OPTN | UNOS

Public Comment Proposal

Pancreas Program Functional Inactivity

OPTN/UNOS Pancreas Transplantation Committee

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Pancreas Program Functional Inactivity

Affected Policies:	*Appendix D.10.A (Functional Inactivity), D.10.B (Notification Requirements for Transplant Program Functional Inactivity)*
Sponsoring Committee:	*Pancreas Transplantation Committee*
Public Comment Period:	*August 3, 2018 – October 3, 2018*

Executive Summary

The majority of programs under review for functional inactivity by the OPTN/UNOS Membership and Professional Standards Committee (MPSC) are pancreas programs. At least one pancreas transplant must be performed during a six consecutive month time period or a pancreas program will be identified as "functionally inactive" according to OPTN Bylaws *Appendix D.10.A: Review of Transplant Program Functional Inactivity*. From January 2011 to September 2016, 61 pancreas programs have come under review for functional inactivity at least once, which is approximately 44% of currently approved pancreas programs (138).

Review of the literature and OPTN data analyses indicate that these low-volume pancreas programs may perform at a level that impacts patient safety and access to transplant. The solution proposed by the Pancreas Committee (hereafter, the Committee) seeks to reduce MPSC review of functionally inactive pancreas programs by narrowing review to programs that have longer waiting times and low volumes. The definition will be more tailored to concerns about patient safety and access to transplant by focusing on programs with longer waiting times, and avoid reviewing programs that are small volume but transplant their patients quickly. Pancreas programs will be reviewed for functional inactivity if they fail to perform two transplants in 12 consecutive months and have an average waiting time above the national average for pancreas programs.

The Committee's solution also addresses the concerns with patient access to transplant and patient safety by increasing communication with patients waitlisted at programs reviewed for functional inactivity. These programs will need to inform patients and potential candidates about other pancreas programs in-state or within 125 miles of the program, and provide information about the program's waiting time compared to the national average. Providing this additional information may empower patients to make informed decisions about their transplant care, and will provide an incentive to pancreas programs to increase their volume and shorten waiting time in order to avoid sending this letter.

The proposed changes will improve waitlisted patient and transplant recipient outcomes by creating new thresholds for identifying functionally inactive pancreas programs that operate below the level that is adequate for their waitlisted candidates.

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

The Committee is adding two elements to the notice that functionally inactive pancreas programs have to send to their patients and potential candidates: information about other pancreas programs in proximity to the functionally inactive pancreas program, and the program's waiting time average compared to a national average. Should other organ programs be required to send comparable information to their patients and potential candidates if flagged for functional inactivity?

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?

Transplant candidate and recipient safety is the impetus for the Membership and Professional Standards Committee's (MPSC's) ongoing monitoring of transplant program volume. For pancreas programs, OPTN Bylaws *Appendix D.10.A: Functional Inactivity* specifies that at least one pancreas transplant must be performed during a six consecutive month time period or the pancreas program will be identified as "functionally inactive." Programs identified as functionally inactive are provided an opportunity to explain its inactivity to the MPSC, which commonly includes an informal discussion with the MPSC.

The majority of programs under review are pancreas programs. From January 2011 to September 2016, 61 pancreas programs have come under review for functional inactivity at least once, which is approximately 44% of 138 currently approved pancreas programs.[1] In the same time period 19 pancreas programs under review for functional inactivity inactivated either upon request of the MPSC or of their own accord.[2]

Analysis of OPTN data and two recent publications which analyzed pancreas transplant recipient outcomes as they relate to center volume indicate that patient safety may be impacted by center volume (see Section "How well does this proposal address the problem statement?" below). Specifically, low center volume was associated with worse pancreas allograft survival, even while low volume centers tended to use higher quality grafts with lower pancreas donor risk indexes (PDRIs) than higher volume programs.[3,4] The Committee also found that a majority of patients from programs that inactivated because of functional inactivity did not relist, indicating an issue for patient access to transplant.[5]

Why should you support this proposal?

The Committee proposes to change the definition of pancreas program functional inactivity to failing to perform 2 transplants in 12 consecutive months and having either a waiting time above the national average or no pancreas candidates on the waiting list for the specified period. Adding a waiting time metric to functional inactivity narrows review to programs that are performing very few transplants ***and*** have patients waiting longer for a transplant than the national average. The Committee felt that adding a waiting time metric would better distinguish programs that are doing a disservice to their patients. The narrower functional inactivity definition will mean the review of fewer programs that have longer waiting times ***and*** low volumes. The definition will be more tailored to concerns about patient safety and access to transplant by focusing on programs with longer waiting times, and avoid reviewing programs that are small volume but transplanting their patients quickly.

