POLICY POL199/7

Pancreas Transplantation: Organ Allocation

This Policy replaces *POL199/6*	**Copy Number**
	Effective **25/01/17**

Summary of Significant Changes

Amendment to blood group rules

Policy

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

The policy has received final approval from the Transplant Policy Review Committee (TPRC), which acts on behalf of the NHSBT Board, and which will be responsible for annual review of the guidance herein.

Last updated: January 2017

Approved by TPRC: July 2016

The aim of this document is to provide a policy for the allocation and acceptance of organs to adult and paediatric recipients on the UK national transplant list. These criteria apply to all proposed recipients of organs from deceased donors.

In the interests of equity and justice all centres should work to the same allocation 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/#noncompliance

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 the allocation or organs in exceptional cases.

1. Allocation policy

The National Pancreas Allocation Scheme (NPAS), managed by NHSBT allocates donated pancreases to patients listed nationally.

1.1 Rationale for allocation policy

Pancreases that are offered through this scheme include those donated after brain death (DBD) and those donated after circulatory death (DCD). Pancreases that are preferentially offered and accepted for multivisceral (e.g. pancreas and small bowel) or multiple organ transplants (e.g. pancreas and liver), with the exception of combined pancreas and kidney transplants and combined islet and kidney transplants, are not offered through this scheme.

1.2 How the allocation policy was developed

The allocation policy was developed with the following objectives:

- All patients on the national transplant list have equal access to transplantation irrespective of their geographical location or the transplant centre at which they are registered
- The maximum benefit is achieved in terms of utilisation and outcome of the available donor organs
- Priority is given to sensitised and hard-to-match patients provided this does not prejudice severely ill patients
- An appropriate proportion of suitable donor organs are allocated to the national islet transplant programme

1.2.1 Justification for sub-groups

Donor to recipient blood group matching is restricted as part of the scheme. This is important to maintain equity of access to a transplant for patients across all blood groups. For example: while pancreases from blood group O donors could be allocated to recipients of any blood group, blood group O recipients are only able to receive organs from blood group O donors for biological reasons. If all blood group O donor organs were allocated to recipients of any blood groups then the number of blood group O pancreases available to blood group O recipients would be much less and the blood group O recipients would be disadvantaged.

Where the recipient is very difficult to find a pancreas for and they are an unusual blood group this rule may be broken, so a blood group AB recipient may receive a blood group A pancreas, a highly sensitised blood group B patient or a very highly sensitised blood group A or AB patient may receive a blood group O pancreas and a very highly sensitised blood group AB patient may receive a blood group B pancreas.

	Potential recipient blood group			
Donor blood group	O	A	B	AB
O	a	a **	a *	a **
A		a		a
B			a	a **
AB				a

* Patients with a calculated reaction frequency of 75% or more only
** Patients with a calculated reaction frequency of 90% or more only

1.3 Allocation policy

In order to prioritise patients for receipt of a pancreas that becomes available, patients are awarded individual points based on a number of clinically relevant donor-, patient-, and transplant-related factors. For each patient, these points are accumulated to give an individual Total Points Score

(TPS). The patient with the highest TPS is ranked first in the offering sequence. All eligible patients appear on the Pancreas Matching Run (PMR) and are ranked according to the highest to lowest TPS.
The scoring system is based on a combination of donor, recipient and transplant factors. Patient scores and ranking positions will therefore differ over time and for each given donor. The algorithm that calculates the TPS is detailed in 1.3.2. An example of how the scoring system is used to prioritise patients is shown in 1.3.3.

1.3.1 Details of policy

The seven elements that are taken into account to calculate the TPS are:

- Total HLA mismatch
- Waiting time
- Sensitisation
- Travel time
- Donor body mass index
- Dialysis status
- Donor to recipient age matching

Total HLA mismatch points

The HLA type ("tissue type") in terms of HLA-A, B and DR antigens of both the donor and patient are recorded. Within each locus (e.g. HLA-A) there are many specific HLA antigens (e.g. A1, A2, A3 etc.) and most donors/recipients will have two HLA antigens for each locus. Some patients are what is known as homozygous and may only have one common antigen within a locus.

These HLA antigens are compared between the donor and potential recipient and the numbers of antigens present in the donor that are not present in the recipient are counted. A patient can therefore have either 0, 1 or 2 mismatches at each locus. Across the HLA-A, B and DR loci the total mismatch count can therefore range between 0 and 6.

