Changes in this version

1.2.1.7 – Re-wording of description of validation rule for checking unacceptable antigens on incoming registrations.

Policy

This policy has been created by the Multi-visceral & Composite Tissue Advisory Group (formerly Bowel 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: June 2022

Approved by OTDT Care 7th June 2022

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 ***POL198***.
(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 the allocation of organs in exceptional cases.

1. Allocation policy

This policy covers the allocation of all UK-wide donor organs or combination of donor organs that include the intestine (please note that this policy does not cover pancreas grafts which are retrieved with a segment of duodenum). These comprise donor organs suitable for patients requiring ***intestine*** (bowel) only, ***multi-visceral*** (liver, bowel, pancreas, with or without stomach), ***modified multi-visceral*** (bowel, stomach, pancreas) or ***intestine together with any combination of kidney or pancreas 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 Churchill 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 and renamed the Multi-visceral & Composite Tissue Advisory Group (MCTAG) in 2017.

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 (SN-ODs). Currently, organs from donation after circulatory death (DCD) donors are not considered suitable for intestinal transplantation but may be considered for approved research purposes.

1.2. Allocation policy

Background - factors influencing donor and recipient matching and graft outcomes for listed intestinal transplant 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 will be prognostic in this population of patients.

1.2.1. Details of policy

1.2.1.1. Donor criteria for 'bowel' retrieval

The donor criteria for bowel retrieval are:

- DBD donors aged < 60 years and donor weight < 90 kg
- Absence of underlying chronic intestinal disease and intra-abdominal sepsis
- For abdominal wall/fascia donation: Absence of extensive surgical scars/damage to the abdominal wall/fascia.

For the purposes of deceased organ donation and donor family consent, a 'bowel' graft is defined as a graft that may contain any or all of the following parts of the gastro intestinal (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, in addition to a bowel graft. Additional consent is needed to be obtained from the donor family in this unique situation (controlled document **SOP6039** provides guidance to SN-ODs on abdominal wall donation).

At present, the National Standards for Organ Retrieval from Deceased Donors (**MPD1043**) (https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/23234/mpd1043.pdf) state that the four intestinal transplant centres are expected to contribute expertise to the retrieval of organs for intestinal transplant recipients. 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.

1.2.1.2. Maximum donor weight

Centres may enter a maximum donor weight on the Intestinal Failure Transplant Recipient Registration form when registering a patient for intestinal transplantation. If entered, patients will subsequently not receive offers of organs from donors that have a weight greater than the maximum weight specified. The maximum donor weight can be updated via ODT Online at any point during the registration, and if a centre wishes for a patient to later be considered for all potential donors, a maximum donor weight corresponding to the maximum donor criteria weight (currently 90kg) should be entered.

1.2.1.3. 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.

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. All preferable blood group matched patients will be ranked above compatible blood group matched patients in the National Bowel Offering Scheme.

Donor blood group	**Potential recipient blood group**			
	O	A	B	AB
O	✓*	✓	✓*	✓
A		✓*		✓*
B			✓*	✓
AB				✓*
✓* = Preferable ✓= Compatible				

1.2.1.4. Prioritisation of patients listed for intestinal transplantation

Bowel transplant recipients requiring other organs (livers, pancreases or kidneys) are prioritised ahead of all non-super-urgent liver recipients and all kidney and pancreas recipients. This policy was put in place for paediatric bowel recipients in 2004 and adult bowel recipients in 2010. 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.

1.2.1.5. 'Super-urgent' transplantation

The need for super-urgent allocation of a multi-visceral graft containing the liver, bowel and pancreas was identified in 2012. Following this, the Bowel Advisory Group (now Multi-visceral & Composite Tissue Advisory Group) and Liver Advisory Group agreed to list and prioritise patients with acute liver failure and intestinal failure or extensive porto-mesenteric venous thrombosis. These super-urgent patients 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 non- super-urgent patients listed to require any type of intestine or liver containing graft.

