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Briefing Paper

Pancreas Program Functional Inactivity

OPTN/UNOS Pancreas Transplantation Committee

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Contents

Pancreas Program Functional Inactivity

Affected Policies:	*OPTN Bylaws Appendices 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*
Board of Director's Date:	*December, 3-4, 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. According to OPTN Bylaws *Appendix D.10.A: Review of Transplant Program Functional Inactivity,* 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." From January 2011 to September 2016, the MPSC reviewed 61 pancreas programs 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 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 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 a median waiting time that is above the 67th percentile of the national waiting time.

The Committee's solution also addresses the concern with patient access to transplant 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 nautical miles of the program, and provide information about the program's waiting time compared to the national median. Providing this additional information may help 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.

Patients languishing at small volume programs with long waiting times could be transplanted elsewhere more quickly. By focusing review of functional inactivity on these small volume programs with long waiting times and empowering patients to make educated healthcare decisions, the proposed changes could improve equity in access to transplant.

What problem will this proposal address?

The majority of programs under review for functional inactivity by the OPTN/UNOS Membership and Professional Standards Committee (MPSC) are pancreas programs. 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, the MPSC reviewed 61 pancreas programs 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 subsequently inactivated, either upon request of the MPSC or of their own accord.[2]

The current definition of functional inactivity could be narrowed to focus on programs that not only have small volumes, but fail to transplant their candidates quickly and may have candidates languishing on the list. These patients could be transplanted elsewhere more quickly but may not know about their options, since the information sent in the current functional inactivity letter is not very specific: it doesn't inform patients about any programs that may be in-state or within driving distance, and it doesn't inform the patient about whether the program has a longer than average waiting time.

While small volume pancreas programs generally have longer waiting times compared to medium or high volume programs, some small volume programs may still transplant their patients efficiently and quickly.[3] Thus, the current definition of functional inactivity is overly broad in encompassing small volume programs with short waiting times, and could be tailored to focus on programs with longer waiting times and less efficient transplantation of patients. The definition is also inflexible in that a small volume program that transplants its list quickly may still get reviewed for functional inactivity later in the year, because the functional inactivity definition requires a transplant in 6 consecutive months instead of a year without providing allowance for gaps in transplant occurrences due to programmatic personnel changes or other situations. In sum, the functional inactivity definition is both too broad and too inflexible, and information that is sent to patients could be improved.

Why should you support this proposal?

The Committee proposes to change the definition of pancreas program functional inactivity to failing to perform two transplants in 12 consecutive months and having either a waiting time above the 67th percentile of the national waiting time 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. 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 access to transplant by focusing on programs with longer waiting times that may have patients languishing on the list, and avoid reviewing programs that are small volume but transplanting their patients quickly.

Changing the portion of the definition that deals with volume, from at least 1 transplant every 6 months to at least 2 transplants in 12 months, will also provide more flexibility to small volume programs by extending the functional inactivity review period from six months to a year. This change would, for instance, allow programs to "catch up" by performing 2 transplants in a second 6 month window if there were personnel or other extenuating circumstances that limited patient listing or transplants in a prior 6

[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] Ibid.

month period. Or 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. Thus, this change would avoids penalizing programs that transplant their patients quickly in the first part of the year and allow programs to account for a previous gap in transplantation if there were extenuating circumstances in the previous 6 month period.

Another proposed change is to send additional information to candidates if a program is reviewed for functional inactivity. Currently programs are required to tell candidates that they are reviewed for functional inactivity, the reason why, and the time period of functional inactivity, as well as send patients the Patient Information Letter (see OPTN Bylaws Appendix *D.10.B: Notification Requirements for Transplant Program Functional Inactivity*). Under the proposed changes, programs would also be required to inform patients of the program's waiting time compared to the 67th percentile of the national waiting time and information about other pancreas programs either in-state or within 125 nautical miles. Requiring pancreas programs to send letters to their patients and potential candidates detailing the program's waiting time compared to the national waiting time, 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*.[4]

Since the initial scrutiny of pancreas program functional inactivity in 2013, the MPSC continued to review many pancreas programs for low transplant thresholds. 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, reviewed, and analyzed a data that stratified different metrics by transplant volume, including:

- Access to transplant
- 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.[5]

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.

<u>Composite Endpoint Approach</u>

[4] OPTN/UNOS Briefing Paper. "Proposed Patient Notification of Functional Inactivity Due to Lack of Transplant Activity." June, 2014.

