OPTN | UNOS

Public Comment Proposal

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

Affected Policies:	*11.3.A (Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old); 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)*
Sponsoring Committee:	*Pancreas Transplantation Committee*
Public Comment Period:	*January 22, 2018 – March 23, 2018*

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/m^2). Pancreas Committee (Committee) analysis and review of current evidence indicates that this waiting time criterion represents an unnecessary and arbitrary limitation to 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 arbitrary because Type 1 and Type 2 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 arbitrarily restricts waiting time 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 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 in alignment with the OPTN second 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 arbitrary waiting time criterion.

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[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.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community.

What problem will this proposal address?

Kidney-pancreas 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/m^2)

Waiting time accrual is critical for KP candidates because it impacts allocation. 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 being listed due to not meeting 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 UNOS 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 arbitrary 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 American and Hispanic represent a greater proportion of Type 2 high BMI simultaneous pancreas-kidney (SPK) candidates and recipients.[14]

Minimal Impact on Kidney-Alone

Inclusion of the 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 proportion of Type 2 candidates has remained steady over the last decade and shown no trends in increasing.[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 populations, all available data suggests the impact on kidney alone populations would be minimal.[17] 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.
[17] Ibid.

evidence suggests that concerns over Type 2 KP recipient outcomes and impact on kidney-alone candidates, which led to the inclusion of 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 and arbitrary policy and provide access to transplant for an underserved population of candidates.

Why should you support this proposal?

UNOS data analyses and review of relevant publications indicate that the current KP waiting time criteria is arbitrary and 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] Within the context of the current BMI restriction for Type 2 candidates that does not exist for Type 1 candidates, Type 2 candidates of non-Caucasian ethnicity are affected to a greater degree than Type 2 Caucasians by representing a greater proportion of high BMI Type 2 candidates and recipients.[23]

The solution to eliminate the KP waiting time criterion and references to maximum allowable BMI would be expected to 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.

Increase in Transplant, LYFT (life years from transplant)

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 and took effect in 2014.

The KP waiting time criteria included a requirement that candidates be on insulin and have a C-peptide ≤ 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 kidney-pancreas candidates that meet the waiting time criteria. This

[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] Chakkera, 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.

criterion was included because of concerns that Type 2 candidates with high BMIs would have worse outcomes.

In the PAS public comment, there was substantial dissent by members of the pancreas community who raised concerns that the maximum allowable BMI would inappropriately 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/m^2
- 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/m^2
- 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/m^2 to 30 kg/m^2. 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/m^2. The PAS included this cap because 30 kg/m^2 is the standard definition of obesity.[26]

Modification of the BMI threshold served as an indicator to the Committee that the qualifying criteria should be re-evaluated. 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 kidney-pancreas 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 the three options to modify policy:

1. Remove the maximum allowable BMI and the KP wait time criterion
2. Change the maximum allowable BMI to another number, or
3. Remove the maximum allowable BMI and keep the table in policy limiting transplantation of high BMI Type 2 candidates

1. Remove the maximum allowable BMI and the KP wait time criterion

The Committee supported this solution as the best option because it would remove a policy that is arbitrary and inhibitory to clinical discretion. This solution has the benefit of directly addressing the problem identified by the Committee. It would support a program's decision to list a patient, the impact on kidney-alone transplants would be minimal, and review of the literature indicates 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 threshold and a KP waiting time criterion unfairly restricts Type 2 candidate access to waiting

[25] OPTN/UNOS Briefing Paper, 2010.
[26] Ibid.

time accrual and transplant without a medical basis for the exclusion.[27,28,29] 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.[30] Raising the maximum allowable BMI would alleviate part of the problem by allowing more candidates to be transplanted, but would still be arbitrary and leave an unequitable policy in place.

3. Remove the maximum allowable BMI and keep the table in policy limiting transplantation of 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/m^2. This option would continue to arbitrarily limit transplantation for Type 2 candidates with a high BMI, and was rejected by the Committee.