1.2.1.6. Overseas donors and recipients

A small number of donor offers are received from several European Organ Donor systems (Eurotransplant, Scandiatransplant, Ital-transplant, ONTS Spain, Swiss-transplant, France-transplant) and from Gibraltar. Due to the logistical issues encountered with flight times, these organs will be offered simultaneously to every centre who has registered to receive fast track offers. At the end of 45 minutes, organs will be allocated in the order of expression of interest.

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

Group 2 intestinal transplant patients are also occasionally accepted for transplantation in the UK. These patients are offered organs only if there is no suitable Group 1 patient. This applies to Group 1 patients on other organ transplant lists; not only the intestinal transplant list. Specifically, the offering sequence for bowels and pancreases is:

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

A Group 2 combined liver/intestinal tier was introduced in January 2022 to the adult and paediatric DBD donor Liver and Intestinal matching runs. This tier appears after the liver fast-tracking sequence (please refer to **POL196** for further information). The new Group 2 combined liver/intestinal tier has the following implications:

- A liver transplant centre can accept a liver for a Group 2 recipient requiring liver-only at the fast-tracking stage, providing it has been declined for all Group 1 recipients.
- As such, this means Group 2 liver-only recipients will be prioritised ahead of Group 2 liver and intestinal, and intestinal-only recipients.

If it is not possible to identify a suitable intestinal 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.

1.2.1.7. Prioritisation of listed patients – the points system

The National Bowel Offering Scheme (NBOS), introduced in 2013, is designed to allocate deceased donor organs to patients listed nationally for grafts containing the intestine, using an objective and clinically appropriate allocation system. A ranked priority is 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 (as defined in section 1.3.1.1), all eligible patients on the national transplant list are given points based on several criteria and the total score is used to determine the order of offering. Given the small number of intestinal transplants performed worldwide, there is limited data on the weighting of the different factors considered for the scoring system. The proposal agreed to by the BAG (now MCTAG) was to introduce this scheme on the basis of best knowledge available and to audit outcomes annually with a view to revising the Scheme on a two-yearly basis.

The following five factors are included in the NBOS:

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 at time of offering.
Adult donors are defined as those aged 16 years or more at time of offering.

Paediatric recipients are defined as those aged < 18 years at time of offering.
Adult recipients are defined as those aged 18 years or more at time of offering.

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 ≤ 35 kg may be given paediatric status in the NBOS, if specified on the Intestinal Failure Transplant Recipient Registration form, 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 ≤35 kg.

The points awarded are as follows:

Donor	Recipient	Points
Paediatric	Paediatric	5000
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 is 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 Transplant Recipient Registration form at the time of registration and can be updated using the Sequential Data Collection form if the clinical status of the patient changes.

Points accrued for additional organs to be transplanted
Some patients on the transplant list require additional organs 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