Changing the definition will also provide more flexibility to small volume programs by extending the functional inactivity review period from six months to a year. For example, consider a program that transplants its full list of three candidates in six months, then is reviewed for functional inactivity after performing no transplants in the following six months. This change avoids penalizing programs that transplant their patients quickly in the first part of the year.

Requiring pancreas programs to send letters to their patients and potential candidates detailing the program's waiting time compared to a national average, as well as the contact information for other pancreas programs within a geographic proximity, creates an incentive for pancreas programs to increase their volume and avoid being reviewed for functional inactivity. It also empowers patients by providing them with more information to make educated decisions about their transplantation options.

How was this proposal developed?

In 2013, the MPSC reviewed all programs flagged for functional inactivity and found a majority were pancreas programs. To improve the system for pancreas candidates, the Pancreas Committee suggested informing patients on the waiting lists of programs reviewed for functional inactivity of the program's review and opportunities to transfer to another list. The MPSC took the recommendation and in June 2014 the Board approved the proposed changes by adding OPTN Bylaws Appendix *D.10.B: Notification Requirements for Transplant Program Functional Inactivity*.

In May 2017, a Work Group composed of Pancreas Committee and MPSC members began convening to discuss pancreas program functional inactivity and continued concern about patient safety at low volume pancreas programs.

Through the remainder of 2017, the Work Group requested and reviewed a data analysis that stratified different metrics by transplant volume, including:

- Access to transplant

[1] OPTN/UNOS Descriptive Data Request. "Pancreas Functional Inactivity." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, September 27, 2018.
[2] Ibid.
[3] Kopp, W., et al. "Center volume is associated with outcome after pancreas transplantation within the Eurotransplant region." *Transplantation*. 2017 Jun;101(6):1247-1253. doi: 10.1097/TP.0000000000001308.
[4] Alhamad, T., et al. "Transplant center volume and the risk of pancreas allograft failure." *Transplantation*, vol. no. 11, 2017, pp. 2757–2764, doi: 10.1097/TP.0000000000001628
[5] OPTN/UNOS Descriptive Data Request. "Pancreas Functional Inactivity." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, September 27, 2018.

- Patient and graft outcomes
- Organ offer turn downs
- Technical failures and complications

The data analysis indicated that low volume programs (defined as an average two or fewer transplants per year) have much longer waiting times on average than high volume programs. Low volume centers were 1.64 times more likely to have a pancreas graft fail compared to high volume centers, and had a much lower offer acceptance rate compared to high volume centers.[6]

The Work Group considered adopting a composite endpoint as a solution, and subsequently used a survey to evaluate whether to adopt a less complex solution. The composite endpoint solution, the survey, and the proposed solution are described below.

