

## INTESTINE: ALLOCATION

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

*The policy has been considered and approved by the Organ Donation and Transplantation Clinical Audit, Risk and Effectiveness Group (ODT CARE), formerly the Clinical Governance Monitoring Group (CGMG) and the Senior Management Team of the Organ Donation and Transplantation Directorate (ODT). It has also received final approval from the Transplant Policy Review Committee (TPRC), who act on behalf of the NHSBT Board, and who will be responsible for annual review of the guidance herein.*

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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 *NHS Blood and Transplant Organ Donation and Transplantation: Policy on Non-compliance with Selection and Allocation policies (July 2012)*.

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 of organs in exceptional cases.

### 1. Allocation policy

This scheme aims to cover the allocation of all UK-wide donor organs or combination of donor organs that include the intestine (please note that this scheme does not cover pancreas grafts which are retrieved with a segment of duodenum). These comprise donor organs suitable for patients requiring *intestine* (bowel) only, *multivisceral* (liver, bowel, pancreas, with or without stomach), *modified multivisceral* (bowel, stomach, pancreas) or *intestine together with any combination of kidney or pancreas transplantation*. If there is a mismatch between donor and recipient size, components of the retrieved grafts may be reduced to enable transplantation.

#### 1.1 Rationale for allocation policy

Intestinal (bowel) transplantation is an established treatment for selected patients (inadequate intravenous access, life-threatening line sepsis, advanced liver disease, severe fluid/electrolyte disturbances) with intestinal failure. This treatment is currently delivered at four nationally designated transplant centres (two paediatric centres – Birmingham Children's Hospital, Birmingham and King's College Hospital, London; two adult centres –

Addenbrooke's Hospital, Cambridge and The John Radcliffe Hospital, Oxford). With the expansion of intestinal transplant activity, an advisory group called the Bowel Advisory Group (BAG) to NHSBT was set up in 2010.

The 2011 National Bowel Allocation Scheme (NBAS) is designed to allocate deceased donor organs to patients listed nationally for grafts containing the intestine, using an objective and clinically appropriate allocation system. The current need for intestinal transplantation is approximately 25–30 grafts per year, with half of these patients requiring a combined liver and intestinal transplant. This has implications for allocation of other transplant organs, especially with respect to the liver, pancreas and kidney.

It is important that all potential deceased donation after brain death (DBD) donor families are approached for bowel donation by the specialist nurses in organ donation. Currently, donation after circulatory death (DCD) donors are not considered suitable for clinical transplantation, but may be considered for approved research purposes. For the purposes of deceased organ donation and donor family consent purposes, a 'bowel' graft is defined as a graft that may contain any or all of the following parts of the GI tract: stomach, duodenum, jejunum, ileum, colon. A very small number of patients with abdominal wall loss or limited abdominal domain may also be listed to require an abdominal wall graft as well, in addition to a bowel graft. Additional consent will need to be obtained from donor families for this unique situation. Although bowel grafts are currently only retrieved from DBD donors, it is likely that in the future selected DCD grafts may be considered for transplantation.

At present, the National Organ Retrieval Standards state that the four intestinal transplant centres are expected to retrieve all organs. Centres can send a surgeon or their own team instead of a National Organ Retrieval Service team but there should be no more than one full team present to retrieve.

As a small proportion of donor offers are received from several European Organ Donor systems (Eurotransplant, Scandiatransplant, Ital-transplant, ONTS Spain, Swiss-transplant, France-transplant), it is expected that these overseas offers will also be offered through the NBAS.

Currently, some UK centres do accept a very small number of European eligible patients for intestinal transplantation, as this treatment option is available at limited European transplant centres.

Transplant centres may also consider use of bowel grafts for approved research purposes provided consent for research has been given by donor families.

## *1.2 How allocation policy was developed*

*1.2.1 Justification for sub-groups:* The "Allocation" subgroup included representation from all four nationally designated intestinal transplant centres. As only a small proportion of DBD donors are suitable for intestine donation, it is essential that a uniform UK wide approach is implemented so as to best allocate these scarce grafts.

### *1.3 Allocation policy*

Factors influencing donor and recipient matching and graft outcomes for listed intestinal failure patients

Several factors determine the suitability of a donor for a particular bowel transplant patient. The key issues relate to size mismatch, especially for patients with short gut and the presence of liver disease as indications for intestinal transplantation. Approximately half of all children waiting for an intestine-containing transplant weigh 10 kg or less and it is this group that experiences the largest discrepancy between donor and recipient organ availability. Most paediatric donors are larger children or teenagers, so the paediatric transplant centres need to consider reduction of these grafts prior to implantation into the smaller patients.