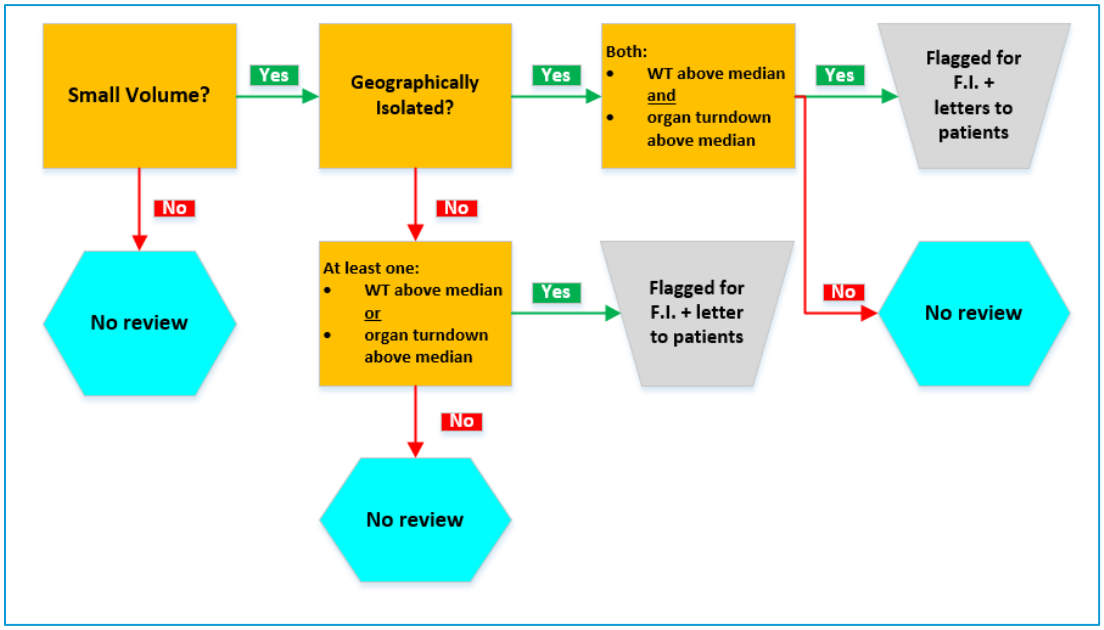
[5] OPTN/UNOS Descriptive Data Request. "Functional Inactivity: Updated Analysis." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, January 31, 2018.

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 raised concerns about the feasibility of successful implementation. Specifically, concerns about understanding the solution could lead to lack of trust in the process, and negatively impact community buy in on the importance of functional activity review. Therefore, the Work Group decided to re-evaluate its approach to see whether it could develop a less complex solution.

Work Group Survey

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.[6]

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

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 noted that keeping the same transplant threshold meant that low volume programs may perform several transplants in short time period, depleting their list, and subsequently still be reviewed for functional inactivity. For example, a small volume program that transplants its full list of three patients in the first part of the year, may have no transplants in the latter half of the year and still be reviewed. Therefore, the Committee proposed requiring a minimum of two pancreas transplants over 12 consecutive months, instead of one 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 over a 6 month period, for example.

The survey also asked whether the definition of functional inactivity should include metrics other than a transplant volume threshold. A majority responded that the functional inactivity definitions should also include a waiting time threshold. The Work Group thought it important to focus on programs that are not only small volume but could have patients languishing on the list. These patients could face an inequitable barrier in access to transplant by waiting longer compared to patients at other pancreas programs that transplant their patients more quickly. Work Group members agreed that a waiting time metric is less complex and easier to communicate to programs, and is therefore more transparent than a full composite endpoint. It would also allow certain low volume programs with short waiting times to avoid being reviewed for functional inactivity. In addition, it focuses attention on programs with significantly longer waiting times, where candidates could face greater barriers to access to transplant than at other pancreas programs.

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 information for patients about pancreas programs within a reasonable driving distance (125 miles) and in-state, since whether a program is in-state can impact insurance coverage. Including these elements could increase the impetus for programs to avoid functional inactivity by performing more transplants and reducing program waiting time in order to avoid sending their patients this additional information. Requiring letters to include geographic proximity of other pancreas programs and program waiting time would also increase patient awareness and address the equity in access to transplant issue by empowering patients to make educated healthcare decisions.

Finally, the survey asked Work Group members if there should be different consequences for programs flagged repeatedly for functional inactivity. 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.

<u>Work Group Solution</u>

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 one in 6 consecutive months to two 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 (see the "Was this proposal changed in response to public comment?" section for post public comment changes to this element of the proposed solution).
2. Add elements to the letter sent to patients of pancreas programs reviewed for functional inactivity:

a. Require that programs provide patients on the waiting list and potential candidates with contact information for all other pancreas programs within 125 nautical miles and all in-state or in-commonwealth 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 Committee considered it important to reach out to certain stakeholders ahead of public comment, to inform, solicit feedback, and disseminate the proposal. Accordingly, the proposed solution was sent to the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) 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.[7] KPCOP members approved of the narrower scope of functional inactivity but noted there could be challenges using waiting time in the definition because programs may not be aware of this information. To avoid confusion, the OPTN will generate a report available to pancreas programs to ensure that this information is easily accessible (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 prove challenging for patients if travel to those centers is difficult or if there are financial barriers. The Committee acknowledges these difficulties, 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 nautical miles. Overall, KPCOP responders approved of the proposed changes.[8] The ASTS also responded that it supported the proposed changes.[9] 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 out for public comment.

How well does this proposal address the problem statement?

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.[10] 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 one pancreas transplant in 6 consecutive months, or two 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.

[7] AST Committee Feedback Form. "Input for the Pancreas Program Functional Inactivity Work Group." Kidney and Pancreas Community of Practice (KPCOP), May 24, 2018.
[8] Ibid.
[9] ASTS Response: "In response to the OPTN/UNOS Pancreas Program Functional Inactivity Work Group request for pre-comment." May 15, 2018.
[10] 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

