POLICY POL229/3

Heart Transplantation: Selection Criteria and Recipient Registration

This Policy replaces
POL229/2

Copy Number

Effective **26/10/16**

Summary of Significant Changes

Policy rewritten to incorporate changes to the existing urgent heart allocation scheme and the introduction of the new super-urgent heart allocation scheme.

Policy

This policy has been created by the Cardiothoracic Advisory Group (CTAG) on behalf of NHSBT.

The policy has been considered and approved by 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.

Last updated: September 2016
Approved by TPRC: July 2014

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.

In the interests of equity and justice all centres should work to the same selection 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.
http://www.odt.nhs.uk/pdf/non_compliance_with_selection_and_allocation_policies.pdf

It is acknowledged that these guidelines will require regular review and refreshment. Where they do not cover specific individual cases, an Adjudication Panel will consider whether transplantation is appropriate.

Heart transplantation is an established treatment in patients who have a likelihood of poor survival or impaired quality of life secondary to acute or chronic heart disease.

Selection criteria for adult transplantation are largely based on outcome measures post-transplant. While the same general principles apply to children, in some circumstances, even a smaller probability of long-term success may be a worthwhile outcome for some children and their families.

In selected patients, heart transplantation improves survival and quality of life. Data on over 78,000 transplants from the Registry of the International Society for Heart and Lung Transplantation show that half of the patients survive for more than 10 years and the median survival for those who survived the first year after transplantation is currently 13 years.[1] Current UK data (UK Transplant Registry) show that current 1 and 5 year survival are respectively 82% and 75% for adults and

92% and 88% for paediatric patients (http://www.odt.nhs.uk/uk-transplant-registry/annual-activity-report/).
The decision to recommend heart transplantation depends on a balance of the benefits, risks and alternatives. However, the scarcity of suitable donor hearts makes it necessary to also consider the population of potential heart transplant candidates; selection is based both on the patient's clinical need and on their capacity to benefit. Decision-making should be fair and transparent.

Transplant centres make decisions about whether to list patients in a multi-disciplinary team (MDT) meeting and in the light of relevant guidelines. Nevertheless, selection cannot be an exact science, and any patient who is dissatisfied with the decision made in his/her case is entitled to an opinion from a second transplant centre.

1. Conditions that are considered for transplantation include:

a) Advanced heart failure usually secondary to ischaemic heart disease or idiopathic dilated cardiomyopathy with severe systolic ventricular dysfunction
b) Severe ventricular dysfunction secondary to valve disease.
c) Diastolic dysfunction usually secondary to idiopathic restrictive or hypertrophic cardiomyopathy
d) Heart failure secondary to congenital heart disease

Patients with other conditions including specific heart muscle diseases may be candidates for transplantation and need to be considered on a case-by-case basis.

2. Referral

Clinicians looking after potential transplant candidates should discuss referral with one of the heart transplant centres in the UK and, when appropriate, arrange for formal referral. Paediatric patients will be referred to one of the two paediatric heart transplant centres. It is advisable to discuss patients with transplant centres at an early stage so a combined approach can be formulated. Guidance is available in the published national guidelines[2].

3. Assessment of candidates for transplantation

Patients should be fully assessed in one of the heart transplant centres. Patients should be discussed at the MDT meeting and, if appropriate for transplantation, should be offered listing.

4. Heart allocation overview

There are three tiers of allocation: the super-urgent heart allocation scheme (SUHAS), the urgent heart allocation scheme (UHAS) and the non-urgent allocation scheme (NUHAS). A patient may be registered on to one of these three schemes according to the selection criteria outlined in this document. The order in which patients are offered donor organs is outlined in the *NHS Blood and Transplant Heart Allocation Policy POL228.*

There are seven licensed heart transplant centres in the UK: Birmingham, Great Ormond Street, Glasgow, Harefield, Manchester, Newcastle, and Papworth. Newcastle transplant adult and paediatric patients; Great Ormond Street transplant paediatric patients only.

4.1 Adult Patients

An adult patient is defined as being a patient aged 16 years or above at the time of registration.

4.2 Paediatric Patients

A paediatric patient is defined as being a patient aged less than 16 years at the time of registration. A paediatric patient who reaches their 16th birthday while on the waiting list will retain their paediatric status.

4.3 Small Adult Patients

A small adult is defined as being a patient with a body weight of 30 kg or less at the time of listing. Paediatric patients and small adults will receive offers for hearts available from a paediatric donor before adult patients.

A centre may request, through the Cardiothoracic Advisory Group (CTAG) Adjudication Panel (Section 7), registration of a small adult, weighing between 30 kg and 40 kg, when there are specific reasons to justify inclusion in this priority group (such as excess fluid retention which may not reflect lean body mass). In such cases, indication for small adult listing should be marked on the registration form.

4.4 Patient Categories

There are three patient categories for which a patient can be registered. **Table 1** indicates which patient category (paediatric, small adult or adult) a patient is classed in depending upon the registered status of the patient (i.e. by age and whether they are registered as a small adult) and which type of centre they are registered at. The type of centre is important because generally a 15 year old patient, for example, registered at an adult centre will, by definition, be of adult size and hence require adult sized organs, whereas generally a 15 year old patient at a paediatric centre will require specialist paediatric treatment and hence paediatric sized organs. A patient will only have one classification and cannot be ‘dual listed’ to receive offers as part of more than one scheme.