There is evidence to suggest that transplants with a very poor HLA match (total mismatch count of 5 or 6) may lead to poorer longer-term post-transplant outcomes compared with transplants with lower numbers of HLA mismatches. It is important to note that in some circumstances a poorly matched transplant may be a good option for the patient and may proceed. The HLA mismatch score aims to minimise the number of transplants with very poor HLA matching without excluding them as an option for some patients.
It is also known that a number of routine pancreatic islet transplant recipients are likely to require a second or subsequent transplant as a priority. To increase the chance of finding an appropriate donor HLA match for the second or subsequent islet transplant, an additional HLA points system is applied to patients receiving their first islet transplant.

Waiting time points

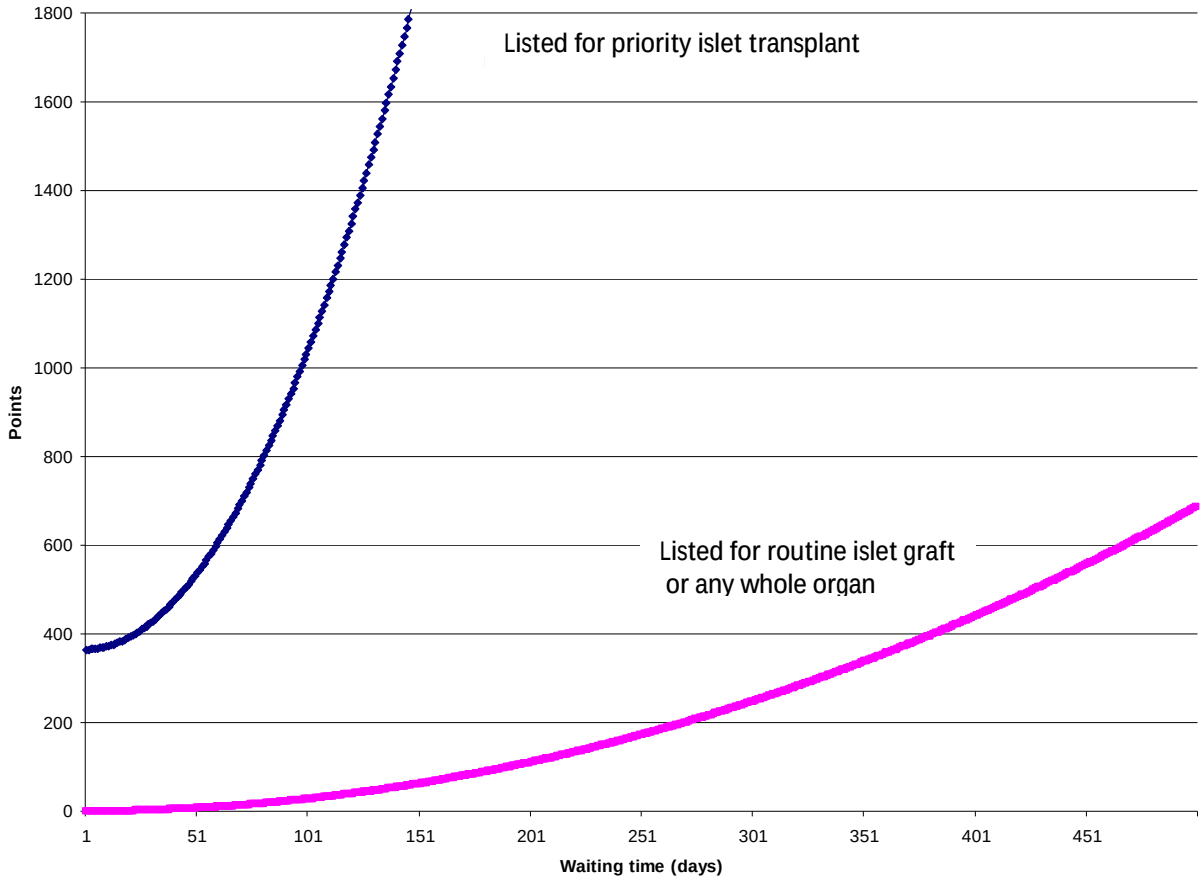
For patients listed for a priority islet transplant, waiting times are calculated from the date of their previous islet transplant. All other waiting times are calculated from the date the patient was first registered on the active national pancreas transplant list. Both waiting time calculations include all days that a patient may have been temporarily suspended from the list (for example, if they go on holiday, or develop a medical complication).

