Changes in this version

4.2.8 change Associate Medical Director to OTDT Medical Director.

Policy

This policy has been created by the Pancreas Advisory Group on behalf of NHSBT.

This policy previously received approval from the Transplant Policy Review Committee (TPRC). This committee was disbanded in 2020 and the current governance for approval of policies is now from Organ and Tissue Donation and Transplantation Clinical Audit Risk and Effectiveness Group (OTDT CARE), which will be responsible for annual review of the guidance herein.

Last updated: September 2024

Approved by OTDT CARE: October 2024

The aim of this document is to provide a policy for the selection of adult and paediatric patients on to the UK national transplant list and, where necessary, criteria for their de-selection. These criteria apply to all proposed recipients of organs from deceased donors and all centres should work to the same selection criteria.

Non-compliance to these guidelines will be handled directly by NHSBT, in accordance with the Non-Compliance with Selection and Allocation Policies
http://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/

It is acknowledged that these guidelines will require regular review and refreshment. Where they do not cover specific individual cases, mechanisms are in place for selection of exceptional cases.

1. Conditions that are considered for transplantation

Patients who are considered for pancreas or islet transplantation fall into three categories:

- Pancreas transplant alone / islet transplant alone
    - Patients with severe hypoglycaemic unawareness and insulin treated diabetes, but normal or near-normal renal function
- Simultaneous pancreas and kidney transplant / Simultaneous islet and kidney transplant
    - Patients with renal failure and insulin treated diabetes
- Pancreas after kidney transplant / islet after kidney transplant
    - Patients with functioning kidney transplants and insulin treated diabetes

The majority of patients who are considered have type 1 diabetes, but a minority of insulin treated type 2 diabetic patients may also be suitable candidates for pancreas transplantation.

2. Assessment of patients

There are three stages of assessment:

- Pre-transplant assessment
- Decision
- Transplant list

2.1 Pre-transplant assessment

The assessment must be completed within 18 weeks of referral although this may be delayed if medical issues that require intervention prior to listing for transplantation are identified. At the end of

assessment, the decision will be made as to whether the patient should be listed for a transplant and this decision communicated to the referring doctor and the patient's general practitioner.

The importance of the multidisciplinary involvement in the assessment of the patient and care received is paramount. The assessment may involve a whole spectrum of healthcare professionals, including physicians, surgeons, radiologists, nurses, transplant co-ordinators, occupational therapists, dieticians, physiotherapists, social workers, pharmacists, psychologists, and, if indicated, psychiatrists.

The full history and examination should include:

Diabetic condition

- History of diabetes – insulin dose, hypoglycaemic episodes, unawareness
- Secondary complications of diabetes mellitus
- For those listed for islet assessment, the opinion of an ophthalmologist may be sought regarding the stability of a patient's eyes as it would be detrimental to perform a transplant if there is unstable eye disease.

Social history

- Domestic status
- Housing
- Employment
- Smoking
- Drugs/alcohol use
- Driving status

Past/concurrent history

- Malignancy
- Cardiovascular history (cardiac, cerebrovascular, peripheral)
- Renal disease
- Liver disease
- Gastrointestinal (peptic ulceration, GI bleeding, diverticular disease)
- Unresolved sepsis in any site
- Previous blood transfusion
- Pregnancies
- Previous transplants
- Normal cervical smear test (females aged 25-64)
- Mammogram (females over 50)
- PSA test (males)

Routine observations

- Temperature
- Blood pressure
- Heart rate
- Height
- Weight (BMI)
- Peripheral pulses

Radiology

- Chest x-ray
- Doppler and/or other imaging of aorta, iliac and peripheral arteries may be indicated

- Liver ultra sound for islet patient

Microbiology assessment
- MSU (mid-stream urine) and urine dipstick
- MRSA screen

Cardiac assessment
- Electrocardiogram (ECG)
- Functional myocardial study (ECHO/MPS etc.)
- Cardiology review may be warranted on the basis of the myocardial perfusion studies and may identify the need for additional tests, i.e. coronary angiogram as clinically indicated

Dental assessment
- Dental examination in the last 12 months
- Advice on dental hygiene

Haematology blood tests
- Blood group
- Antibody screen (ABO)
- Full blood count

Biochemistry test
- Urea and electrolytes
- Creatinine
- HbA1c
- C-peptide assessment
- Calcium, phosphate
- Spot urine albumin/creatinine ratio
- Glomerular filtration rate (GFR)/radioisotope glomerular filtration rate if needed (PAK, PTA)
- Kidney biopsy if indicated (PAK PTA)
- Liver function tests
- Amylase
- Fasting blood glucose
- Fasting and stimulated C-peptide levels if needed (patients with BMI >30kg/m2)
- Fasting blood lipids

Additional studies may include oral or intravenous glucose challenge, anti-insulin, anti-GAD and islet cell antibodies, proinsulin level and lipoprotein.