Proposed Solution

The Committee supports removing the KP waiting time criterion and maximum allowable BMI over alternative solutions because this solution best addresses the problem. Alternative solutions would keep in policy a waiting time criterion that is arbitrary and unfair. By removing the KP waiting time criterion, Type 1 and Type 2 diabetic candidates with high BMIs will be treated equally in their ability to accrue waiting time. The number of KP 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.

Kidney Committee Feedback

In October 2017 the Committee presented the proposal to the Kidney Committee and received feedback from this stakeholder. 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 led 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 higher fixed 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.

The Subcommittee reviewed feedback from the Kidney Committee and issued a recommendation to the full Pancreas Committee. On November 8, 2017, the Subcommittee unanimously supported a recommendation to the Pancreas Committee to remove the KP waiting time criterion and references to maximum allowable BMI cap. On November 13, 2017, the Committee unanimously voted to remove the KP waiting time criterion and references to the maximum allowable BMI, in accordance with the Subcommittee’s recommendation.

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.

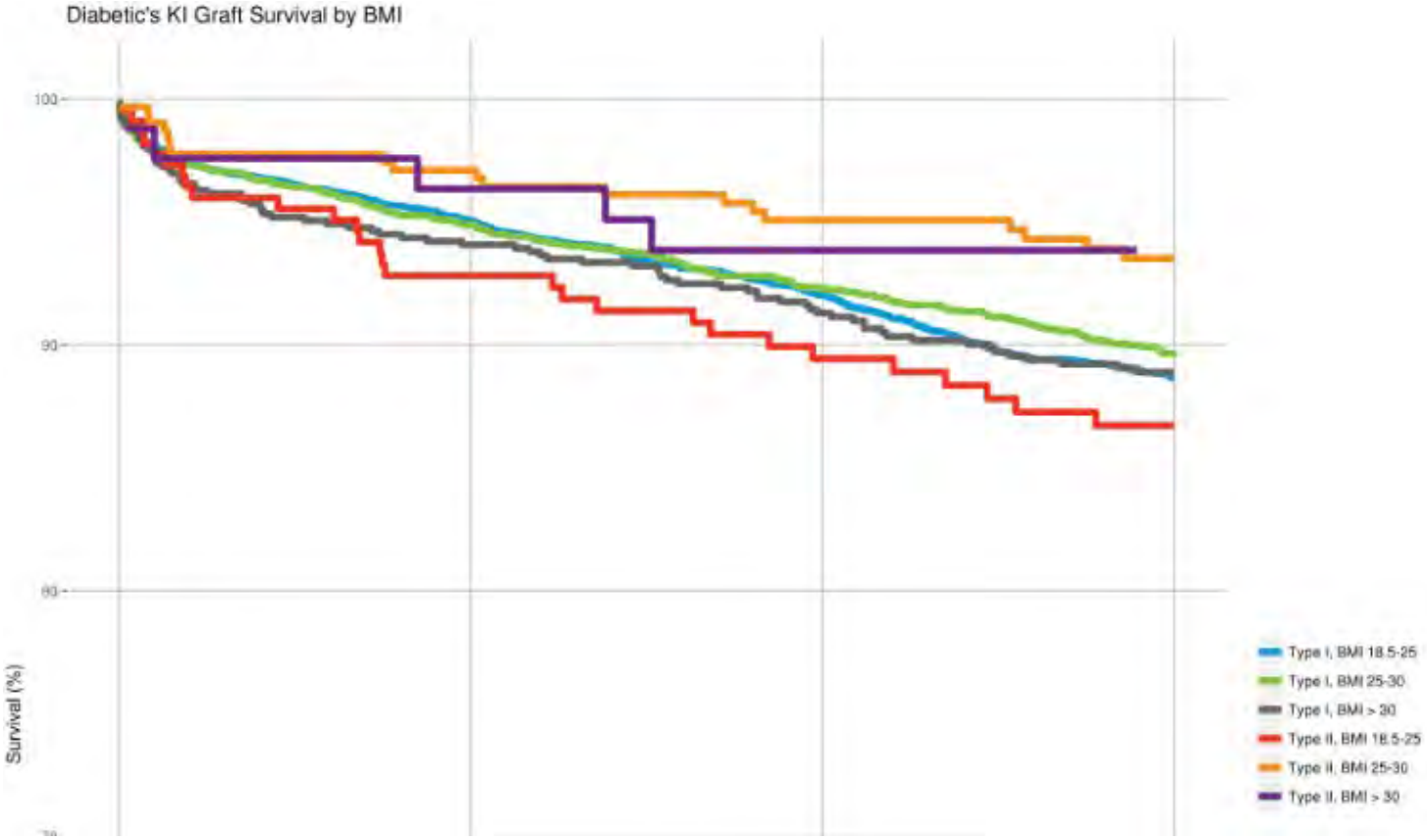
[27] Redfield, 2017.
[28] Sampaio, 2010.
[29] Forbes, 2017.
[30] Urban, 2017.