The highest risk of mortality on the transplant list is for patients with advanced liver disease accompanied by small recipient size. Markers of advanced liver disease in patients with intestinal failure are different from end-stage cirrhosis and include: high serum bilirubin (level >200 µmol/l associated with increased mortality) and low platelet count. These may occur in the absence of coagulopathy and hypoalbuminaemia. For this reason, it is unlikely that existing liver disease assessment scores such as Model for End-stage Liver Disease (MELD) score and UK End-stage Liver Disease (UKELD) score, currently used to prioritise adult elective liver transplant patients, will be able to be applied to this population of patients.

The international Intestinal Transplant Registry (ITR) has identified three factors associated with favourable outcomes after intestinal transplantation and these are:

1. Transplantation from home
2. Increased experience of the transplant centre
3. Intestinal transplantation with liver transplantation (only patients who have survived one year after transplantation are considered)

The ITR has also demonstrated that in patients who have survived a year after transplant, there is a liver protective effect with significantly better long-term survival in recipients of grafts containing the liver compared with those intestinal grafts transplanted without a liver. This survival advantage is not seen when survival is analysed from the date of transplantation as there is a greater mortality in bowel grafts containing the liver during the first year.

#### *1.3.1 Details of policy*

##### 1.3.1.1 Donor criteria for 'bowel' retrieval

The donor criteria for bowel retrieval are:

- DBD donors aged ≤65 years and donor weight ≤100 kg, with a BMI ≤30 kg/m<sup>2</sup> for adult offers
- DBD donors aged <16 years for paediatric offers, then adult offers
- Stable haemodynamics, short inpatient stay, treated sepsis, modest inotrope use, with up to minimally deranged liver and/or renal function tests

### 1.3.1.2 Donor–recipient blood group criteria

Donor to recipient blood group matching is preferable for the following reasons:

1. To maintain equity of access to a transplant for patients across all blood groups and, in particular, to minimise the disadvantage to blood group O patients (blood group O donor organs are compatible with all blood group patients)
2. Transplantation between compatible but non-identical blood groups may result in increased risk of graft-versus-host disease, including immune-mediated haemolytic anaemia

However, in cases where the patient has an uncommon blood group this rule should not apply, so a blood group AB patient may receive a blood group A intestine and a blood group B patient may receive a blood group O intestine.

Identical blood group matching is preferable together with blood group AB patients receiving blood group A donor offers and blood group B patients receiving blood group O donor offers, as per table below; other compatible blood group matching is allowed but is less favourable.

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

### 1.3.1.3 ‘Super-urgent’ transplantation

A recent case in the UK identified the need for super-urgent allocation of a multivisceral graft containing the liver, bowel and pancreas. Following this, the Bowel Advisory Group has agreed to list and prioritise patients with acute liver failure and intestinal failure or extensive porto-mesenteric venous thrombosis. These super-urgent patients would have the same priority and status as current patients listed to receive emergency liver transplants for acute liver failure or acute liver graft failure, and ahead of all patients listed to require any type of intestinal containing graft.

### 1.3.1.4 Prioritisation of listed patients – the points system

A ranked priority will be calculated for all patients on the national transplant list using a points system, along similar lines to that used for the prioritisation of kidney and pancreas patients. This applies to patients listed for bowel grafts (non super-urgent), with or without combination of other organs.

When a donor becomes available that is suitable for the purposes of intestinal transplantation, all eligible patients on the national transplant list are given points based on several criteria and the total score is used for ranking. Given the small number of intestinal transplants performed worldwide, there is limited data on the weighting of the different factors considered for the proposed scoring system. The proposal agreed to at the BAG was to introduce this scheme on the basis of best knowledge available and to audit outcomes annually with a view to revising the document on a two-yearly basis.

Current allocation procedures allow prioritisation of additional organs transplanted to bowel transplant recipients ahead of non super-urgent liver recipients (paediatric in 2004, adults in 2010), pancreas and kidney recipients. This is to allow the small numbers of vulnerable bowel patients (with historically the highest transplant list mortality, and with severely limited donor pool options) to have UK-wide access to the small numbers of paediatric and small adult DBD donors. An audit performed in 2010 showed no impact on paediatric liver recipient transplant list mortality 4 years following the introduction of this pathway.

The following five factors have been included in the NBAS:

1. Donor and recipient age match points
2. Waiting time points
3. Urgency (medical complications) points
4. Points accrued for additional organs to be transplanted
5. Sensitisation points

#### Donor and recipient age match points

Paediatric donors are defined as those aged < 16 years.

Adult donors are defined as those aged 16 years or more.

Paediatric recipients are defined as those aged < 18 years.

Adult recipients are defined as those aged 18 years or more.

A cut-off age of 18 years for adult recipients allows patients between 16 and 18 years to be treated at either an adult or a paediatric centre.

