

Definition of Pancreas Graft Failure

*Pancreas Committee
June 2015*

The Problem

- No consistently used definition for pancreas graft failure
 - Leads to inconsistent reporting
 - No current MPSC pancreas graft outcomes reviews
 - Deficiencies in Tiedi help documentation
- See next slide for examples

Current Tiedi Guidance on Reporting Pancreas Graft Status

- **Functioning:** The graft has sufficient function so that the recipient is NOT receiving any insulin or oral medication for blood sugar control
- **Partial Function:** The patient is taking some insulin, but $\leq 50\%$ of the usual amount taken before transplant, or C-Peptide is present
- **Failed:** The graft has totally failed and the patient is completely dependent upon insulin or oral medication for blood sugar control

Strategic Plan Alignment

Goal 3: Improve survival for patients post-transplant

- By providing a standardized definition that will enable programs to properly analyze and compare pancreas programs' outcomes.

Proposed Solutions

- Define pancreas graft failure as any of the following:
 - Recipient's pancreas is removed
 - Recipient re-registers for a pancreas
 - Recipient registers for an islet transplant after receiving a pancreas transplant
 - Recipient's insulin is greater than or equal to 0.5 units/kg./day for 90 consecutive days
 - Recipient dies

Proposed Solutions

- Update pancreas and kidney-pancreas Transplant Recipient Registration and Transplant Recipient Follow-Up forms

Clinical Information			
Height:	<input type="text"/>	ft. <input type="text"/>	in. <input type="text"/> cm ST= <input type="text"/>
Weight:	<input type="text"/>	lbs. <input type="text"/>	kg ST= <input type="text"/>
BMI:	kg/m ²		
Graft Status: *	<input type="radio"/> Functioning <input type="radio"/> Partial Function <input type="radio"/> Failed		
If death is indicated for the recipient, and the death was a result of some other factor unrelated to graft failure, select Functioning.			

Public Comment Themes

- Concern over the insulin/kg criteria for graft failure
- C-peptide analysis is “inadequate”
- Clarify that insulin use is calculated by combining total long-acting and short-acting insulin amounts used in one day
- Collect data on other oral agents that the pancreas transplant recipient (without graft failure) may be using to manage insulin resistance

Post-public comment action

- Clarified calculation of insulin use
 - Include the word “total*” in data form, with * explaining that total means long-acting and short-acting
- Declined to collect data on other oral agents the pancreas recipient may be using to manage insulin resistance

What Members will Need to Do

- Transplant centers will need to:
 - Report pancreas graft failure according to the definition
 - Report additional information when filling out the pancreas and kidney-pancreas OPTN TRR and TRF
 - Require centers to report fasting C-peptide serum level, HbA1c, and insulin use to the OPTN
 - Pancreas Committee will revisit definition in the future with more complete data collection nationally

Overall Project Impact

Product

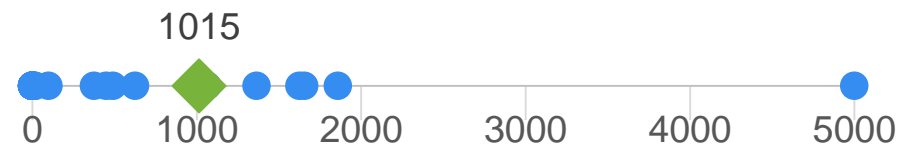
Policy

Target Population Impact:

All pancreas transplant recipients

Total IT Implementation Hours

1015/ 16,680



Total Overall Implementation Hours

1205/ 23,685



Board Policy Group Recommendation

- Discussion agenda, approve

Resolution 25 (page 111)

- RESOLVED, that changes to Policies 1.2 (Definitions) and 3.6 (Waiting Time) as set forth below, are hereby approved, effective September 1, 2015.