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 reported to the SRTR found that BMI did not reach significance as a risk factor for poor post-transplant outcomes.[31] Comparable outcomes were achieved in patients with a BMI ≥ 30 to those with a BMI < 30 in Type 2 recipients.[32] A single center study of 44 Type 2 recipients, 9 of which had BMIs above 30, also found higher BMIs do not impact outcomes.[33] An abstract under submission to the American Transplant Congress (ATC) 2018 based on UNOS analysis 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.[34] 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.[35]

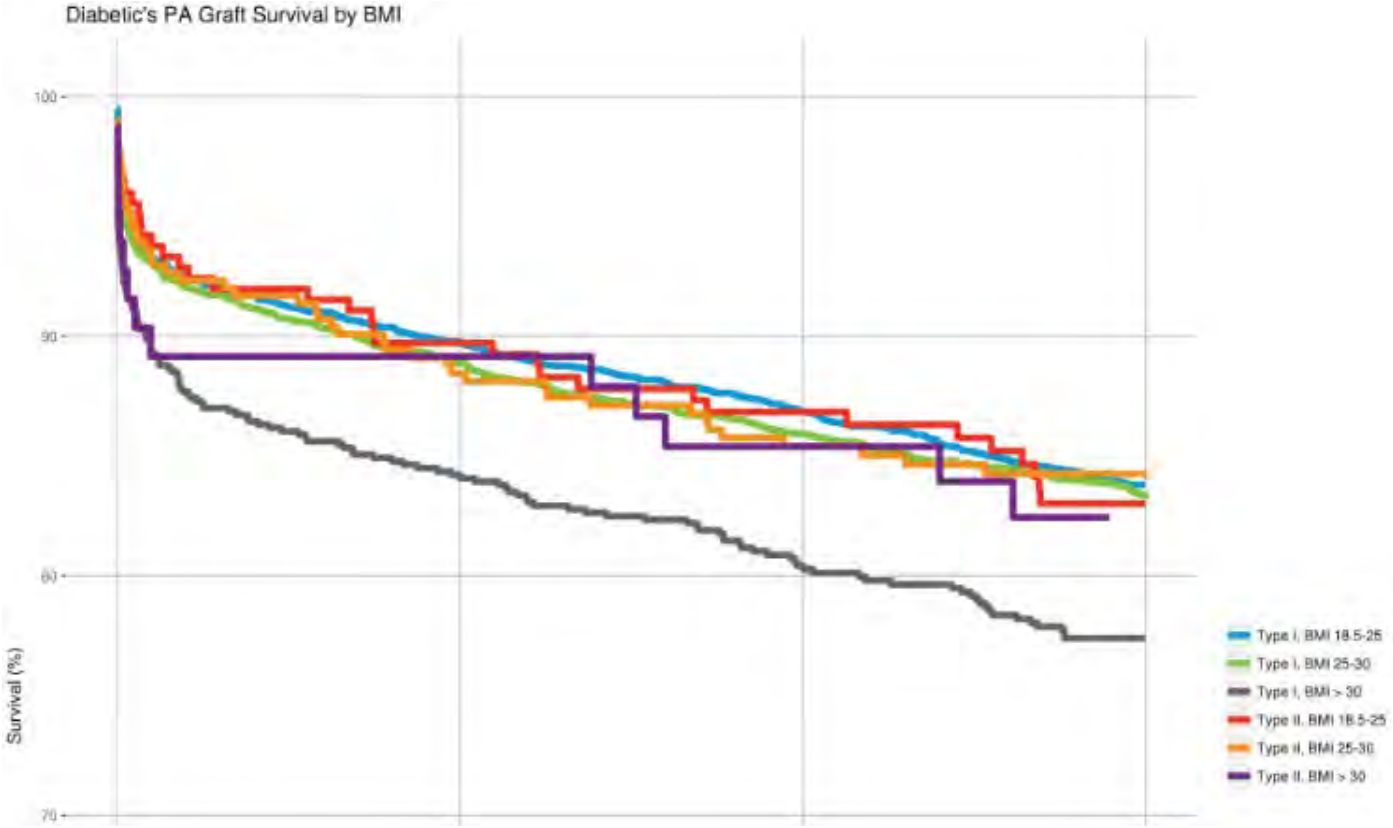
Figures 1 and 2 show graft survival out to three years for Type 1 and Type 2 recipients stratified by BMI categories from this analysis. These figures highlight that Type 2 recipients with higher BMIs may have comparable outcomes to those of Type 1 recipients in general. In fact, the analysis indicates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