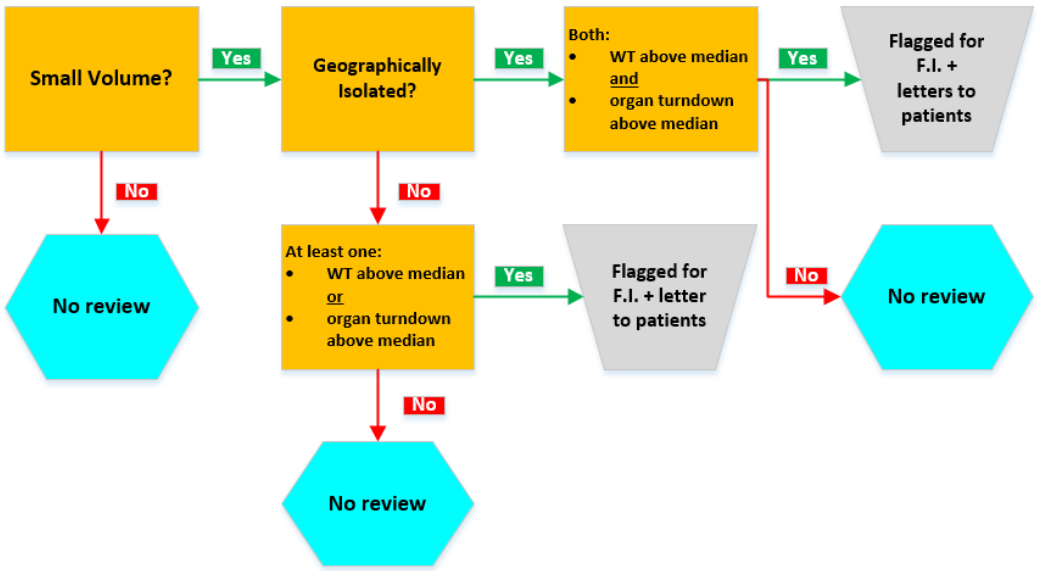
Composite Endpoint Approach

Based on the data analysis, the Work Group identified several metrics that could be added to the functional inactivity definition to better target under-performing programs: waiting time, proximity to large or medium volume pancreas centers, and offer turndown rate. The Work Group created a composite endpoint based on a program meeting the following criteria:

- average waiting time above the national median for pancreas programs
- average organ turndown rate above the national median for pancreas programs
- geographic proximity within 200 kilometers of an in-state large or medium volume pancreas program
- performs fewer transplants than the transplant threshold of one transplant in six consecutive months

If a low volume program met the geographic proximity threshold, the program would need to meet one of the criteria in waiting time or organ turndown to be considered functionally inactive. If a low volume program was considered geographically isolated, the program would need to meet both thresholds to be considered functionally inactive. Figure 1 shows how the composite endpoint approach would work.

Figure 1: Composite Endpoint Approach



In subsequent Work Group calls the members recognized the complexity of the composite endpoint approach and how this complexity could inhibit transparency and make the solution difficult to implement. Programs may struggle to keep track of their average waiting time and organ turndown rates in relation to national medians, while also considering whether they are geographically isolated and currently low volume. The complex nature of the solution could hurt transparency in the community and raises concerns about the feasibility of successful implementation. Therefore, the Work Group decided to re-evaluate its approach to see whether it could develop a less complex solution.

Work Group Survey

[6] OPTN/UNOS Descriptive Data Request. "Functional Inactivity: Updated Analysis." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, January 31, 2018.

The Work Group responded to a survey assessing support for modification of the functional inactivity definition, modification to the letters sent to patients and increasing consequences for programs that are repeatedly flagged.[7]

Survey results demonstrated that a majority of Work Group members supported keeping the current functional inactivity level at six consecutive months. However, some Committee members raised concerns that low volume programs may perform transplants quickly, perhaps three in the first part of the year, and none for the second half. Therefore, the Committee proposed requiring a minimum of 2 pancreas transplants over 12 consecutive months, instead of 1 over 6 consecutive months. This would provide more flexibility for the programs that may quickly transplant the patients on their list and have no pancreas transplants for over a 6 month period.

The survey also asked whether the definition of functional inactivity should include metrics other than a transplant threshold. A majority responded that the functional inactivity definitions should also include a waiting time threshold. Work Group members felt that this is relatively easy for programs to figure out, and is therefore more transparent than a full composite endpoint. It would also allow low volume programs that have waiting times shorter than the national average to avoid being flagged for functional inactivity.

The survey also sought the Work Group's feedback regarding the content of the notification letters functionally inactive programs must send to their candidates. Most Work Group members responded that the notifications should include geographic proximity to other medium or high volume pancreas programs in-state and program waiting time compared to a national median should be included in the letter. Including these elements could increase the impetus for programs to avoid functional inactivity in order to avoid sending their patients this information. Requiring letters to include additional information about geographic proximity and program waiting time would also increase patient awareness.

Finally, the survey asked Work Group members if there should be different consequences for programs flagged for functional inactivity repeatedly. Work Group members supported increased consequences for these programs. However, subsequent Work Group conversations identified limitations to having separate consequences for programs reviewed multiple times. In particular, doing so removes flexibility for the MPSC in considering the particular circumstances of the pancreas program under review when determining appropriate action. The Work Group and the Pancreas Committee encouraged the MPSC to consider modifying its approach to programs reviewed for functional inactivity multiple times, but ultimately refrained from proposing modifications to the Bylaws with regard to multiply reviewed pancreas programs in order to avoid inhibiting the flexibility of the MPSC review process.