For the majority of patients, waiting time starts at 0 on the day they are established as 'active' on the pancreas transplant list. However, in line with kidney alone listing policy, any patient receiving a simultaneous pancreas and kidney (SPK) graft or a simultaneous islet and kidney (SIK) graft whose kidney fails within the first 180 days post-transplant starts with a waiting time on the kidney transplant list as it was on the day of that (failed) transplant. Patients with pancreas or islet graft failure within 180 days of a SPK, SIK, pancreas-only or islet-only transplant should not receive

priority over existing SPK or SIK waiting list patients and would lose their previous waiting time points. The failure must be reported to NHSBT through a follow-up return to enable the waiting time to be calculated accurately.

Patients that require a priority islet transplant are awarded points using a different scoring system to all other patients listed for a routine islet or vascularised pancreas transplant. It is clinically preferable that priority islet patients receive their second or subsequent islet transplant within a short time of their first graft. Patients listed for a priority islet graft therefore accrue waiting time points considerably quicker than all other patients. The two points systems are shown in Figure A.

Figure A. Points for waiting time to transplant (days)



Sensitisation points

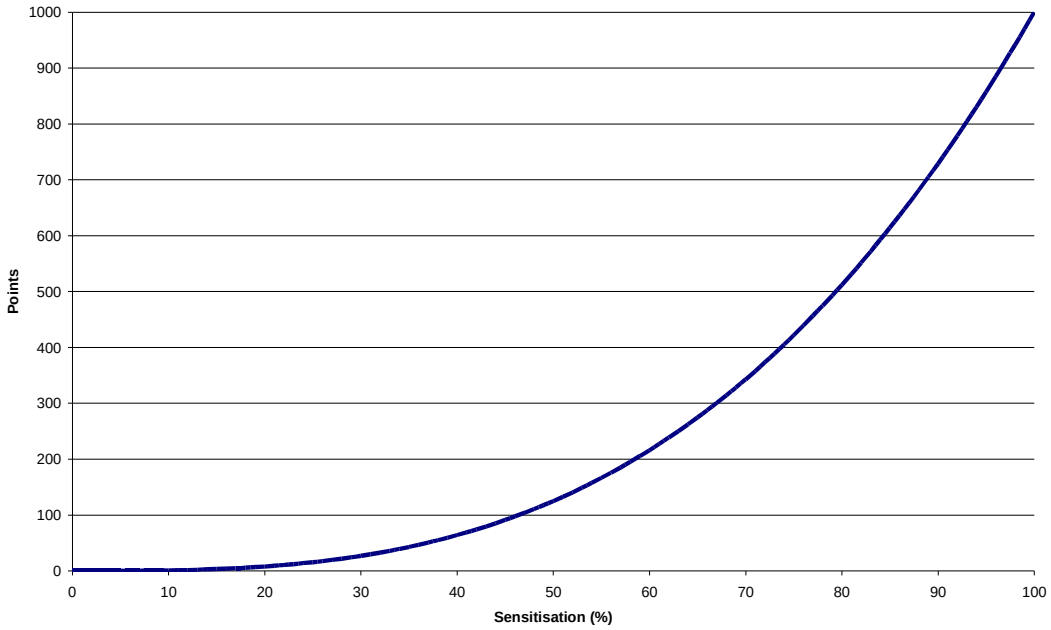
Potential recipients can develop a number of different HLA antibodies as a result of exposure to the different HLA antigens through blood transfusion, previous transplants and pregnancy. Many patients, however, have no detectable HLA antibodies. If a potential recipient has an antibody to an HLA antigen then they cannot receive a transplant from a donor with that HLA antigen, thus restricting the pool of potential donors. Patients who are clinically incompatible with the donor are excluded from the Pancreas Matching Run.

For a given patient with detectable HLA antibodies, the proportion blood group identical donors from a pool of 10,000 and for which they would be HLA compatible is calculated. This percentage of donors is termed the 'calculated Reaction Frequency' (cRF), more commonly referred to as the sensitisation level. Patients with no detectable HLA antibodies will have 0 sensitisation (0% cRF).

The allocation scheme prioritises patients according to their varying levels of sensitisation. The aim is to maximise the chance of patients with high levels of sensitisation receiving an offer when a pancreas from an HLA compatible donor becomes available. This is particularly important for

patients with high levels of sensitisation and does not unduly affect patients with low levels because they are HLA compatible with a much larger pool of donors. The scoring system used is shown in Figure B.