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



[31] Redfield, 2017.
[32] Ibid.
[33] Bry, 2013.
[34] Forbes, 2017.
[35] Ibid.

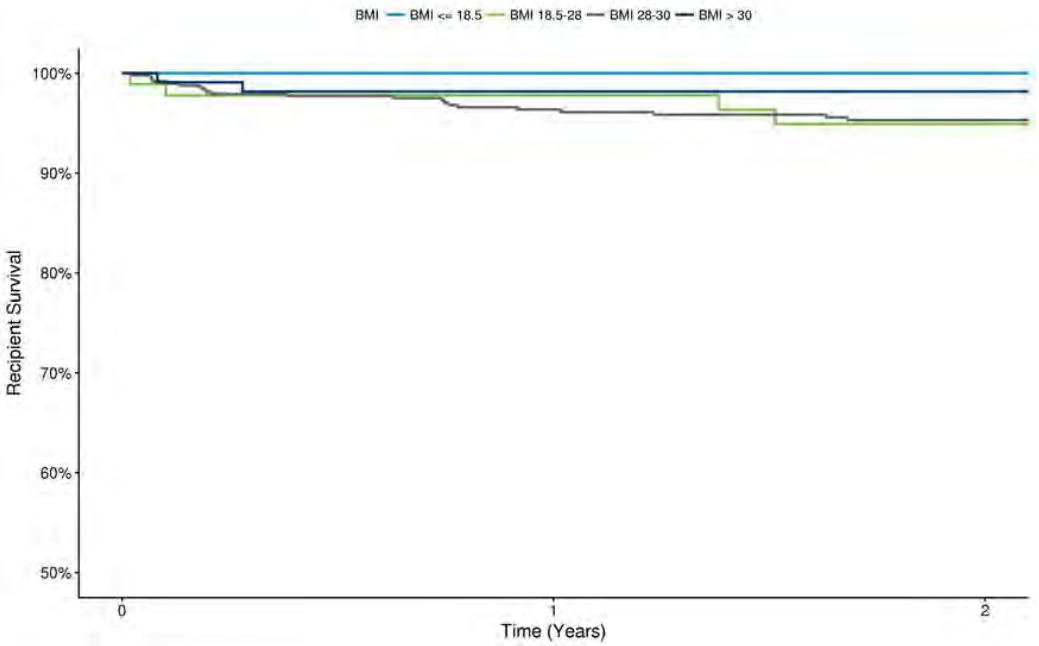
Figure 2: PA Graft Survival in SPK recipients stratified by recipient category and by BMI



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.[36] Figure 3 shows Type 2 recipient survival over 2 years, segmented by BMI. It highlights that candidates with BMIs above 30 (n=92) and those with BMIs from 28-30 (n=114) did similarly 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.