Proposed Solution

Based on the Work Group survey and subsequent discussion, the Work Group proposed the following solution:

1. Modify the pancreas program functional inactivity definition:
    a. Change the transplant threshold from 1 in 6 consecutive months to 2 in 12 consecutive months.
    b. Add a waiting time metric that, in addition to the transplant threshold, would also need to be met to incur functional inactivity review: an average waiting time longer than the national average waiting time for pancreas candidates or no waiting time for the specified time period.
2. Add elements to the letter sent to patients of pancreas programs reviewed for functional inactivity:
    a. Require that programs provide patients and potential candidates with contact information for all other pancreas programs within 125 miles and all in-state or in-U.S. territory programs.
    b. Require that programs provide their waiting time average compared to the national average; if the program has no waiting time average because it has no candidates on the waiting list, potential candidates must be informed of this as well.

The proposed solution was sent to the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) for feedback in May. The AST issued full support for the preview proposal but asked that comments from members of the Kidney and Pancreas Community of Practice (KPCOP) be taken into consideration.[8] KPCOP members approved of the narrower scope of functional inactivity but noted there could be challenges using average waiting time in the definition. To avoid confusion for small volume programs, the OPTN will generate a report easily available for small volume programs to compare their average waiting time to the national average (see the "How will the OPTN implement this proposal?" section).

KPCOP members also noted that informing patients of other centers is beneficial in terms of transparency, but could provide challenging for patients if travel to those centers is difficult. The Committee acknowledges this difficulty, but considers that it is still important to empower patients by providing them with relevant information about their program's waiting time and other opportunities in-state and within 125 miles. Overall, KPCOP responders approved of the proposed changes.[9] The ASTS also responded that it supported the proposed changes.[10] The Work Group voted unanimously in support of the proposed solution on May 23, 2018. On May 31, 2018 the Pancreas Committee reviewed the Work Group's recommendation as well as the feedback from stakeholders, and voted unanimously to send the proposal to public comment.

[7] OPTN/UNOS PowerPoint Presentation: "Pancreas Program Functional Inactivity Work Group." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, March 28, 2018.

[8] AST Committee Feedback Form. "Input for the Pancreas Program Functional Inactivity Work Group." Kidney and Pancreas Community of Practice (KPCOP), May 24, 2018.

[9] Ibid.

[10] ASTS Response: "In response to the OPTN/UNOS Pancreas Program Functional Inactivity Work Group request for pre-comment." May 15, 2018.

How well does this proposal address the problem statement?

Numerous studies have indicated that center volume and outcomes are often related, but this impact has not been examined as fully for pancreas transplantation as for other organ types.[11] Two recent studies of European and U.S. pancreas transplantation indicate that center volume may impact patient safety by low volume programs being associated with worse pancreas allograft outcomes compared to high volume centers.[12,13]

A 2017 study by Kopp et al. examined outcomes in patient and pancreas graft survival from 2008 to 2013 in the Eurotransplant region.[14] The study found that high volume centers (defined as 13 or more transplants a year) utilized donor organs with a higher pancreas donor risk index (PDRI), indicating these organs were more marginal than those used by medium and small volume programs (which were defined as less than 5, and 5-13 transplants per year, respectively). However, high volume programs also had better outcomes compared to low volume programs. So, the Kopp study showed that more increased-risk organs were being transplanted by the high volume programs, while low volume programs were transplanting better quality organs with worse results.[15]

Another study published last year looked at U.S. pancreas transplantation, center volume and patient outcomes. The Alhamad et al. study defined center volume slightly differently (1-6 low, 7-13 medium, 14-34 high) but found similar results.[16] As with the Kopp publication, the Alhamad study found higher PDRI associated with high volume programs. Low volume centers were associated with higher pancreas allograft failure rates at 3 months, and 1, 5 and 10 years. High volume centers showed better pancreas graft survival for all categories of PDRI.[17]

Pancreas transplantation has not had the same analysis of center volume and outcomes as other organ types, and not everyone agrees that center volume is correlated with pancreas graft failure. A 2017 publication by Young et al. found similar graft survival across center volume, defined by dividing the total cohort over a 2009 to 2012 time period into tertiles. However, the study also found that low volume centers had longer length of stay compared to medium and high volume centers, high volume centers had shorter wait list periods compared to medium and low volume centers, and high volume centers were more likely to utilize higher risk organs.[18] The authors noted that high volume centers utilizing higher risk organs while having similar outcomes explained the absence of an observed volume-outcome effect, and could be an "argument in defense of higher-volume" pancreas programs.[19]

These results from recent publications suggestion that patient safety is indeed impacted by a center's volume, particularly in the organ acceptance practices of the center and in outcomes of the patient. The Committee performed its own analysis to assess impact on patients and center practices by center volume. Below is a discussion.