Figure B. Sensitisation points based on calculated reaction frequency



Travel time points

Once the pancreas has been recovered at the donor hospital, it is important to implant the organ as soon as possible. Although the intervening time is determined by a number of factors, the allocation scheme can help minimise this by minimising the transport time between the donor hospital and transplant centre where the surgery will occur.

There are eight designated pancreas transplant centres throughout the UK. Travel time points work differently for each type of donor and for patients listed for vascularised pancreas transplants and islet transplants, but as a general principle organs are not sent a long way for transplant unless necessary.

- **Donors after brain death**

  For potential recipients listed for a vascularised pancreas transplant, a computer programme automatically identifies the closest three transplant centres in relation to the donor hospital. Points are then awarded to all patients listed at any of those three closest centres. Potential recipients listed at any of the other five transplant centres are awarded 0 travel time points. All patients listed for an islet transplant receive travel time points by default because all pancreases are sent to one of only three islet isolation laboratories prior to transplantation

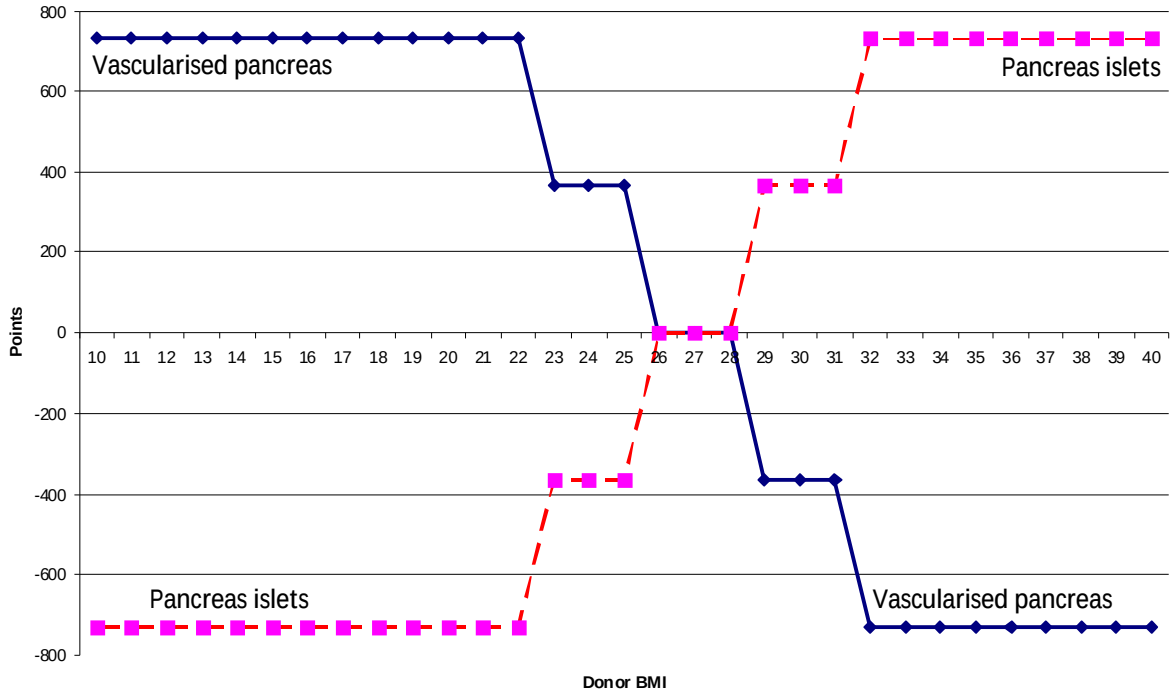
- **Donors after circulatory death**

  Organs retrieved from donors after circulatory death are very sensitive to ischaemia (the time they are out of the body before being transplanted). It is therefore even more imperative to reduce the travel time for such pancreases. A considerably higher weighting is given to patients listed at the closest transplant centre to minimise the time these organs spend in transit. All patients listed for an islet transplant will only receive travel time points if one of the on-call isolation centres is within 150 miles of the donor hospital

Donor body mass index (BMI) points

The NPAS incorporates patients listed for both vascularised pancreas and islet transplantation. It is clinically desirable that pancreases from donors with a low BMI are used for vascularised pancreas transplantation and often a higher yield of pancreas islets can be extracted from pancreases recovered from a donor with a high BMI. There is also a range of donor BMIs that are considered clinically desirable for both types of transplant. The donor BMI scoring system is in place to account for each of these three considerations. The scoring system is shown in Figure C.