[36] Curry, 2016

Figure 3: Type 2 recipient survival by BMI



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 of the PAS implementation to October 31, 2016.[37] 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 registered 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.[38]

That there is 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.[39] The analysis indicated a correlation between age and BMI, finding the "most influential risk factors for technical failures…were increased donor age (over 30 years), no induction therapy and PRA level > 20%."[40] 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.[41] 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.

[37] Ibid.
[38] Ibid.
[39] Laftavi, 2017.
[40] Ibid.
[41] Sampaio, 2010.

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.[42,43,44,45] A single center study from 2002 to 2015 found 73 Type 2 SPK recipients "maintained long-term euglycemia and stable renal function."[46] A retrospective analysis from 2000 to 2007 comparing 582 Type 2 recipients and 6141 Type 1 recipients found similar patient and graft survival.[47] 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 performing significantly better than 2002-2018.[48] The paper concluded that patient and graft outcomes after SPK for Type 2 recipients significantly improved over time.[49]

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 high BMI candidates for both Type 1 and Type 2 recipients, policy should not arbitrarily 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 Alone 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, which 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.

The Pancreas Committee appreciates the Kidney Committee's feedback and their concerns. However, all available evidence indicates that transplantation of Type 2 candidates would remain a small proportion of total pancreas transplants performed each year. Figure 4 shows total number of KP transplants per year from 2006 to 2016, for both Type 1 and Type 2 candidates and recipients.

[42] 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
[43] Bry, 2013.
[44] Chakkera. 2013.
[45] Nath, et al. "Outcomes of Pancreas Transplants for Patients with Type 2 Diabetes Mellitus." Clin Transplant. 2005 Dec;19(6):792-7.
[46] Wong, 2016.
[47] Samaio, 2011.
[48] Laftavi, 2017.
[49] Ibid.