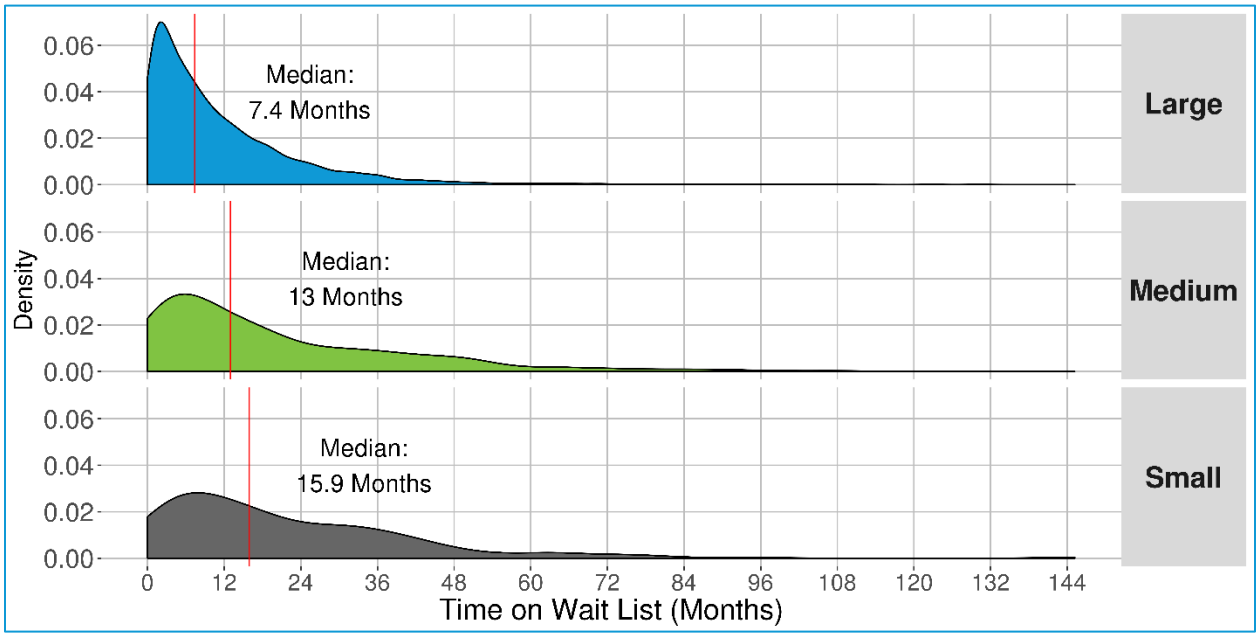
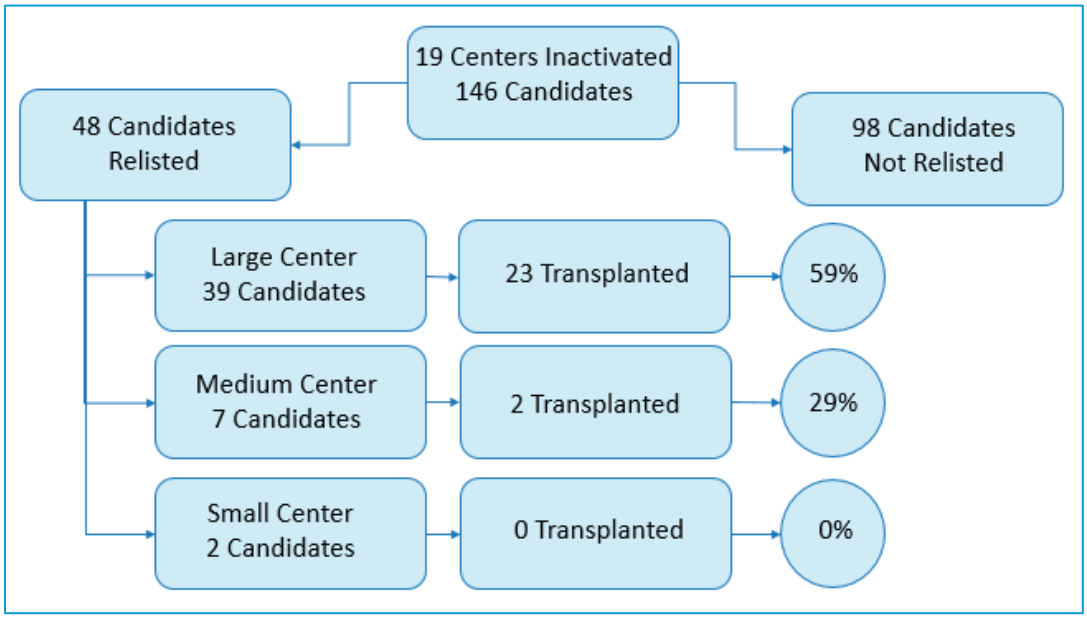


Figure 2 indicates that candidates at small volume programs wait on average 8.5 months longer than candidates at large volume programs.[11] While the average waiting time is over twice as long longer at small volume programs, there is still a fair amount of variation within small volume program waiting times as some small volume programs have short waiting times near or below the national median. Figure 2 supports the change to the functional inactivity definition to include a waiting time metric. While small volume programs with short waiting time would not get reviewed under the new proposal, those that with longer waiting times will be reviewed if the program also performs fewer than 2 transplants in 12 consecutive months. Figure 2 highlights the disparity in access to transplant that may be experienced by patients at some small volume centers that have long waiting times. The proposed changes may lessen the inequitable disparity in access to transplant by focusing MPSC review on programs with longer waiting times, and by providing additional information to candidates.

Figure 3 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 inactivate after review 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 3 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 waiting time.

[11] Ibid.

Figure 3: Patient Relisting Data



The change from the transplant threshold of 1 transplant in 6 months to 2 in 12 months arose from Committee consensus. In particular, Committee members that came from smaller pancreas programs felt that this change would provide more flexibility while not having a negative impact on patient safety. It was also estimated that this could contribute to efficiency by potentially reducing the number of programs reviewed unnecessarily by the MPSC. Public comment indicated support for this change for additional flexibility (see "Was this proposal changed in response to public comment?" for more details).

