with a C-peptide > 2 and BMI > 30 , who currently cannot accumulate waiting time. Additionally, since Asians, African Americans and Hispanics represent a greater proportion of Type 2 high BMI candidates, modifying this KP waiting time criterion may improve equity by eliminating a potential barrier to transplant for vulnerable populations by allowing these candidates to accrue waiting time.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

How will the OPTN implement this proposal?

This proposal requires programming in UNetSM because it involves modifications to managing KP registrations within WaitlistSM. Specifically, C-peptide and BMI would be removed from the KP Waiting time logic in WaitlistSM. UNOS IT provides cost estimates for each proposal that will need programming to implement, ranging from small to enterprise. The IT estimate for this proposal is small.

The OPTN will follow established protocols to inform members and educate them on any policy changes through Policy Notices posted on the OPTN website and in Transplant Pro.

⁶¹ Urban, 2017

⁶² Redfield, 2017

How will members implement this proposal?

This proposal will not impact histocompatibility labs.

For OPOs, the potential for an increase in pancreata recovered could impact the budget process, but not substantially.

Transplant hospitals will need to educate staff regarding the change in policy. Staff will need to be aware of the changes to KP waiting time criteria. This will affect their procedures regarding candidate recruitment and listing.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

The proposed language will not require new routine monitoring of OPTN members. If the C-peptide and BMI criteria for kidney-pancreas candidates are removed from policy, then monitoring of these criteria would also be removed from routine site surveys.

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

The Committee will formally evaluate the impact of the proposal approximately 6 months, 1 year, and 2 years post-implementation. Analyses after 2 years will be performed at the request of the Committee. The OPTN will monitor the following data, and any other subsequently requested by the Committee to assess the impact of this policy:

1. Pre vs post policy trends of Type 1 and Type 2 KP candidates and recipients, including BMI, C-peptide, and insulin usage.
2. Pre vs. post policy trends of kidney-alone candidates and recipients stratified by age.
3. KP post-transplant outcomes for patient survival as well as pancreas and kidney graft survival, stratified by donor and recipient characteristics identified by this proposal including, but not limited to, Type 1 and Type 2 diabetes, BMI, and ethnicity.
4. Kidney-alone post-transplant outcomes for patient and graft survival, stratified by age as well as overall.
5. Pre vs. post-policy trends in organ offers to pediatric kidney-alone candidates.

Policy or Bylaws Language

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

1 **RESOLVED, that changes to Policies 11.3.B (Kidney-Pancreas Waiting Time Criteria for**
2 **Candidates At Least 18 Years Old) and 11.3.D (Waiting Time Assignments for Kidney, Kidney-**
3 **Pancreas, Pancreas, and Islet Candidates), as set forth below, are hereby approved, effective**
4 **pending implementation and notice to OPTN members.**

5 6 **11.3.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18** 7 **Years Old**

8 If a kidney-pancreas candidate is 18 years or older on the date the candidate is registered for a
9 kidney-pancreas, then the candidate begins to accrue waiting time once the candidate has met all
10 of the following conditions:

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- 12 1. The candidate is registered for a kidney-pancreas.
 - 13 2. The candidate qualifies for kidney waiting time according to *Policy 8.4: Waiting Time*.
 - 14 3. The candidate is on insulin, ~~meets at least one of the following criteria:~~
 - 15 a. ~~Is on insulin and C-peptide less than or equal to 2 ng/mL~~
 - 16 b. ~~Is on insulin and C-peptide greater than 2 ng/mL and has a body mass index (BMI) less~~
17 ~~than or equal to the maximum allowable BMI.~~

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19 Once a kidney-pancreas candidate begins to accrue waiting time, the candidate will remain
20 qualified for waiting time, ~~unless the candidate was registered for a kidney-pancreas prior to~~
21 ~~implementation of this policy. A candidate who was registered for a kidney-pancreas, and~~
22 ~~accrued waiting time prior to implementation of this policy, will remain qualified if the candidate~~
23 ~~qualifies for kidney waiting time according to *Policy 8.4: Waiting Time*.~~