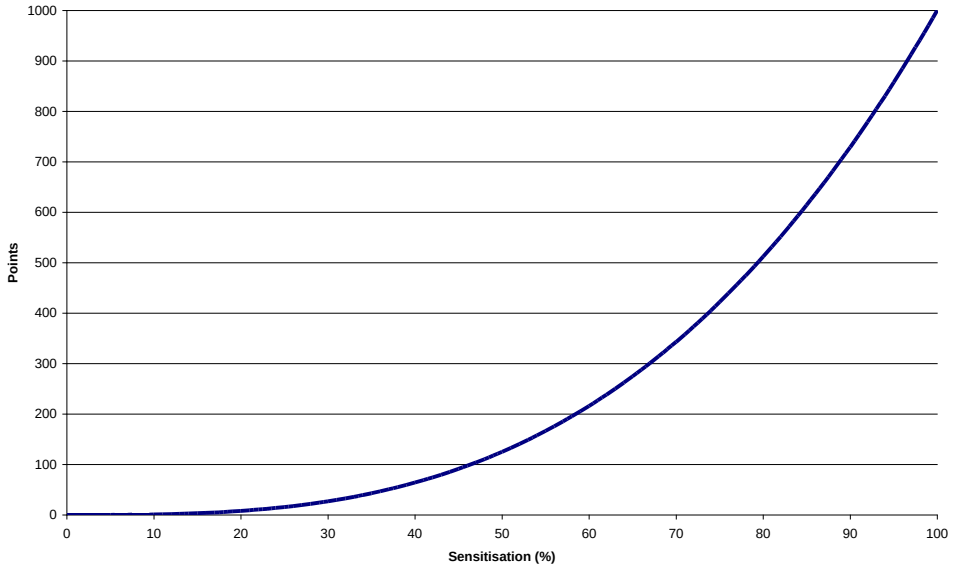
Sensitisation points
Potential recipients may have pre-existing human leukocyte antigen (HLA) antibodies as a result of exposure to the different HLA antigens through blood transfusion, previous transplants and pregnancy. In the event that the donor human leukocyte antigen (HLA) is known prior to offering, listed patients with known HLA antibodies that are present in the donor HLA type will be excluded from the matching run and therefore not be offered the organs.

For a patient changing transplant centre, any incoming registration that does not contain one or more of the unacceptable antigens already recorded for a patient will be checked with the tissue typing laboratory to ensure a patient isn't disadvantaged.

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



1.2.1.8. Calculating the total points score (TPS)

TPS = **Donor to recipient age matching points:**

Paediatric donor to paediatric recipient	= 5000 points
Adult donor to adult recipient	= 500 points
Adult donor to paediatric recipient	= 250 points
Paediatric donor to adult recipient	= 0 points

+ 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 µmol/l or greater)	= 1500 points
Liver failure (serum bilirubin of 100–199 µmol/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:** $Sensitisaton(\%)^3/1000$
(See Figure 1)

2. Acceptance of offered organs

2.1. Blood-borne Positive Donor Virology Scheme

To reduce the length of the donation process the positive donor virology scheme was introduced.

2.1.1. Positive donor virology scheme offering criteria

The positive donor virology scheme is initiated when NHSBT is notified that a donor has an initial positive result for any of the markers listed below:

- Hepatitis B surface antigen (**not Hepatitis B** core antibody positive alone, with negative HBsAG)
- Hepatitis C antibody
- HIV 1 and 2 antibody
- HTLV 1 and 2 antibody

2.1.2. Offering via the positive donor virology scheme

Centres must 'opt-in' to receive offers of the bowel through the positive donor virology scheme. When the bowel from a deceased donor meets the positive donor virology criteria, the organ will be offered simultaneously to each of the bowel 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 bowel. Failure to respond within the 45-minute window is equivalent to a declined offer. The bowel will be allocated to the accepting centre with the highest priority patient listed although that centre may transplant the bowel in to any locally listed patient. Upon inspection, if the accepting centre decides the bowel is unusable, it will be offered to the accepting centre with the second highest priority patient listed and so on, until either the bowel has been transplanted or all accepting centres have declined the offer of the organ.

3. Special prioritisation

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

In exceptional cases where it is felt that a patient has missed out on waiting time due to an administration error, the facility exists to add additional waiting time points if it is agreed the patient is entitled to it. The process is:

1. Centres detail in writing (via email) the reasons why they believe their patient is entitled to additional waiting time and the number of days they are asking to be added. This should be sent to the Chair of MCTAG (formerly BAG) (if the patient is from the same centre as the Chair, the other adult or paediatric centre representative will be contacted) for review.
2. A response in writing (via email) would be sent to the centre, and copied to OTDT Information Services, within one week as to whether it was agreed by the

Chair of MCTAG (formerly BAG) (or Deputy) that additional waiting time could be added.

3. OTDT Information Services would then add the agreed number of days for the patient.