Review of relevant data and Committee consensus indicated that adding a waiting time metric, increasing the information sent to patients and adding more flexibility to the transplant threshold would lead to a safer and more efficient functional inactivity review process for pancreas programs.

Was this proposal changed in response to public comment?

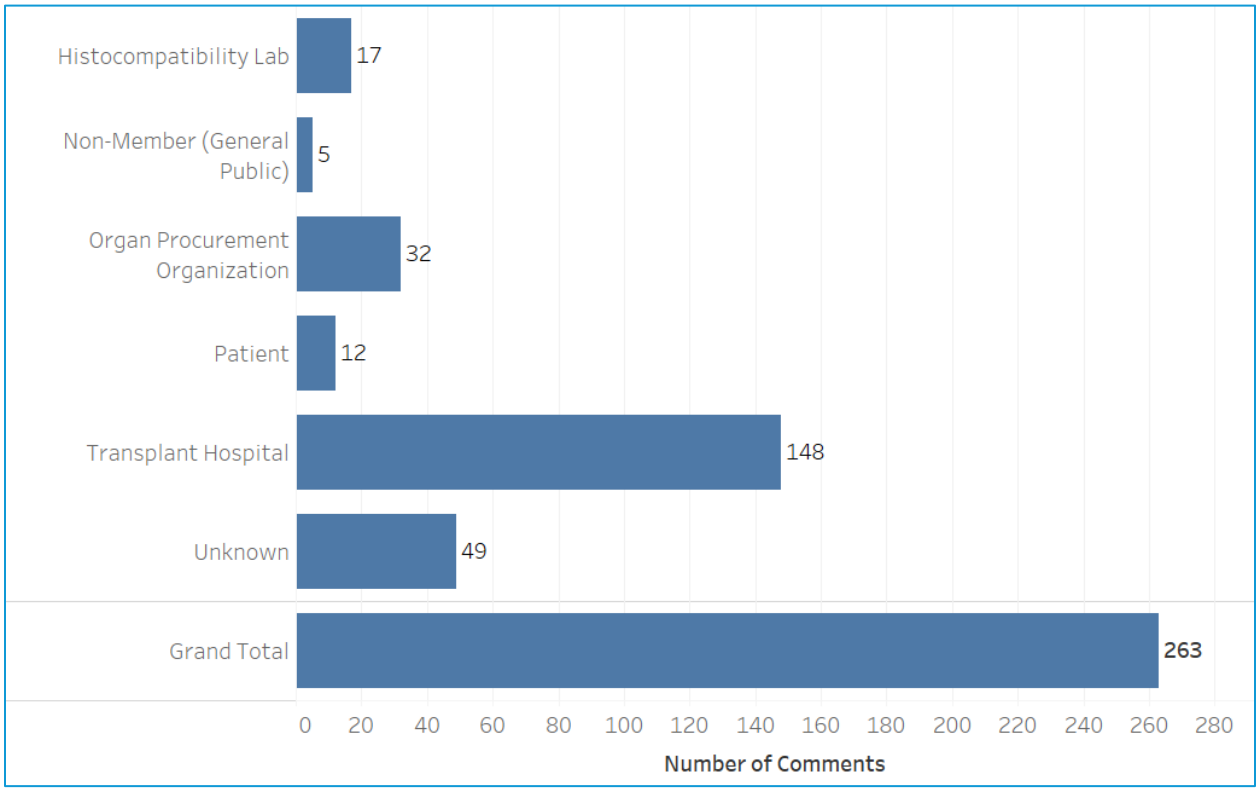
This proposal was changed in response to public comment. The Committee changed the waiting time metric to focus on programs with a median waiting time above the 67th percentile of the national waiting time, instead of an average waiting time above the national average waiting time. The Committee made this change because the focus of the project has consistently been on those programs that have significantly worse waiting times than the average. As some pointed out in public comment, having a waiting time one day above the national average is essentially equivalent to the national average instead of being significantly worse. Thus, the Committee decided it would be more appropriate to focus on those programs whose candidate waiting time is distinctly longer than average.

Generally, public comment feedback was supportive of the proposal. A summary of that feedback, the Committee's response to it, and the post-public comment changes are discussed in the section below.

Public Comment Feedback

The transplant community reviewed the proposal during public comment from August 3, 2018 to October 3, 2018. The proposal received 263 comments. Most (n = 148) comments were from transplant hospitals.

Figure 4: Public Comment Participation



Feedback from public comment indicated a positive response from most stakeholders, who found the proposed changes reasonable. There was a high degree of support with over 80% of respondents either supporting or strongly supporting the proposal. Of 11 regions, nine regions supported the proposal and two regions had mixed support and opposition (regions 1 and 8 – see Table 1). The proposal was on discussion at the regional meetings. The American Nephrology Nurses Association (ANNA), American Society for Histocompatibility and Immunogenetics (ASHI), American Society of Transplantation (AST), and American Society of Transplant Surgeons (ASTS) issued public comments in support of the proposal. The proposal was presented to the Membership and Professional Standards Committee (MPSC), Transplant Coordinators Committee (TCC), Patient Affairs Committee (PAC), Kidney Committee, and Transplant Administrators Committee (TAC).