Committee Analysis

An OPTN/UNOS data request examined number of candidates on the waitlist, patient and graft outcomes, and what happened to patients of programs that were inactivated because of functional inactivity.[20] The cohort studied included 8151 KP and 2616 pancreas alone candidates, as well as 4580 SPK, 720 PAK and 493 PTA recipients from 2010 to 2015. The data request examined outcomes by center volume, defined as 32 small volume centers (≤ 2 transplants per year), 29 medium volume centers (3-4 transplants per year), and 77 large volume centers (> 4 transplants per year). The Committee used these cohorts based on the current definition of functional inactivity in the Bylaws, which is less than 1 pancreas transplant in 6 consecutive months, or 2 per year.

Figure 2 shows time on the waitlist for large, medium, and small volume pancreas programs. The red lines indicate the median wait time.

[11] Young, K., et al. "The center volume-outcome effect in pancreas transplantation: a national analysis." *Journal of Surgical Research*, (2017), doi: 10.1016/j.jss.2017.02.025.
[12] Kopp, 2017.
[13] Alhamad, 2017.
[14] Kopp, 2017.
[15] Ibid.
[16] Alhamad, 2017.
[17] Ibid.
[18] Young, 2017.
[19] Ibid.
[20] OPTN/UNOS Descriptive Data Request. "Functional Inactivity: Updated Analysis." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, January 31, 2018.

Figure 2: Center Volume and Time on the Waitlist

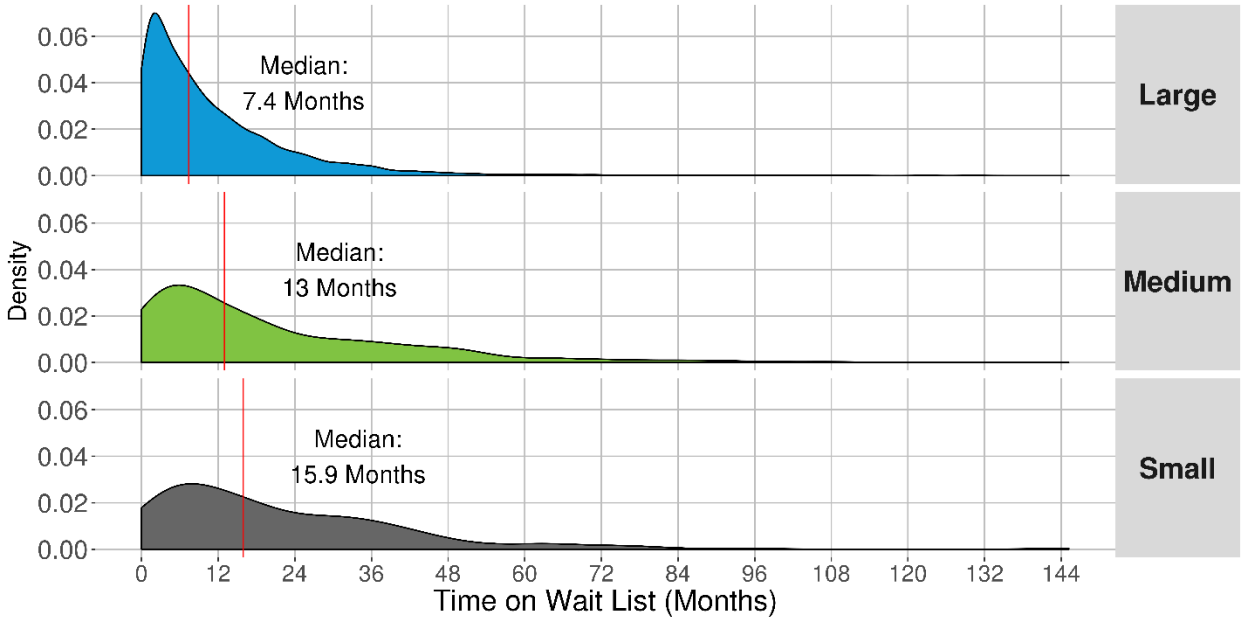
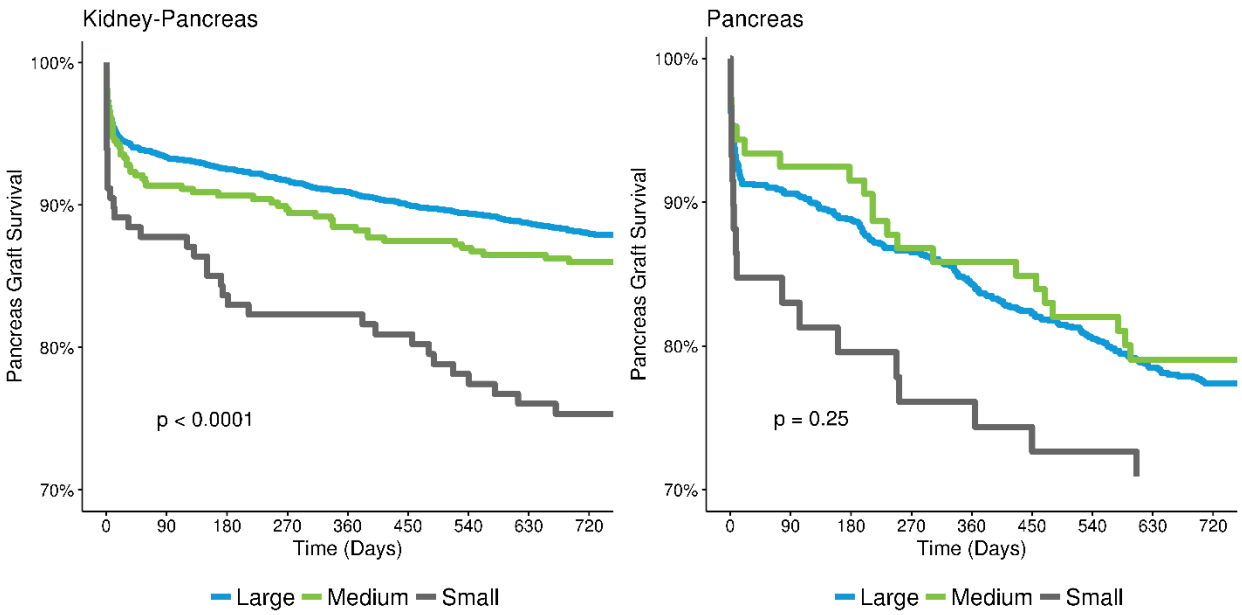


