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
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 ≤ 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
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

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

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