Table 1: Regional Feedback*

Region	Feedback	Support/Oppose
1	2-6-2-3-1	Mixed Support/Oppose
2	8-13-2-1-3	Support
3	8-13-0-0-0	Support
4	12-7-1-0-0	Support
5	8-13-0-0-0	Support
6	23-15-0-1-1	Support
7	8-12-2-1-0	Support
8	3-5-9-4-2	Mixed Support/Oppose
9	6-9-0-1-0	Support
10	4-12-4-1-1	Support
11	4-11-4-0-0	Support

**From left to right the feedback were tallied accordingly: Strongly support – support – abstain/neutral – oppose – strongly oppose*

Figure 5 shows support and opposition stratified by member type, indicating that general public members were neutral to support, and most other member types were support/strongly support with a few oppose/neutral responses. Figure 6 shows support and opposition stratified by geography, with most areas of the country indicating support for the proposal.[12]

Figure 5: Sentiment by Member

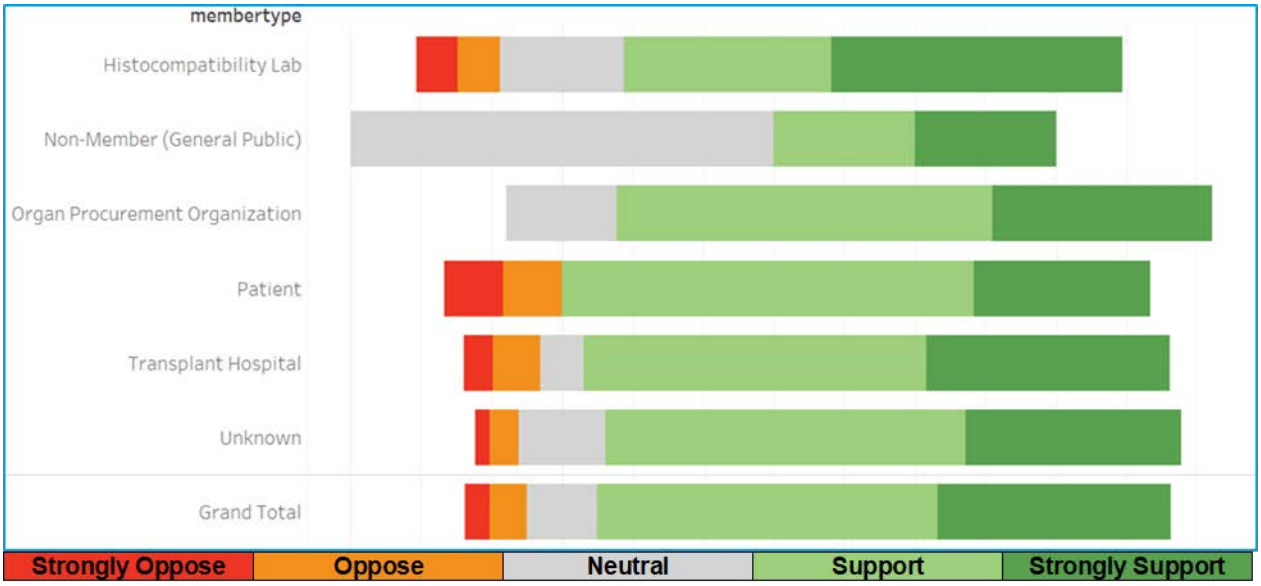
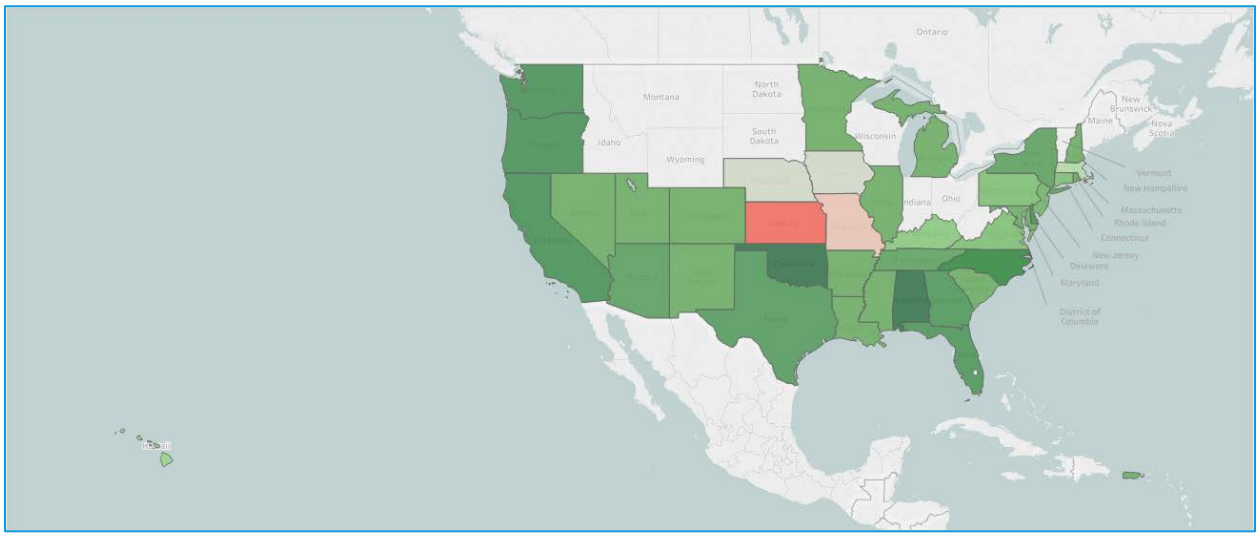


Figure 6: Sentiment by State



Feedback focused on these themes:

1. Broad support for 1 in 6 to 2 in 12 month change in definition
2. Confusion about the impact on outcomes and patient safety

[12] Some commenters did not identify their state. Therefore, they are not included in Figure 6. Notably, the state was not collected for participants at the region 10 meeting.