Figure 2 indicates that candidates at small volume programs wait on average 8.5 months longer than programs at large volume programs.[21] While the average waiting time is longer at small volume programs, there is still a fair amount of variation within small volume program waiting time. Figure 2 supports the change to the functional inactivity definition to include average program waiting time. While small volume programs with short waiting time will not get reviewed, those that show a waiting time longer than the average national waiting will be reviewed if the program also performs fewer than 2 transplants in 12 consecutive months.

Figure 3 shows the pancreas graft survival stratified by center volume. Unadjusted analyses showed that 2-year pancreas graft survival was worse for kidney-pancreas recipients at small volume centers compared to large volume programs, but not significantly different between medium and large volume programs. For pancreas alone recipients, there was also an observed difference in pancreas graft survival between large and small volume programs but because of small numbers of patients this did not reach statistical significance.

[21] Ibid.

Figure 3: Center Volume and Pancreas Graft Outcomes

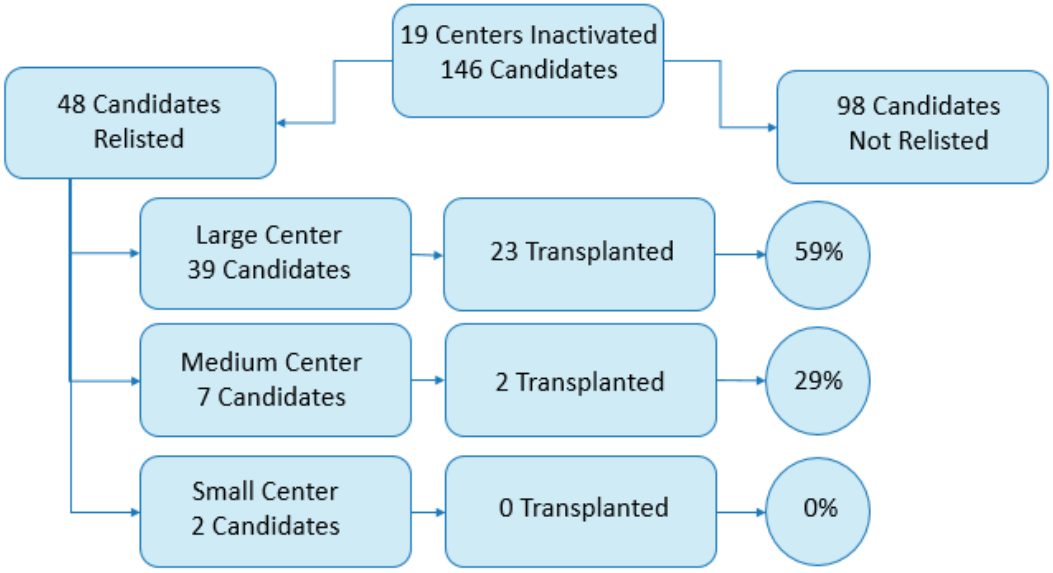


Adjusted analyses showed that 2-year pancreas graft survival was worse for SPK recipients at small center vs larger centers. The rate of pancreas graft failure was 2.24 times higher for small volume centers when compared to large volume centers.[22] Analyses were adjusted for volume, age, ethnicity, CPRA, PDRI, and BMI. A limitation of this analysis is that pancreas graft outcomes were center reported, because no national definition of graft failure existed at the time of the analysis. Despite this limitation, the Committee analysis and previously discussed publications from Kopp and Alhamad provide substantial evidence of an important correlation between center volume and pancreas graft survival.

Figure 4 shows the impact of functional inactivity of pancreas programs on their patients. Nineteen centers inactivated while under MPSC review for functional inactivity during this 5 year period, with 98 or 67.1% of 146 candidates not relisting. Of the 48 candidates relisted, most were relisted at large volume programs. This figure highlights the potential impact on access to transplant for patients listed at small volume programs that could be reviewed for functional inactivity. If a program inactivates while under the functional inactivity review, patients may seek or be eligible for listing at another program. Figure 4 provides support for strengthening the letter sent to patients that highlights other options for transplant, and provides data on the program's waiting time compared to a national average.

[22] Ibid.

Figure 4: Patient Relisting Data



In sum, patients listed at large volume pancreas transplant centers have shorter wait times and better pancreas graft survival despite utilization of pancreata with higher PDRIs. If a small volume program inactivates due to functional inactivity, their patients may not get relisted and transplanted. Discrepancies in access and outcomes at small versus large pancreas transplant centers exist. Patients listed at small programs should be adequately informed about their program's waiting time and options for listing elsewhere.