Serology blood sample for immunity to the following viruses
- Hepatitis B and C
- HIV
- Human T-cell leukemia/lymphoma virus (HTLV)
- Epstein Barr virus (EBV)
- Syphilis
- Rubella
- Toxoplasma
- Varicella-zoster
- Herpes simplex
- Cytomegalovirus
- HEV

Immunology blood tests

- Human leukocyte antigen (HLA) typing and antibody screening

Other

- Additional evaluations may be required by other healthcare professionals as indicated

2.2 Decision
The decision to place a patient on the transplant list is a multidisciplinary one and dependent on the Selection Criteria set out in section 3. The patient and their relatives will be informed of the outcome and given the opportunity to discuss it with a representative of the transplant team.

2.3 Transplant list
If the patient decides to go forward for transplantation, he or she is then registered with NHSBT and placed on the National Transplant List.

If the patient is not deemed suitable and/or declines the option of transplantation, the appropriate clinician will explain to the patient and their family the options available to them, including referral to another transplant unit for a second opinion. The GP and referring clinicians should be informed of the outcome of the assessment.

3. Selection criteria
3.1 Clinical criteria for selection
All patients listed for **pancreas** or **islet transplantation** should have insulin treated diabetes.

Patients listed for **islet transplantation** should have type 1 diabetes or diabetes secondary to pancreatectomy / pancreatitis. All should have confirmed C-peptide negativity in presence of glucose more than 10 mmol/l.

- Patients listed for **pancreas transplantation** with type 2 diabetes must have calculated BMI of 30 kg/m^2 or less at the time of listing.

- Patients listed for **pancreas transplant alone / islet transplant alone** must have at least two severe hypoglycaemic episodes, as defined by the American Diabetes Association* (ADA), within the last 24 months and be assessed by a diabetologist to have disabling hypoglycaemia.

- Patients listed for **simultaneous kidney pancreas transplant / simultaneous islet kidney transplant** must be receiving dialysis or have a calculated or measured GFR of 20mls/min or less at the time of listing.

- Patients listed for an **islet after kidney transplant** should have a history of severe hypoglycaemia (ADA definition*) within last two years or HbA1C more than 53 mmol/mol at time of listing.

- Patients listed for a **priority islet transplant** should be listed within 12 months of routine graft and have a functioning routine transplant (C-peptide of 50 pmol/l or more) at the time of listing.

It is recognised that the above criteria may exclude a small group of patients who would otherwise be appropriate candidates for listing. In such cases, the centre should write to the Pancreas Advisory Group Exemptions Panel, as outlined in section 4.2, to determine whether such excluded

patients should be placed on the national transplant list.* ADA definition of severe hypoglycaemia: “an event requiring the assistance of another person to actively administer carbohydrate, glucagon or other resuscitative actions. These episodes may be associated with sufficient neuroglycopenia to induce seizure or coma.”

3.2 Multiple organ transplant
Simultaneous pancreas and kidney or simultaneous islet and kidney transplantation is the primary treatment for pancreas patients and selection criteria are as described in section 3.1.