3. Concern about waiting time (inactive, impact on highly sensitized, definition, average)
4. Suggestion to add regional wait time comparison
5. Additional information for patients
6. Impact on pediatric programs
7. Miscellaneous

Below is a discussion of each of theme and the Committee's responses.

1. Broad support for 1 in 6 to 2 in 12 month change in definition:

There was positive feedback that the change to 2 in 12 months for the transplant threshold would be helpful in providing more flexibility to small volume programs. A member of the TCC indicated it would help programs like hers that are low volume but still transplant their patients quickly and do not let them languish on the list. This element of the proposal could reduce review for the MPSC of programs that are small volume but do due diligence by their patients. Generally, feedback was positive on this change.

2. Confusion about the impact on outcomes and patient safety:

There was concern from some commenters that the Committee didn't adequately demonstrate a relationship between longer waiting time and poor outcomes. Specifically, AST, PAC, MPSC, Region 7 and an individual commenter asked about the connection between outcomes and patient safety and argued that it had not been demonstrated to justify the reliance on waiting time in the new functional inactivity definition. PAC expressed concern that worse outcomes at small volume centers indicated that patients could be adversely impacted by reviewing fewer small volume programs, although one of its members did leave a comment in support of the proposal because it would give patients more information about their options in potentially getting transplanted at a higher volume center. The main concerns from commenters were that reviewing fewer programs won't impact outcomes, and could have a negative impact on patient safety if those programs should have been reviewed. However, the main purpose of the proposal was not to improve outcomes, but to promote transplant and candidate safety by increasing communication with patients and letting them know their options. Patient safety is also impacted by focusing on programs that have longer waiting times to avoid patients languishing on the list.

While there could be a program that has a short waiting time but poor outcomes, there is a separate process for reviewing outcomes that is already in place in the Bylaws (see *Appendix D.11.A: Transplant Program Performance*). Modifying that section is out of scope of this project, which is focused specifically on functional inactivity.

In their discussion of this feedback at the October 10th in-person meeting, Committee members noted that some of the confusion comes from including a public comment slide that indicates a correlation between outcomes and volume. That slide served to provide a general justification for MPSC review of functional inactivity because patient safety is the genesis of MPSC review. In general, more low volume pancreas programs have worse pancreas graft survival than higher volume programs, even while the pancreata transplanted at small volume programs are higher quality. However, this is an average of all small volume programs, indicating that some small volume programs do not have an issue with pancreas graft outcomes. While this slide and graph were used in the public comment proposal and presentations to provide general evidence for the importance of MPSC review of functional inactivity, the Committee agreed that including this information actually hurt an understanding of the proposal by focusing on outcomes, which are not specifically applicable to the proposal. It was recommended to remove this information from future communications and presentations to avoid further confusion.

The Committee also agreed with the PAC that the primary goal for this proposal is not improving outcomes, although that is a secondary goal. While the PAC considered that the primary goal was improving efficiency of the OPTN by reducing the number of programs reviewed by the MPSC, the Committee considers the primary goal equity in patient access to transplant, which was the genesis of the project from the very beginning. Although the proposal also impacts efficiency, that is a by-product of producing a functional inactivity definition and notification to patients that adequately addresses patient

access to transplant at low volume centers by empowering patients with increased information about other programs where they could be listed. Outcomes are potentially impacted because they can be related to patient access to transplant, but the current inequity in small volume patient access to transplant is the direct and most important goal and that has been updated in the proposal accordingly.

3. Concern about waiting time (inactive, impact on highly sensitized, definition)

The Committee discussed at length concerns that were raised about the proposed waiting time metric. As written in the public comment proposal, the new functional inactivity definition would include a transplant threshold (not performing 2 transplants in 12 months) and a waiting time metric (having a longer waiting time than the national average). Programs would have to meet both elements to be reviewed for functional inactivity.

Inactive waiting time
Some commenters during public comment were concerned that the proposal included inactive candidates in the calculation of waiting time, because programs may strategically keep patients on inactive waiting time while waiting for a living donor, for example, or for other reasons that should not reflect poorly on the program. It was reiterated that the only programs that would be evaluated in terms of their waiting time were those that failed to meet the transplant threshold of 2 transplants in 12 months. The Committee also discussed that not including inactive waiting time could be potentially complicated to calculate, because patients may go on and off active waiting time depending on their circumstances. Also, programs could avoid functional inactivity simply by listing their patients as inactive if inactive waiting time wasn't included. This could inadvertently provide a loophole to avoid review by the MPSC. Although programs could try to avoid functional inactivity even if inactive waiting time were included by de-listing a patient, that is a more significant step that includes informing the patient of the de-listing and the reason, as well as paying a fee to re-list the patient. Thus the current proposal, while not perfect or immune to any program manipulation or loopholes, would be more robust and reduce instances where programs could easily avoid review of functional inactivity.

Highly Sensitized
A comment from Region 11 and Region 1 was that highly sensitized patients could be the reason the program has a longer waiting time because highly sensitized patients on average wait longer for a transplant. Again, the Committee reiterated that the only programs reviewed would be those that already did not meet the transplant threshold of 2 in 12 months. Also, the waiting time would only be taken into account to initially flag the program for functional inactivity review by the MPSC. The MPSC could review the program's candidate list and release them from inactivity review upon consideration that the list consisted of highly sensitized candidates. The Committee did not consider it appropriate to modify the waiting time metric based on particular circumstances that the MPSC would already take into account, and that would be irrelevant if the program had performed 2 transplants in 12 months.