Figure C. BMI weighting for whole organ and islet patient points



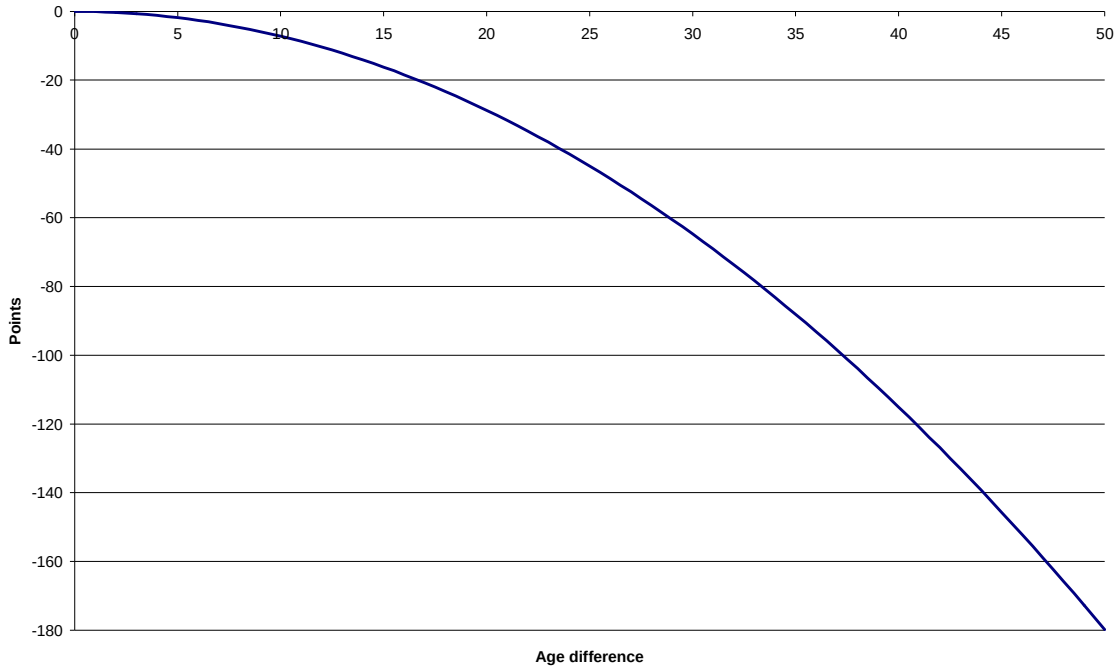
Dialysis status points

Diabetes is often associated with chronic kidney disease (CKD) which can lead to kidney failure. The severity of CKD can be estimated and in the most severe cases will be treated with dialysis. Around 40% of pancreas transplantation patients are listed approximately six months before they are expected to require dialysis. This is usually referred to as pre-emptive listing. Other patients may have been on dialysis for some time before being listed for transplantation and these patients receive some degree of priority over those who are not yet on dialysis.

Donor to recipient age matching points

Although not clinically necessary, donor and recipient age matching has been included in the scheme as a tie breaker between patients with very similar scores. This factor is the least influential on the overall scores. The scoring system is shown in Figure D.

Figure D Age matching points



1.3.2 Calculating the total points score (TPS) algorithm

TPS =
Total HLA-A, B & DR mismatch count points:
0 to 4 HLA mismatches = 730 points
5 to 6 HLA mismatches = 0 points

+ for patients listed for first islet graft:
0 mismatches = 0
1 to 2 mismatches = -150
3 to 4 mismatches = -350
5 to 6 mismatches = -700

+ waiting time points (see Figure A):
For all vascularised and routine islet grafts: $\frac{\text{Waiting time (days)}^2}{365}$

For patients listed for a priority islet graft:

$$365 + \frac{\text{Waiting time (days)}^2}{15}$$

+ sensitisation points: $\frac{\text{Sensitisation (\%)}^3}{1000}$
(see Figure B)

+ dialysis points:
On dialysis = 180 points
Not on dialysis = 0 points

+ travel time points (donor hospital to transplant centre)

For donors after brain death:

Closest three centres	=	365 points
Centres outside closest three	=	0 points
Islet patient (by default)	=	365 points

For donors after circulatory death:

Closest centre	=	10,000 points
Closest three centres (excluding closest)	=	5000 points
Centres outside closest three	=	0 points
Within 150 miles of isolation lab*	=	10,000 points

* NB All patients listed for islet transplantation will receive points if an isolation lab is within a 150 mile radius of the donor hospital. Oxford and the London isolation labs share an on-call rota, therefore the 150 mile radius is calculated based on a hospital halfway between the two (High Wycombe).