3.2.1 Selection for combined liver and pancreas (CLP) transplantation
Combined liver and pancreas transplantation (with or without a kidney) is only undertaken in patients with diabetes mellitus who have end stage liver disease sufficient to justify a liver transplant alone, but in addition they have a complication of diabetes such as:

- Hypoglycaemic unawareness, and have required at least two third party interventions for hypoglycaemia in the preceding 12 months
- Another complication as ratified by the PAG Exemptions Panel

3.3 Contraindications
Pancreas only, islet only, simultaneous pancreas/kidney, simultaneous islet/kidney, pancreas after kidney and islet after kidney
3.3.1 Absolute contraindications

- Excessive cardiovascular risk including:
  - Angiography indicating clinically significant and severe and non-correctable coronary artery disease
  - Recent myocardial infarction (within 6 months)
- Non-curable malignancy
- Active sepsis
- Active peptic ulcer
- Major psychiatric history likely to result in non-adherence
- Inability to withstand surgery and immunosuppression

3.3.2 Relative contraindications

- Ejection fraction below 50%
- Cerebrovascular accident with severe long-term impairment
- Active infection with Hepatitis B or C virus
- Body mass index greater than 30 kg/m^2 (absolute contraindication for PTA and for type 2 diabetics)
- Extensive aorta/iliac and/or peripheral vascular disease
- Continued abuse of alcohol or other drugs
- Insulin requirements >100 units/day

3.4 De-selection criteria
Patients are de-selected from the transplant list if they develop contraindications whilst on the transplant list.

Patients listed for a priority islet transplant will have their priority status withdrawn if their current routine transplant fails. In this circumstance if the patient wishes to remain on the islet transplant list with a routine status, the centre is required to contact ODT Information Services to amend the registration status and ensure the patient maintains their accrued waiting time.

3.5 Selection for re-transplant

The criteria for selection for re-transplant are the same as the then current criteria for primary transplant treatment. See section 3.1 for details.

4. Exemption request process

4.1 Any patient who is not satisfied with the decision of the transplant centre may request a second opinion from another pancreas transplant centre.

4.2 If a clinician considers that a transplant candidate is unfairly disadvantaged by the selection criteria he/she may lodge an exemption request to be considered by the Pancreas Advisory Group Exemptions Panel or in the case of islet exemption requests, the PAG Islet Steering Group.
4.2.1 The Exemptions Panel will be chaired by the Chair of the Pancreas Advisory Group / PAG Islet Steering Group or deputy where the request has come from the Chair's transplanting centre.
The panel will consist of an independent non-voting Chair or deputy and one representative from each of the pancreas or islet transplant centres. The clinician responsible for the patient may present the case to the Panel, but the representative for the centre where the application is from cannot vote.
4.2.2 The request for exemption will be made by electronic means to the Pancreas Advisory Group / PAG Islet Steering Group Chair who will circulate the application to the members of the Exemptions Panel / PAG Islet Steering Group.
4.2.3 The Chair will decide whether a teleconference is needed.
4.2.4 There should be a majority decision and a minimum of five pancreas or three islet voting centres must respond in order for a decision to be valid. There should be discussion within a centre prior to the centre response from the designated clinician. If the initial decision is not a majority, the Chair will have a casting vote.
4.2.5 All decisions made by the PAG Islet Steering Group will be ratified by the PAG Chair on behalf of the Pancreas Advisory Group.
4.2.6 The Chair will notify the applicant clinician of the decision.
4.2.7 The outcome of every request will be presented to the next meeting of the Pancreas Advisory Group.
4.2.8 The candidate's consultant may appeal to the OTDT Medical Director and the appeal considered at the next meeting of the Solid Organ Advisory Group Chairs Committee.

5. Follow-up on list

The patient should receive detailed explanation and key information pertaining to the waiting period for transplantation. This will be carried out according to each centre's protocols and practice. During the waiting period the transplant centre will maintain contact with the patient and his/her family to offer support, information and guidance according to their needs. Clinical review of patients on the transplant list will be an annual requirement.

The condition of patients on the transplant list will be monitored according to the centre's local practice. This may include regular (annual) review or may depend on the local renal physician to identify relevant changes.

6. Transplant list management

Transplant centres are required to review data relating to their listed patients via ODT online on a regular basis to ensure data relevant to the Pancreas Allocation Scheme are accurate and patients are prioritised accordingly with in the allocation scheme. See the *Pancreas Allocation Policy* http://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/ for details.

In particular, they should notify ODT Information Services if a patient's dialysis status changes, their waiting time appears inappropriate or if the patient has moved between transplant centres.

If a centre considers a transplant candidate to be unfairly disadvantaged by amendments to patient data, he/she may raise the issue with the Chair of the Pancreas Advisory Group as outlined in section 4.3 of the Pancreas Allocation Policy.

7. Audit

NHSBT conducts regular audits on organ allocation and outcomes.