Definition of waiting time
The way the Committee calculated waiting time in its original data analysis was by time to transplant. One comment during an MPSC presentation on the proposal noted that this wasn't the most appropriate way to measure waiting time, because the overarching goal of the Committee has been to narrow review to focus on programs that may have patients languishing on the list, as identified by not meeting a transplant threshold and having a higher than average waiting time. However, time to transplant identifies only candidates that become recipients; it does not capture candidates that are removed for other reasons or those that are still on the list. Instead, a more appropriate calculation to use would be time on the waiting list (determined by the difference between listing date and when the MPSC reviews the program's waiting time).

The Committee found this suggestion helpful and agreed to change the waiting time calculation accordingly. In particular, the Committee appreciated that time on the waiting list would better capture potential candidates that could be languishing at small volume programs that should be reviewed for functional inactivity. In its comment, the AST suggested using a waiting time based on the SRTR PSR on time to transplant. While the Committee considered making the waiting time metric identical to the SRTR

metric used in the PSR to reduce confusion for members, this would be in conflict with the effort to focus the waiting time on candidates who could be languishing on the waiting list and not getting transplanted. The information regarding the calculation of waiting time will be included in the Evaluation Plan and available in the pancreas program's individual data reports that will be available through the data services portal on Secure Enterprise.

Waiting time average
The Committee also received feedback that it wasn't fair to flag programs with waiting time even one day above the national average waiting time. In essence, this would be flagging programs that have essentially "average" waiting time. Instead, it would be more appropriate to flag programs that have significantly higher waiting times than the national average. This could be achieved by reviewing programs with waiting time that is a percentile or standard deviation above the national median waiting time.

The Committee considered several options for a waiting time that would be more indicative of programs that truly have longer waiting times than the average program. The Committee reviewed data on the 60th, 67th, and 75th percentile of national waiting time and 1 standard deviation above the national waiting time average. The data analysis used a 2016-2017 cohort and looked at programs that performed less than 4 transplants in that 2 year period to categorize the programs as small volume.[13] The data indicated the 60th and 67th percentile would result in review of 24 and 21 pancreas programs respectively, while the 75th percentile and standard deviation above would result in review of 9 and 5 pancreas programs, respectively.[14] In the original analysis performed before public comment, which compared a program's average waiting time with the national average waiting time, 24 programs were projected to be reviewed.[15] Because the 75th percentile and standard deviation above the national average would imply a substantially different cohort of review for the MPSC compared to the proposed public comment calculations, the Committee focused on the 60th and 67th percentiles above the national waiting time as the best options to capture small volume programs exhibiting longer waiting times for the MPSC to review further. Ultimately, the Committee expressed support for using the 67th percentile of national waiting time as a comparator because it included programs with waiting times longer than two-thirds of all U.S. pancreas programs. This aptly focuses on programs with substantially longer waiting times than average, in accordance with the original intent of the proposal.

The Committee agreed that it would be beneficial to use a waiting time metric that included programs above a 67th percentile of national waiting time in order to focus on programs where candidates wait longer. This is consistent with the original proposal and the effort to narrow the MPSC's review of pancreas programs that clearly demonstrate functional inactivity, while preserving the flexibility by changing the transplant threshold from 1 in 6 months to 2 in 12 months. The Committee voted unanimously to modify the waiting time metric from using a national average waiting time to the 67th percent of national waiting time on a November 7th teleconference.

Because the Committee worked closely with the MPSC during the development of this proposal, the Committee informed the MPSC leadership about the proposed changes, which MPSC leadership thought were reasonable and helpful.

4. <u>Suggestion to add regional WT comparison</u>

Region 1 and the TCC suggested that the Committee add in a regional waiting time comparator either to the functional inactivity definition or the letter sent to patients in order to give a more local and relevant comparator of waiting time. However, UNOS staff noted that there could be areas of the country where there are no regional comparisons, or all the regional comparisons of other pancreas programs are also functionally inactive programs. The Committee would not want to allow functionally inactive programs to

[13] OPTN/UNOS Descriptive Data Request. "Functional Inactivity Waiting Time Metric." Prepared for Pancreas Committee Conference Call, November 7, 2018.
[14] Ibid.
[15] OPTN/UNOS Descriptive Data Request. "Functional Inactivity: Updated Analysis." Prepared for Pancreas Program Functional Inactivity Work Group Conference Call, January 31, 2018.

avoid review simply because they were compared with similarly inactive programs. The Committee also noted that the OPTN/UNOS community is working on removing arbitrary geographic boundaries such as regions from certain areas of policy, so it seemed potentially problematic to add it to patient letters.

5. Additional information for patients

The PAC suggested (along with the TCC) that more information be sent to patients of functionally inactive programs related to program metrics. This section of the Bylaws already requires that programs send patients the OPTN Contractor's Patient Information Letter. The TCC and PAC suggested more information could be sent to patients about the SRTR portal that allows patients to research different programs and be more informed. However, including this link in the Bylaws is problematic because if the link ever changed, the Bylaws would have to be changed. Generally, anything included in the Bylaws or in policy should not be impermanent. However, the Committee agreed with the suggestion to increase the information sent to patients. Instead of including it in the Bylaws, the Committee will communicate with the PAC about updating the Patient Information Letter to include more links to the SRTR website, empowering patients to make more informed decisions. This information was passed along to the UNOS staff that support the PAC.

In the original public comment proposal, the Committee asked for feedback on whether the additional information that functionally inactive pancreas programs must include in communicating with their patients should be applied to other organ programs that are flagged for functional inactivity. In developing this proposal, the Committee felt that it was out of scope and not appropriate for the Pancreas Committee to change what other organ programs send to their patients. However, in discussions with the MPSC, it was agreed to ask the community during public comment if these changes should apply to other organ programs reviewed for functional inactivity. Any feedback would be passed along to the MPSC, which would review it.