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25 The maximum allowable BMI, for accruing waiting time, for a kidney-pancreas candidate, who is
26 at least 18 years old at the time of kidney-pancreas registration, is 28 kg/m². Every six months,
27 the OPTN Contractor will determine the percent of kidney-pancreas candidates that meet criterion
28 3.b above. The OPTN Contractor will then modify the maximum allowable BMI according to ~~Table~~
29 ~~11-1~~ below:

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31 **Table 11-1: Maximum Allowable BMI**

If the percent of active kidney-pancreas candidates that meet criterion 3.b:	Then the OPTN Contractor will:
Is greater than 15% nationally	Reduce the maximum allowable BMI by 2 kg/m²
Is less than 10% nationally	Increase the maximum allowable BMI by 2 kg/m²

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33 The OPTN Contractor may not modify the maximum allowable BMI to exceed 30 kg/m². If the
34 OPTN Contractor modifies the maximum allowable BMI, it must publish the modification and
35 notify all kidney programs and pancreas programs.

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37 Once a kidney-pancreas candidate qualifies for waiting time, the candidate will remain qualified
38 for waiting time regardless of any changes to the maximum allowable BMI.

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~~For candidates who qualify for kidney-pancreas waiting time, waiting time will begin when the candidate qualifies for waiting time according to this Policy. Transplant programs must document when and how a kidney-pancreas candidate qualified for waiting time.~~

11.3.D Waiting Time Assignments for Kidney, Kidney-pancreas, Pancreas, and Islet Candidates

The OPTN Contractor may assign multi-organ candidates waiting time from one waiting list to another waiting list according to *Table 11-2* below.

Table 11-21: Waiting Time Assignments for Multi-organ Candidates

From this registration:	To this registration:
Kidney	Kidney-pancreas; if criteria in <i>Policy 11.43.B: Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old</i> are met.
Kidney	Pancreas
Kidney-pancreas	Kidney
Kidney-pancreas	Pancreas
Pancreas	Pancreas -Islets; if criteria in <i>Policy 11.3.D.i</i> below are met.
Pancreas -Islets	Pancreas; if criteria in <i>Policy 11.3.D.ii</i> below are met.

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Waiting time accrued by an isolated pancreas candidate or ~~an pancreas-islet candidate~~ while registered on the waiting list will not be assigned to the listing for a combined kidney-pancreas transplant or an isolated kidney transplant unless the candidate qualifies for a waiting time modification according to *Policy 3.7: Waiting Time Modifications*.

Waiting time accrued by ~~an pancreas-islet candidate~~ while registered on the waiting list will not be assigned to the registration for a combined kidney-pancreas transplant or an isolated kidney transplant except as outlined in *Policy 3.7: Waiting Time Modifications*.

Additionally, a kidney-pancreas candidate who received a kidney transplant and subsequently registered on the pancreas or ~~pancreas-islet~~ waiting list will be assigned waiting time beginning on the *earliest* of the following dates:

1. The date the candidate registered for a pancreas transplant.
2. The date the candidate registered for a kidney-pancreas transplant.
3. The date the candidate began accruing waiting time for a kidney-pancreas transplant.

11.3.D.i Criteria to assign Pancreas Waiting Time to Islet Waiting Time

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Waiting time accrued by an isolated pancreas transplant candidate while registered on the waiting list will be assigned to the registration for ~~an pancreatic-islet cell~~ transplant after consideration and approval of a request for transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that the transfer is reasonable and is in the candidate's best interest, and comply with other application requirements set by the Committee. These requests, along with decisions of the Pancreas Transplantation Committee, will be reported to the Board of Directors retrospectively.

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11.3.D.ii Criteria to assign Islet Waiting Time to Pancreas

Waiting time accrued by an islet cell-transplant candidate while registered on the waiting list will be assigned to the registration for an isolated pancreas transplant after consideration and approval of a request for transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that the transfer is reasonable and is in the candidate's best interest, and comply with other application requirements set by the Committee. These requests, along with decisions of the Pancreas Transplantation Committee, will be reported to the Board of Directors retrospectively.

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