+ donor BMI points (see Figure C):

Donor BMI	*Vascularised*	*Islet*
22 or less	+730	-730
23 to 25	+365	-365
26 to 28	0	0
29 to 31	-365	+365
32 or over	-730	+730

- **donor to recipient age matching:** $\frac{\text{Age difference (years)}^2}{13.9}$
  (See Figure D)

1.3.3 Example: Total points score

Donor details: Aged 45 years, BMI 28, Churchill Hospital, Oxford, donor after brain death

Patient A details*

- Requires a vascularised pancreas
- Listed at Oxford for 200 days
- cRF 85%
- On dialysis
- Aged 40 years

Patient B details*

- Requires a priority islet graft
- Listed at Newcastle for 50 days
- cRF 0%
- Not on dialysis
- Aged 35 years

Patient C details*

- Requires a routine islet graft
- Listed at Oxford for 300 days
- cRF 10%
- Not on dialysis
- Aged 55 years

* *Assuming all have less than 5 HLA mismatch counts with the donor*

Total Points Score Calculation Examples

	Points Score		
Factor	Patient A	Patient B	Patient C
HLA MM score	730	730	730
First islet MM score	N/A	N/A	-350
Waiting time	110	532	247
Sensitisation	614	0	1
Dialysis status	180	0	0
Travel time points	365	365	365
Donor BMI index	-365	365	365
Age match	2	7	7
TPS	**1636**	**1999**	**1365**

Pancreas Matching Run Result Example

Patient	TPS	Rank
B	1999	1 (First offer)
A	1636	2 (Second offer)
C	1365	3 (Third offer)

In this example, the pancreas would be offered first to the transplant team responsible for Patient B. They may choose to accept or reject the offer on behalf of that patient. If declined, the transplant team responsible for Patient A will receive the next offer and so on.

2. Acceptance of offered organs

2.1 The Pancreas Fast Track Scheme

To optimise the utilisation rate of pancreases available for transplantation a Pancreas Fast Track Scheme (PFTS) was introduced.

2.1.1 Pancreas Fast Track Scheme offering criteria for deceased donor pancreases

Pancreases from deceased donors will be offered through the Fast Track Scheme if any of the following criteria are met:

- If, at any point, the pancreas is deemed to be unsuitable by a SNOD or a member of the retrieving or transplanting team.
- Four (three for DCD donors) pancreas transplant centres decline a pancreas or islet offer for either donor or organ quality reasons. The reasons given may differ between centres but must relate specifically to the donor or organ quality.
- Where the pancreas has not been accepted at the point of knife to skin.

2.1.2 Offering via the Pancreas Fast Track Scheme

Centres must 'opt-in' to receive offers of pancreases through the PFTS. To qualify, centres must provide NHSBT with a 24 hour fax or single SMS number and have access to the Electronic Offering System.

When a pancreas from a deceased donor meets the Fast Track Scheme criteria, the organ will be offered simultaneously to each of the pancreas and islet transplant centres that have opted-in to the scheme. Each centre has 45 minutes, from the time of offer, to confirm whether or not they would like to accept the pancreas. Failure to respond within the 45 minute window is equivalent to a declined offer. The fast tracked pancreas will be allocated to the accepting centre with the highest priority patient listed although that centre may transplant the pancreas in to any locally listed patient. Upon inspection, if the accepting centre decides the pancreas is unusable, it will be offered to the accepting centre with the second highest priority patient listed and so on, until either the pancreas has been transplanted or all accepting PFTS centres have declined the offer of the organ.

2.2 Reallocation of pancreas

If a pancreas needs to be reallocated because the patient for whom the pancreas has been accepted cannot subsequently receive the transplant, the following rules apply:

- If the pancreas has not been dispatched to the transplant centre it will continue to be offered for prioritised patients in the usual way.
- If the pancreas has been dispatched to the transplant centre, the pancreas can be kept by that centre. The centre will select the most appropriate patient from their local list.