Adult recipients with a weight  $\leq 35$  kg may be listed on the paediatric transplant list as it is almost impossible to find size matched donors from the adult donor pool

This will have a minimal impact on paediatric graft availability, for example: as at 27 June 2011, there were no UK adults listed weighing  $\leq 35$  kg.

Donor	Recipient	Points
Paediatric	Paediatric	1000
Adult	Adult	500
Adult	Paediatric	250
Paediatric	Adult	0

### Waiting time points

Patients on the transplant list receive 1 point for each day on the transplant list. Points start to be accrued only when the patient is activated on the transplant list for the first time, but continue to be accrued during periods when the patient is subsequently inactivated or suspended.

### Urgency (medical complications) points

Patients awaiting intestinal transplantation vary in urgency and it is appropriate that this should be reflected in the prioritisation scheme. The following table lists the additional points allocated for specified urgency criteria. If a patient satisfies more than one of these criteria then the points allocated for each of the urgency criteria satisfied will be added together to give the total points allocated for urgency.

Urgency criteria		Points
Loss of intravenous line access	Single remaining conventional access site (supradiaphragmatic)	1000
Liver failure	Serum bilirubin of 200 µmol/l or greater	1500
	Serum bilirubin of 100–199 µmol/l	750
Diagnosis of malignancy		500
In-hospital status		500

These data are collected on the Intestinal Failure Transplant Recipient Registration form at the time of registration. It is expected that these data will be collected on a monthly basis while the patient is registered on the transplant list.

### Points accrued for additional organs to be transplanted

Some patients on the transplant list for intestinal transplantation require organ transplants in addition to the intestine. This has an effect on transplant list prognosis and is, therefore, reflected in the points allocated as follows. If a patient requires a combination of organs then the points allocated for each additional organ required will be added together to give the total points allocated for additional organs to be transplanted.

Additional organ required	Points
Liver	300
Kidney	200
Pancreas	100
Abdominal wall	100

The preferred allocation of renal and pancreatic donor organs to patients listed for intestinal transplantation is currently based on an individual patient need. Parallel to adoption of this points allocation system, there is a need for this to be discussed and agreed to by both the Kidney and Pancreas Advisory Groups to NHSBT, similar to the agreements reached with the Liver Advisory Group for liver allocation.

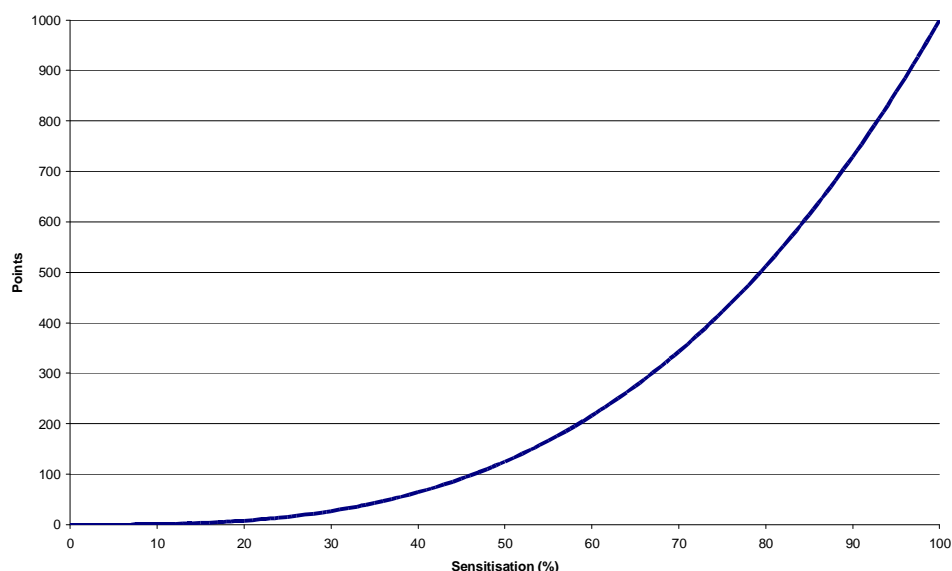
### Sensitisation points

Potential recipients may have pre-existing human leukocyte antigen (HLA) antibodies as a result of exposure to the different HLA antigens through blood transfusion, previous transplants and pregnancy. The precise significance of HLA antibodies in intestinal transplantation remains a matter of debate, but there is some evidence (ref) that bowel transplantation that is carried out in the presence of donor-reactive antibodies will be complicated by rejection and poorer outcome (although there is no evidence that hyper-acute rejection occurs as in kidney, heart and lung transplants).