During public comment, committees and regions that gave feedback on this question expressed little concern for having these changes apply to other organ programs. One comment from a TCC member expressed support for sending more information to patients but indicated that organ-specific committees should make the determination whether to make this change. Region 8 did not support having this change apply to other programs, although there was confusion about whether this proposal would make those changes (it will not). Regions 4 and 2 expressed support for this change applying to other organ programs. This information has been communicated to MPSC leadership for their consideration.

6. Impact on pediatric programs

Region 5, ASTS and two individual commenters expressed concern about having the proposed changes apply to pediatric pancreas programs, that do very few transplants, which means they would inactivate and have to reactivate if they needed to meet the 2 transplants in 12 months threshold and the waiting time metric. However, current policy allows that pediatric programs have to meet a different threshold than adult pancreas programs. See Table 2, which reproduces *Table D-1: Functional Inactivity Periods* from the OPTN Bylaws.

Table 2: Functional Inactivity Periods

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas or Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

Table 2 indicates that pediatric pancreas programs currently don't have to meet the 1 in 6 threshold, and wouldn't have to meet the 2 in 12 threshold under the proposed changes. In short, the pediatric programs are held to a separate set of thresholds and are unaffected by the changes this proposal focuses on. While there still may be concern about the way that pediatric programs are reviewed for functional inactivity, that is beyond the current scope of this project.

7. Miscellaneous

Overall, there were a few comments that thought either the proposal didn't do enough to hold small volume programs accountable or that considered the proposal too stringent on small volume programs. Region 4, an anonymous commenter and members of PAC expressed concern that the proposal did not go far enough. Regions 8 and 11, as well as ASHI indicated the proposal could be more lenient. This speaks to the "middle of the road" option that the Committee pursued, in not being too punitive but serving to protect patient safety and create a more efficient review system.

In its review, AST commented that the change in functional inactivity definition may be at odds with the CMS definition of functional inactivity, and that could create confusion. In response, the Committee advises the community to continue sending CMS whatever CMS requires for functional inactivity; these changes do not impact what CMS requires, nor does it impact what a program has to send to CMS.

Another question asked by a TAC member was why the Committee chose 125 miles as the area around the program for giving patients information about other pancreas programs. The reason is because 125 miles is close to about 2 hours of driving for a patient to travel in search of a different center.

Summary of post-public comment changes

Below are a summary of changes that the Committee made post-public comment. The waiting time change has been discussed and explained previously; the change from miles to nautical miles and "and" to "or" are non-substantive and explained below.

- Waiting time metric:
  - Program waiting time above the national average is changed to program waiting time that is above the 67th percentile of the national waiting time
- Nautical miles
  - Change 125 miles to 125 nautical miles to be consistent with the rest of policy and the Bylaws
- "and" to "or"
  - The Committee previously voted on language that said patients must be informed about multi-listing and transfer of accrued waiting time to another transplant hospital; however, some states do not allow multi-listing so this "and" must be changed to "or"

The Committee voted unanimously on November 7th to adopt the aforementioned changes.

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 creates an incentive for pancreas programs to not come under functional inactivity review, which could serve as an impetus to increase program volume.

2. *Improve equity in access to transplants:* Patients languishing at small volume programs with long waiting times could be transplanted elsewhere more quickly. By focusing review of functional inactivity on these small volume programs with long waiting times and empowering patients to

make educated healthcare decisions, the proposed changes improves patient access to transplant.

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 compared to the national waiting time for pancreas candidates with the 67th percentile indicated.. The OPTN will communicate with members the new requirements in policy notices and in Transplant Pro.

The fiscal impact on all departments is small. A small amount of staff time for routine monitoring activity will be required; however, this monitoring effort will be accomplished through an existing process. This proposal will not require programming in UNet.

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 that is above the 67th percentile of the national median. 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 nautical miles, in-state or in-commonwealth and 2) the program’s average waiting time compared to the 67th percentile of the national waiting time. 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. A very small amount of staff time may be required each moth to monitor OPTN reports. Staff time communicating with patients will only be required for those programs under review. Over time, members may see decreased administrative costs due to a decrease in OPTN reviews.

OPOs and Histocompatibility Laboratories

This proposal will have no fiscal impact on transplant programs or histocompatibility laboratories.

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. The Committee has no expectation that this should change because the proposed changes do not change the options available to the MPSC in reviewing functionally inactive programs.
3. Trends in relisted candidates (i.e. transferred from an inactivated program to an active program) and their outcomes. If more patients are aware of other programs as options available to them, the number of relisted candidates could increase.
4. Patient and graft survival of pancreas recipients stratified by center volume. The proposed changes create 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, which could be reflected in improved patient or graft survival.

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~~).

RESOLVED, that changes to Bylaws D.10.A (Functional Inactivity) and D.10.B (Notification Requirements for Transplant Program Functional Inactivity), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

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: • A median waiting time of the program's kidney-pancreas and pancreas candidates that is above the 67th percentile of the national waiting time • 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 or 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 all pancreas programs within the same state or commonwealth and all pancreas programs within 125 nautical miles of the functionally inactive program regardless of state or commonwealth boundaries.
6. The following information:
    a. For potential candidates and candidates on the waiting list, the program's median waiting time in the consecutive 12 month period for kidney-pancreas and pancreas candidates compared to the 67th percentile of the national waiting time.
    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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