3. Allocation policies for multiple organs

3.1 Prioritising liver and pancreas patients

A patient listed for a combined liver and pancreas transplant will receive priority over all patients listed for a vascularised pancreas or pancreas islet transplant so that when the liver is allocated to such a patient, the pancreas (where offered for donation) will also be allocated.

3.1 Prioritising kidneys from DBD donors between SPK / SIK and kidney only patients

Kidneys from DBD donors are allocated through the National Kidney Allocation Scheme (NKAS) with the exception of multivisceral and multiple organ transplants (including combined pancreas and kidney transplants and combined islet and kidney).

When donor kidneys become available for transplantation they are first offered for transplantation through the National Kidney Allocation Scheme (NKAS). This scheme prioritises patients within five pre-defined tiers (A to E). Patients actively listed for a kidney only transplantation ranked in Tiers A to C on the Kidney Matching Run will receive priority over all patients listed for a vascularised pancreas or pancreas islet transplant. If there is no more than one suitable kidney only patient listed within Tiers A to C, then one kidney may be offered with the pancreas within the National Pancreas Allocation Scheme for patients listed for a simultaneous pancreas and kidney or simultaneous islet and kidney transplant. Should the kidney not be allocated through NPAS, it will then be offered back through the NKAS to kidney only patients listed in Tiers D and E.

If both kidneys are allocated to kidney only patients listed within Tiers A to C of the NKAS, the pancreas will be offered in isolation through the NPAS but only patients listed for an isolated pancreas transplant or a pancreatic islet transplant will be considered.

3.2 Prioritising kidneys from DCD donors between SPK / SIK and kidney only patients

Each year approximately 40 pancreas transplants are performed using organs from DCD donors and many of those are simultaneous pancreas kidney transplants. On each occasion a pancreas from a DCD donor aged 65 years or less is considered suitable for clinical transplantation, a single kidney should also be offered with the pancreas. The other (paired) kidney will be offered according to the local kidney transplant centre policy.

Combined kidney and pancreas and combined islet and kidney offers are made through the 2010 National Pancreas Allocation Scheme in the following way:

If the donor HLA-type is known at the time of offering
The combined kidney and pancreas or combined islet and kidney will be offered via the National Pancreas Allocation Scheme. If the pancreas is accepted for pancreas only or pancreatic islet transplantation then the kidney will be offered back to the local kidney transplant centre and the kidney will be allocated according to the local kidney transplant centre policy.

If the donor HLA-type is not known at the time of offering
The combined kidney and pancreas or combined islet and kidney will be offered to the local pancreas transplant centre first and may be accepted on behalf of any locally listed patient. If the organs are declined by the local pancreas transplant centre the kidney and pancreas will then be offered via the Pancreas Fast Track Scheme. If no offer is accepted within 45 minutes OR if at any stage the pancreas is accepted for pancreas only or pancreatic islet transplantation the kidney will be offered back to the local kidney transplant centre and will be allocated according to the local centre policy.

If the kidney from a DCD donor is not used as part of a SPK or SIK transplant then it will be offered for kidney only transplantation. In such cases, the kidney will be first offered back to the local kidney transplant centre. If the kidney has been transported to a pancreas transplant centre that is different from the local kidney transplant centre then the local kidney transplant centre can request that the kidney is transported back. In the interest of optimising kidney utilisation, if further transportation is not deemed practical and the local kidney transplant centre agree, the kidney may be retained by the pancreas transplant centre for kidney only transplantation in a locally listed patient of their choice. In such circumstances no kidney 'payback' will be required.

To be compliant with the current National Pancreas Allocation Scheme policy, pancreas or islet transplant centres are entitled to accept just the pancreas when it is offered with a kidney and in such cases the kidney will then offered to the local kidney transplant centre and may be allocated according to local policy.

If only one kidney from a DCD donor is available for transplant, the kidney will not be offered with the pancreas and will instead be offered for kidney only transplantation and allocated via local kidney transplant centre policy.

The transplant team who are first to confirm acceptance of a single kidney or combined kidney and pancreas offer may request either the left or right kidney.

3.3 Prioritisation of intestinal patients

Intestinal patients are given prioritisation of additional organs required for their bowel transplant ahead of non super-urgent liver recipients, pancreas and kidney patients, and islet and kidney patients. This is to allow the small numbers of vulnerable bowel patients (with historically the highest transplant list mortality, and severely limited donor pool options) to have UK-wide access to the small numbers of paediatric and small adult DBD donors.