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

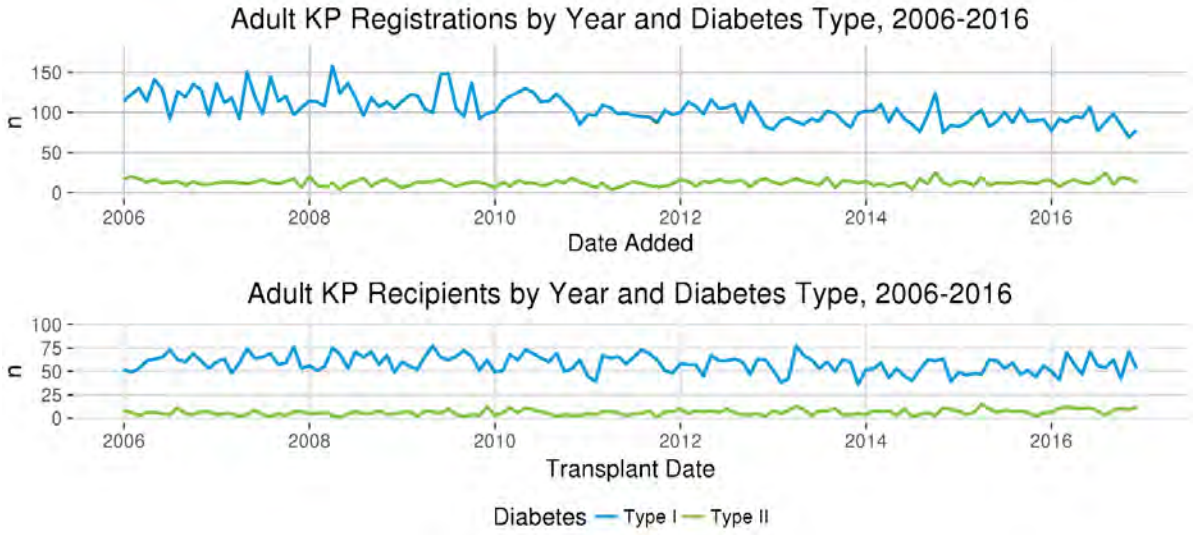


Figure 4 indicates that the rate of Type 2 registrations and Type 2 recipients has held steady at a low level from 2006-2014, when there was no BMI restriction for Type 2 candidates. Moreover, the rate of Type 2 registrations and Type 2 recipients has not increased since PAS went into effect in 2014. Meanwhile, Type 1 registrations have dropped slightly. Again, 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 10 transplants a year. [50] Thus, the concern that the Kidney Committee raised regarding a trend in Type 2 KP candidates or recipients 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 being 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). Choosing inappropriate candidates for KP transplantation that resulted 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 an arbitrary barrier to accruing waiting time for candidates who may be appropriate for transplantation.

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.[51] 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,

[50] Redfield, 2017.

[51] Urban, 2017.

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.[52]

Figure 5 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 6 shows that the proportion of minority KP Type 2 recipients is greater than minority KP Type 1 recipients from 2013 to 2016.

Figure 5: Adult KP Registrations by Ethnicity and Year, Stratified by Diabetes Type, 2013-2016

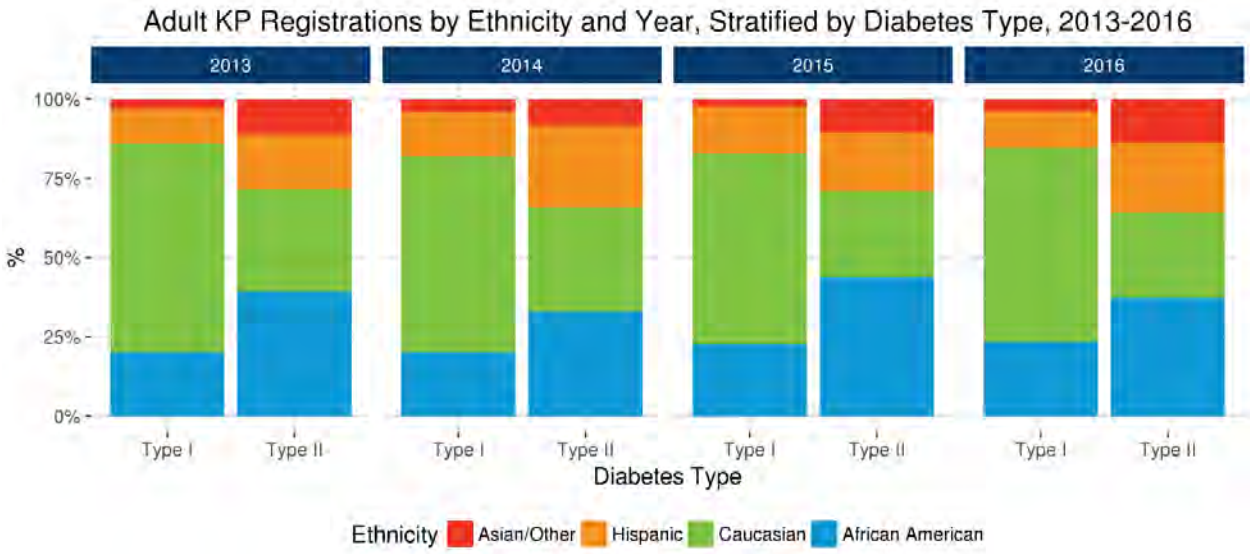


Figure 6: Adult KP Recipients by Ethnicity and Year, Stratified by Diabetes Type, 2013-2016

