

OPTN Policy Notice

Pancreas Program Functional Inactivity

Sponsoring Committee:	Pancreas Transplantation Committee
Policy/Bylaws Affected:	OPTN Bylaws Appendices D.10.A (Functional Inactivity), D.10.B (Notification Requirements for Transplant Program Functional Inactivity)
Public Comment:	August 3 – October 3, 2018
Effective Date:	April 8, 2019

Problem Statement

The majority of programs under review for functional inactivity by the OPTN Membership and Professional Standards Committee (MPSC) are pancreas programs. 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. Transplant candidates with long waiting times who are listed at small-volume programs could be transplanted elsewhere more quickly, and could receive more information about their transplant options.

Summary of Changes

This change to the functional inactivity definition addresses concerns about patient safety and access to transplant. The definition focuses on pancreas programs with longer waiting times, and avoids review of pancreas 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 either a median waiting time that is above the 67th percentile of the national waiting time or no candidates on the kidney-pancreas and pancreas waiting lists.

In addition to current patient notification requirements, pancreas programs reviewed for functional inactivity need to inform patients and potential candidates about other pancreas programs in-state, in-commonwealth or within 125 nautical miles of the program, and provide information about the program's waiting time compared to the 67th percentile of national waiting time.

The MPSC will use the new criteria to identify programs for functional inactivity review at its July 2019 meeting.

What Members Need to Do

Pancreas programs under review for functional inactivity need to put additional information in the letter they send to both candidates on the waitlist and potential candidates. This letter must include:

- names and contact information of other pancreas programs within 125 nautical miles, in-state or in-commonwealth, and

- the program's median waiting time compared to the 67th percentile of the national waiting time.

Programs still need to include the information previously included in *D.10.B: Notification Requirements for Transplant Program Functional Inactivity*:

- the dates during which fewer than two transplants were performed
- the reason fewer than two transplant were performed
- options available to candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital
- the OPTN Contractor's Patient Information Letter

New OPTN Data Report

Pancreas transplant programs will have access to a new data report that shows the transplant program's median waiting time compared to the 67th percentile of national waiting time. The data report will be updated monthly and reflects the previous 12 months of waiting time. The comparison of the program's median waiting time with the 67th percentile of the national waiting time focuses functional inactivity review on those programs that, in addition to failing to perform at least 2 transplants in 12 months, also have significantly longer waiting times than the national average.

Kidney-pancreas and pancreas-alone candidate waiting times are substantially different, both at the program and the national level, and are therefore reported separately. If either the pancreas-alone or kidney-pancreas median program waiting time is longer than the national 67th percentile for that respective time period, the MPSC may initiate an inquiry for that program regarding its functional inactivity.

The UNetSM Data Services Portal contains a variety of useful reports for OPOs and transplant centers. You can access these reports with a few easy steps:

1. Check with the UNetSM security administrator to make sure you have permission to view the portal. They can grant you access by checking the data services option at the bottom of your security admin page.
2. Once you have proper permission, simply log onto UNetSM, select Resources from the main navigation bar, and choose Data Services from the dropdown menu. From the headings in the left column, select Data Files, then the data report.

Affected Policy Language

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:	<u>Inactive Period</u> Functional inactivity is defined as:
Kidney, Liver, or Heart	<u>Failure to perform at least 1 transplant in 3 consecutive months</u>
Pancreas or Lung	<u>Failure to perform at least 1 transplant in 6 consecutive months</u>

For this transplant program type:	Inactive Period Functional inactivity is defined as:
Stand-alone pediatric	<u>Failure to perform at least 1 transplant in 12 consecutive months</u>
<u>Pancreas</u>	<u>Both of the following:</u> <u>1. Failure to perform at least 2 transplants in 12 consecutive months</u> <u>2. Either of the following in 12 consecutive months:</u> <u>• A median waiting time of the program's kidney-pancreas and pancreas candidates that is above the 67th percentile of the national waiting time</u> <u>• The program had no kidney-pancreas or pancreas candidates registered at the program</u>
<u>Islet, intestinal, and VCA</u>	<u>No functional inactivity definitions have been established</u>

~~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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