Which populations are impacted by this proposal?

This proposal changes which pancreas programs are reviewed for functional inactivity and the types of information given to candidates listed at reviewed programs. The changes impact pancreas transplant candidates generally and more specifically those at small volume programs.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* This proposal disincentives pancreas programs from coming under functional inactivity review, which could serve as an impetus to increase program volume.

2. *Improve equity in access to transplants:* There is no impact on this goal.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* The proposed changes will improve waitlisted patient and transplant recipient outcomes by creating new thresholds for identifying functionally inactive pancreas programs that operate below the level that is adequate for their waitlisted candidates. Improving patient access to relevant information regarding waiting time and options for other pancreas programs in the state or territory may improve waitlisted patient outcomes by improving access to transplant.

4. *Promote living donor and transplant recipient safety:* Transplant candidate and recipient safety is the impetus for the MPSC's ongoing monitoring of transplant program volume. Improving patient access to transplant by increasing communication with candidates about transplant center options, geographic access and program waiting times may promote transplant recipient safety by allowing patients to make informed decisions about transplant care.

5. *Promote the efficient management of the OPTN:* This proposal will increase the efficiency of the MPSC's review of programs for functional inactivity. There is also the intention that this bylaw change will increase the efficiency of the pancreas organ allocation process by reducing habitually low-volume programs or encouraging programs to maintain a volume that prevents review for functional inactivity.

How will the OPTN implement this proposal?

The OPTN will make a report available on the UNet^{SM} data services portal that includes average program waiting time and average national waiting time for pancreas candidates. This proposal will not require programming in UNet.

The OPTN will communicate with members the new requirements in policy notices and in Transplant Pro.

How will members implement this proposal?

Transplant Hospitals

Fewer transplant programs will likely be reviewed for functional inactivity because an element is being added to the functional inactivity definition for pancreas programs in an average waiting time higher than the national average The functional inactivity threshold is also being changed from 1 in 6 months to 2 in 12 months, which is essentially the same transplant rate but with more flexibility for transplant programs. There might be a slight reduction in the number of reviewed programs due to this change.