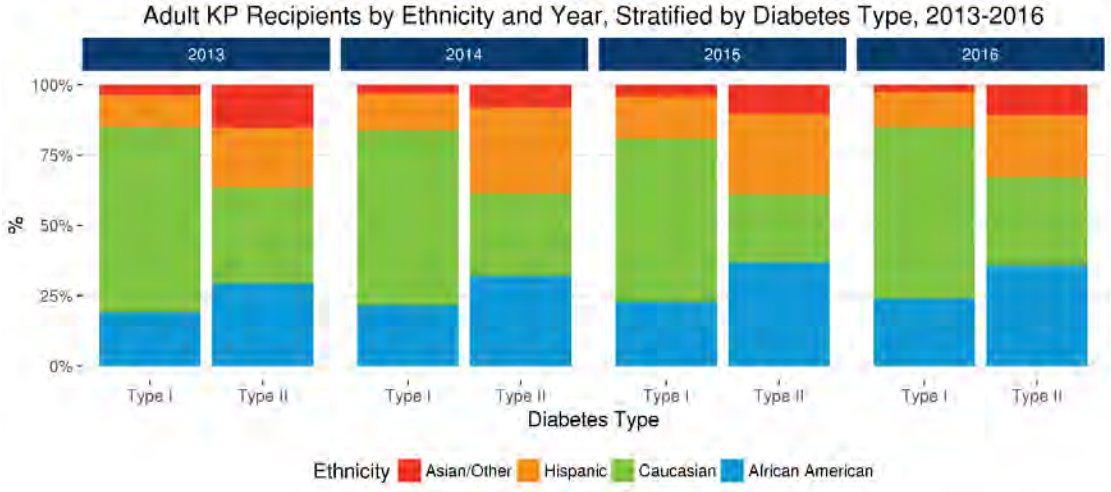
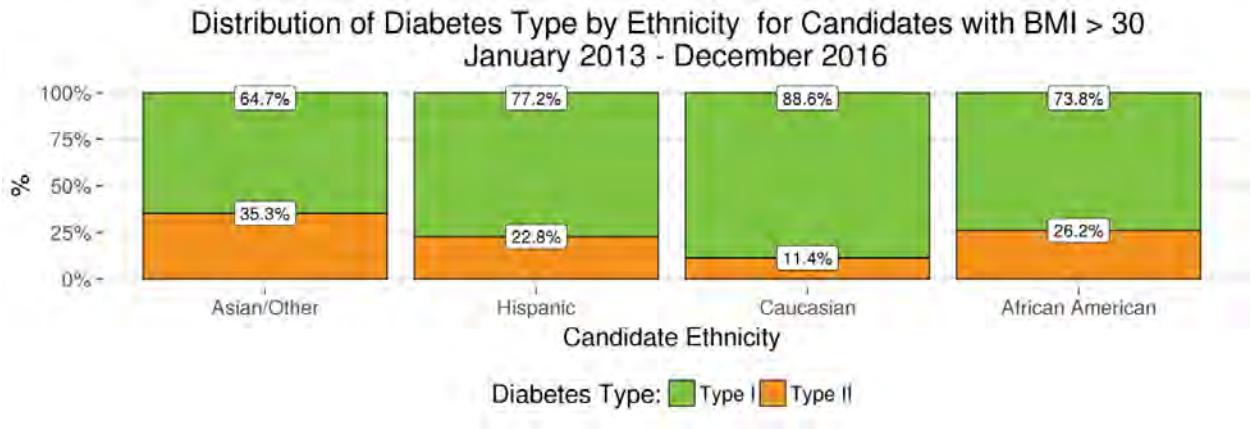


Figure 7 shows that the proportion of minority populations who would benefit from removing the KP waiting time criterion limiting waiting time accrual for Type 2 candidates with a BMI > 30 kg/m^2 may be greater than the proportion of Caucasian candidates who would benefit. This graph shows that a higher percentage of Asian, Hispanic and African American candidates with BMI > 30 kg/m^2 are Type 2 diabetics, and are thus directly impacted by the current KP waiting time criterion. Eliminating this restriction for patients with Type 2 diabetes may increase relative access to pancreas transplantation for certain minority patients, by allowing them to accrue waiting time.