It is desirable that, as far as possible, organs are allocated in such a way as to maximise the probability that patients with high levels of sensitisation receive donor organs with a negative cross-match. For this reason, patients on the transplant list are given points in proportion to the level of sensitisation, as shown in Figure 1 (taken from pancreas allocation algorithm).

The aim is to maximise the chance of patients with high levels of sensitisation receiving the offer when 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.

Figure 1. Sensitisation points taken from the pancreas allocation algorithm





#### 1.3.1.4 Calculating the total points score (TPS)

TPS = Donor to recipient age matching points:	
Paediatric donor to paediatric recipient	= 1000 points
Adult donor to adult recipient*	= 500 points
Adult donor to paediatric recipient	= 250 points
Paediatric donor to adult recipient*	= 0 points

\* Note: adult recipients with a weight  $\leq 35$  kg may be listed on the paediatric transplant list as it is almost impossible to find size matched donors from the adult donor pool.

+	Waiting time points: Waiting time in days	
+	Urgency points:	
	Loss of intravenous line access (single access site remaining)	= 1000 points
	Liver failure (serum bilirubin of 200 $\mu\text{mol/l}$ or greater)	= 1500 points
	Liver failure (serum bilirubin of 100–199 $\mu\text{mol/l}$ )	= 750 points
	Diagnosis of malignancy	= 500 points
	In-hospital status	= 500 points
+	Requirement for other organs points:	
	Liver	= 300 points
	Kidney	= 200 points
	Pancreas	= 100 points
	Abdominal wall	= 100 points
+	Sensitisation points: $\frac{\text{Sensitisation (\%)}^3}{1000}$ (See Figure 1)	

#### 1.3.1.5 Example: TPS

Assume compatibility of blood groups between donor and patient

Donor 1:	Aged 8 years, donation after brain death donor
Donor 2:	Aged 45 years, donation after brain death donor
Patient 1:	Aged 4 years, waiting 724 days, cRF 0%, serum bilirubin of 451 $\mu\text{mol/l}$ , requires liver and pancreas, in hospital
Patient 2:	Aged 36 years, weight 35 kg, waiting 611 days, cRF 80%, serum bilirubin of 13 $\mu\text{mol/l}$ , requires kidney, in hospital, loss of intravenous line access
Patient 3:	Aged 16 years, waiting 252 days, cRF 10%, serum bilirubin of 12 $\mu\text{mol/l}$ , requires no additional organs (bowel only)
Patient 4:	Aged 45 years, weight 55 kg, waiting 165 days, cRF 25%, serum bilirubin 102 $\mu\text{mol/l}$ , requires liver, kidney and pancreas, diagnosis of malignancy, in hospital



### Total points score calculation examples

Factor	Points score							
	Patient 1		Patient 2		Patient 3		Patient 4	
	Donor 1	Donor 2	Donor 1	Donor 2	Donor 1	Donor 2	Donor 1	Donor 2
Age match	1000	250	1000	250	1000	250	0	500
Waiting time	724	724	611	611	252	252	165	165
Urgency								
Loss of intravenous line	0	0	1000	1000	0	0	0	0
Liver failure	1500	1500	0	0	0	0	750	750
Diagnosis of malignancy	0	0	0	0	0	0	500	500
In-hospital status	500	500	500	500	0	0	500	500
Other organs required	400	400	200	200	0	0	600	600
Sensitisation	0	0	512	512	1	1	16	16
Total Points Score (TPS)	4124	3374	3823	3073	1253	503	2531	3031

### Bowel matching run result examples

Donor 1			Donor 2		
Patient	TPS	Rank	Patient	TPS	Rank
1	4124	1 (First offer)	1	3374	1 (First offer)
2	3823	2 (Second offer)	2	3073	2 (Second offer)
4	2531	3 (Third offer)	4	3031	3 (Third offer)
3	1253	4 (Fourth offer)	3	503	4 (Fourth offer)

### Bowel grafts not placed through the UK National Bowel Allocation Scheme

If it is not possible to identify a suitable intestinal failure recipient on the UK transplant list, then these potential bowel grafts should be offered to the other European Organ Transplant Systems (e.g. Eurotransplant). As the liver and pancreas will have been allocated, it is likely that only isolated intestine grafts will be available for offer to other European intestinal transplant centres via their organ procurement organisations. It is hoped that in the future there will be similar formal Europe-wide arrangements, in order to maximise the use of this very scarce and valuable international resource.

### Contributors

Peter Friend, John Radcliffe Hospital, Oxford  
 Andrew Butler, Addenbrooke's Hospital, Cambridge  
 Nigel Heaton, King's College Hospital, London  
 Kerri Barber, Principal Statistician, NHSBT, Bristol  
 Darius F Mirza, Birmingham Children's Hospital and Chair of BAG