Pancreas programs under review for functional inactivity will need to put additional information in the letter they send to both candidates on the waitlist and potential candidates: 1) informing them of other pancreas programs within 125 miles, in-state or in-US territory and 2) the program's average waiting time compared to the national average. Programs will still need to include the information previously included in *D.10.A: Functional Inactivity*: the dates fewer than 2 transplants were performed, the reason fewer than 2 transplant were performed, and options available to candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital.

Will this proposal require members to submit additional data?

This proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

The MPSC Performance Analysis and Improvement Subcommittee will continue to monitor compliance with bylaw requirements as part of its existing review of functional inactivity. OPTN Contractor staff will continue to request information from programs that are identified for lack of transplant activity based on the parameters defined in the Bylaws, including information on the program personnel's ability to maintain currency and the factors involved in the lack of transplant activity. Staff will also continue to request confirmation that candidates were notified of the period(s) of functional inactivity, in compliance with the content and timing requirements by requesting a representative copy of the notification and the list of patients that received the notification.

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

The Committee will request and review the following data to assess the proposed policy pre vs. post implementation.

1. Number of pancreas programs under review for functional inactivity. Because the new definition will be narrower, the Committee expects to see the number of pancreas programs reviewed decrease.
2. The number of pancreas programs inactivated while under functional inactivity review.
3. Trends in relisted candidates (i.e. transferred from an inactivated program to an active program) and their outcomes.
4. Patient and graft survival of pancreas recipients stratified by center volume.

Evaluation will be performed at 6 months, and 1 year post implementation as well as at the request of the Committee.

Policy or Bylaws Language

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

D.10 Review of Transplant Program Functional Activity

A. Functional Inactivity

Each transplant program must remain functionally active by performing a minimum number of transplants. For purposes of these Bylaws, functional inactivity is defined ~~as the failure to perform a transplant during the periods defined~~ according to Table D-1 below:

Table D-1: Functional Inactivity ~~Periods~~

For this transplant program type:	**~~Inactive Period~~ Functional inactivity is defined as:**
Kidney, Liver, or Heart	Failure to perform at least 1 transplant in 3 consecutive months
~~Pancreas or~~ Lung	Failure to perform at least 1 transplant in 6 consecutive months
Stand-alone pediatric	Failure to perform at least 1 transplant in 12 consecutive months
Pancreas	*Both* of the following: 1. Failure to perform at least 2 transplants in 12 consecutive months 2. *Either* of the following in 12 consecutive months: • An average waiting time of the program's kidney-pancreas and pancreas candidates that is higher than the national average waiting time for kidney-pancreas and pancreas candidates • The program had no kidney-pancreas or pancreas candidates registered at the program
Islet, intestinal, and VCA	No functional inactivity definitions have been established

~~Functional inactivity thresholds have not been established for pancreatic islet, intestinal, and VCA transplant programs.~~

B. Notification Requirements for Transplant Program Functional Inactivity

If a transplant program is notified by the MPSC that the program has been identified as functionally inactive, the transplant program must provide written notice to *all* of the following:

1. Potential candidates
2. All candidates registered on the waiting list

For all transplant programs except pancreas programs, written notice must be provided within 30 days of the date of the MPSC notification to the program and must include *all* of the following:

1. The dates identified in the MPSC notification during which no transplants were performed.
2. The reason no transplants were performed.
3. The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital.
4. A copy of the OPTN Contractor's Patient Information Letter.

For pancreas programs, written notice must be provided within 30 days of the date of the MPSC notification to the program and must include *all* of the following:

1. The dates identified in the MPSC notification during which fewer than 2 transplants were performed.
2. The reason fewer than 2 transplants were performed.
3. The options available to the candidates, including multiple listing and transfer of accrued waiting time to another transplant hospital.
4. A copy of the OPTN Contractor's Patient Information Letter.
5. The names and contact information of any pancreas programs within the same state, same commonwealth or 125 miles of the functionally inactive program.
6. The following information:
    a. For potential candidates and candidates on the waiting list, the program's average waiting time in the consecutive 12 month period for kidney-pancreas and pancreas candidates compared to the national waiting time average for kidney-pancreas and pancreas candidates.
    b. For potential candidates, that the program had no kidney-pancreas or pancreas candidates on the waiting list in the consecutive 12 month period.

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