[52] Ibid.

Figure 7: 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/m^2, 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 is in line with evidence suggesting that race and C-peptide should not be barriers to SPK transplantation.[53,54]

Kidney-Alone 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 suggested the Pancreas Committee look at 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, the UNOS research analysis 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.[55]

The Committee does not foresee that this proposal would negatively impact pediatric kidney-alone, 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,[56] 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 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.

[53] 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.
[54] Light, 2005.
[55] Urban, 2017
[56] Redfield, 2017.

2. *Improve equity in access to transplants:* Removing the maximum allowable BMI and 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, and those not on insulin, who currently cannot accumulate waiting time. Additionally, since Asians, African Americans and Hispanics represent a greater proportion of Type 2 high BMI candidates, removing 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 UNet^{SM} as it involves modifications to managing kidney-pancreas registrations within Waitlist^{SM}. KP candidates who are able to accrue waiting time under this new policy change will be given the waiting time they would have accrued if the KP waiting time criterion was not in place when they first registered for a KP transplant.

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.

How will members implement this proposal?

Transplant Hospitals

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 insulin, 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. Trends of Type 1 and Type 2 KP candidates and recipients, including BMI, C-peptide, and insulin usage.
2. 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.

Policy or Bylaws Language

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

11.3 Waiting Time

Waiting time for pancreas and islet candidates begins on the date the candidate is first registered as a pancreas or islet candidate on the waiting list.

Pancreas, kidney-pancreas, and islet candidates continue to accrue waiting time while registered as active or inactive.

~~11.3.A Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old~~

~~To accrue waiting time for a kidney-pancreas transplant, a kidney-pancreas candidate who is less than 18 years old at the time of kidney-pancreas registration does not have to meet the qualifying criteria according to *Policy 11.3.B* below.~~

11.3.~~B~~A Kidney-Pancreas Waiting Time Criteria ~~for Candidates At Least 18 Years Old~~

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

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

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

~~The maximum allowable BMI, for accruing waiting time, for a kidney-pancreas candidate, who is at least 18 years old at the time of kidney-pancreas registration, is 28 kg/m^2. Every six months, the OPTN Contractor will determine the percent of kidney-pancreas candidates that meet criterion 3.b above. The OPTN Contractor will then modify the maximum allowable BMI according to *Table 11-1* below:~~

~~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~~

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

~~The OPTN Contractor may not modify the maximum allowable BMI to exceed 30 kg/m^2. If the OPTN Contractor modifies the maximum allowable BMI, it must publish the modification and notify all kidney programs and pancreas programs.~~

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

~~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.~~C~~B Islet Waiting Time Criteria

An islet candidate will retain waiting time through three registrations at the registering transplant hospital, including the waiting time from the previous registrations and any intervening time. After a candidate has received a series of three islet infusions at the registering transplant hospital, waiting time will be reset, and the candidate will retain waiting time through another three infusions.

11.3.~~D~~C Waiting Time Assignments for Kidney, Kidney-~~p~~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~~1* below.

Table 11-~~2~~1: Waiting Time Assignments for Multi-organ Candidates

From this registration:	To this registration:
Kidney	Kidney-pancreas; if criteria in Policy ~~11.4.B~~11.3.A: *Kidney-Pancreas Waiting Time Criteria ~~for Candidates At Least 18 Years Old~~* are met.
Kidney	Pancreas
Kidney-pancreas	Kidney
Kidney-pancreas	Pancreas
Pancreas	~~Pancreas~~ Islet~~s~~; if criteria in *Policy 11.3.~~D~~C.i* below are met.
~~Pancreas~~ Islet~~s~~	Pancreas; if criteria in *Policy 11.3.~~D~~C.ii* below are met.

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~~C.i Criteria to assign Pancreas Waiting Time to Islet Waiting Time

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.

11.3.~~D~~C.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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