3.3.1 Group 2 intestinal patients

Patients who are ordinarily resident but not necessarily a UK citizen, or someone entitled under reciprocal arrangements, can receive treatment in the UK as a Group 1 patient. All other patients are Group 2 (as defined by the NHS Blood and Transplant (Gwaed a Thrawsbkniadau'r GIG) (England) Directions 2005 - Guidance). (http://www.odt.nhs.uk/odt-structures-and-standards/regulation/#directions)

Group 2 patients for pancreas and bowel donor organs will be offered these two organs only if there are no suitable Group 1 pancreas or islet patients. Thus, the order will be:

1. Group 1 pancreas and bowel patients
2. Group 1 pancreas/islet patients and Group 1 bowel patients
3. Group 2 pancreas and bowel patients
4. Group 2 pancreas/islet patients and Group 2 bowel patients.

4. Special prioritisation

4.1 Protocol for prioritisation of pancreas patients following identification of an error affecting allocation

A recipient who is identified as having missed out on an offer of a pancreas, due to a data error (e.g. delayed reactivation following a period of suspension), may be awarded prioritisation in subsequent pancreas matching runs for suitable donors, until they receive an offer of a pancreas. Where a recipient is awarded pancreas matching run prioritisation, they will be ranked above all other non-prioritised recipients in the pancreas matching run.

Where two or more recipients are awarded special prioritisation within the same matching run, they will be ordered using their matching run points total. Matching runs for pancreases from overseas donors will **not** award special prioritisation when ranking patients. Matching runs for pancreases from DCD donors will **not** award special prioritisation when ranking patients.

Recipient prioritisation will cease when one of the following events occurs:

1. The recipient receives an offer of a pancreas (for a pancreas or islet transplant) regardless of whom receives the transplant – i.e. even if the offer does not result in the prioritised recipient being transplanted
2. The recipient is transplanted with a pancreas or islets
3. The recipient is removed from the pancreas or islet waiting list
4. The recipient dies

A prioritised recipient who receives an organ offer which is declined will have their special prioritisation immediately suspended. Once confirmation of the final offer outcome has been received, the recipient's prioritisation status will be permanently ended if the organ offer results in a transplant, or reactivated if the organ offered does not result in a transplant.

All patients affected by a transcription error will automatically be prioritised and cases of administrative error will be reviewed by the Chair of the Pancreas Advisory Group.

4.2. Protocol for awarding additional waiting time points to pancreas patients following an error

A recipient who is identified as having less pancreas or islet waiting time than they ought to (e.g. through late registration following transplant centre admin error) may be awarded extra pancreas or islet waiting time to compensate for the difference.

4.3 Process for requesting special prioritisation

If a clinician considers that a transplant candidate has been unfairly disadvantaged by the one of the scenarios described above in sections 4.1 to 4.2, he/she should raise a request for special prioritisation with the Chair of the Pancreas Advisory Group. The request should be sent electronically to the Chair, the Statistical Lead and the ODT Information Services Project Co-ordinator.

4.4. Patient transfer between centres or transplant lists

The time spent on the pancreas or islet transplant list contributes to a patient's prioritisation within the pancreas allocation scheme. For this reason, waiting time accrued for prior, associated registrations can be transferred in the four scenarios described below. In all four scenarios described, the centre must contact ODT Information Services to notify them of the change in circumstances and ensure accrued waiting time is also transferred.

1. Any pancreas or islet patient who transfers from one UK pancreas or islet transplant centre to another.
2. Any patient registered for a pancreatic transplant (pancreas alone, simultaneous pancreas and kidney, simultaneous islet and kidney or islet transplant) who requires a transfer to another pancreatic transplant list.
3. Any patient registered for a kidney alone transplant who requires a transfer to simultaneous pancreas and kidney or simultaneous islet and kidney transplant. Waiting time accrued on the kidney transplant list can be transferred.
4. Any islet patient whose priority status is removed due to the failure of their routine graft.

Any patient transfers which differ from those described above will require the approval from the Chair of the Pancreas Advisory Group. The process for requesting approval is outlined in section 4.3.

4.5 Exemption request process

If the Multi-Disciplinary Team (MDT) caring for the patient forms the view that the patient should be listed even though they do not meet agreed criteria then the MDT may seek approval for listing from the Pancreas Advisory Group Exemptions Panel, as outlined in section 4.0 of the Pancreas Selection Policy http://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/#pancreas

A patient not accepted for transplantation in a centre has the right to request and obtain a second opinion from another centre.