Table 1: Patient category for allocation (paediatric/small adult/adult) by patient status and centre type

Status of patient	Adult Centre (Harefield, Papworth, Birmingham, Manchester, Glasgow)	Adult & Paediatric Centre (Newcastle)	Paediatric Centre (GOSH)
Aged under 16	Adult	Paediatric	Paediatric
Aged 16 or above (not small adult)	Adult	Adult	Paediatric
Small adult Aged 16 or above and weight ≤30kg or Aged 16 or above, weight between 30-40kg and agreed by Adjudication Panel	Small adult	Small adult	Paediatric

Note that Newcastle is referred to as an adult and a paediatric centre interchangeably throughout this document.

5. Listing of Patients

Transplant centres should request NHSBT to place eligible patients on the UK national heart transplant list. Patients who have not been registered should not be offered an organ. Patients are required to consent to transfer of their data onto the UK Transplant Registry, which is maintained by NHSBT in order to ensure equitable allocation and follow-up data are used to monitor outcomes.

Patients will be placed on the national transplant list when a registration form has been received and key information is validated by NHSBT. Discrepancies or missing information will be followed up with the local centre and might cause a delay in registration.

Determination of eligibility for NHS treatment should be determined by the hospital and advice may be given by the national Department of Health. Accepted patients are classified as Group 1 or Group 2 (as defined by The NHS Blood and Transplant, England, Directions 2005 – Guidance: http://www.odt.nhs.uk/odt/regulation/NHSBT-directions-2005/). Nevertheless it should be noted that nationals of a non-UK country may only be registered on a transplant list after they have been accepted by a consultant as suitable for treatment.

5.1 Non-Urgent Heart Allocation Scheme (NUHAS)

5.*1.1 Listing criteria for NUHAS heart transplantation*

Table 2 outlines guideline criteria for non-urgent heart registration. These criteria are applicable for all patient categories. Generally speaking, two or more criteria need to be met for listing.

Table 2: Guideline listing criteria for Non-Urgent Heart Allocation Scheme registration: two or more criteria need to be met

- Persistent NYHA Class III/IV symptoms despite optimum medical therapy (inc CRT if indicated)
- Peak VO_2 <14 ml/kg/min or <50% predicted in diagnostic CPEX test
- Unable to complete satisfactory CPEX because of cardiac status
- BNP persistently >400 pg/ml or NT-proBNP >1600 pg/mL, or increasing despite treatment
- Low cardiac index (<2 L/min/m^2)
- Two or more admissions with decompensated heart failure in last 12 months despite adequate medical therapy and adherence
- Deteriorating WHO Group II pulmonary hypertension
- Deteriorating renal function due to cardiorenal syndrome
- Persisting hyponatraemia (<130 mmol/L) despite optimum medical treatment
- Recurrent ventricular arrhythmia despite drug, EP and device treatment
- Deteriorating liver function due to right heart failure despite optimum medical treatment
- Persistent/recurrent symptomatic pulmonary oedema or serious systemic congestion despite optimum medical treatment

5.1.2. NUHAS Registration Process

In order to register a patient on the NUHAS, the transplant centre must complete the '*Heart/Lung Registration Form*' (FRM4847) via ODT Online and select the option for 'Heart'.

5.2 Urgent Heart Allocation Scheme (UHAS)

Patients who have advanced heart failure and a very poor short-term prognosis are prioritised by placing them on the Urgent Heart Allocation Scheme (UHAS).

5.2.1 Listing criteria for UHAS heart transplantation

Table 3 outlines the criteria for adult urgent heart registration. These criteria are applicable for patients registering under the adult or small adult patient categories.

Table 3: Listing criteria for adult Urgent Heart Allocation Scheme registration

- Category 21 - Adult inpatient dependent on intravenous inotropes which cannot be weaned
- Category 22 - Adult long-term VAD or TAH patient with one of the following complications:
  - Right ventricular failure dependent on inotropes
  - Recurrent systemic infection related to VAD/TAH
  - Other VAD/TAH issues including recurrent or refractory VAD/TAH thrombosis. Patient registration must be agreed by CTAG Adjudication Panel and evidence of agreement emailed to NHSBT (Section 7)
- Category 23 - Exceptionally sick adult patient - high risk of dying or having an irreversible complication but does not meet urgent listing criteria. Patient registration must be agreed by CTAG Adjudication Panel and evidence of agreement emailed to NHSBT (Section 7).
- Category 31 - ACHD arrhythmia patients. Refractory arrhythmia (> 1 hospital admission over last 3 months with haemodynamic instability or associated with kidney or liver dysfunction).
- Category 32 - ACHD patients with no option for conventional escalation of therapy. Inpatients unsuitable for inotropes and/or VAD with one of the following:
  - Bilirubin and transaminases > 2x normal
  - Deteriorating renal function (eGFR <50ml/min/1.73m , or 20% reduction from baseline);
  - Requirement for dialysis/CVVH for fluid or electrolyte management; recurrent admissions (> 3 in preceding 3 months) with episodes of right heart failure or protein losing enteropathy requiring ascites drainage.

For any paediatric urgent listing there must be agreement between the two paediatric centres. This should involve the clinical leads or in their absence an appointed deputy. If there is disagreement this should be noted at the time of discussion with the chair of CTAG. **Table 4** outlines the criteria for paediatric urgent heart registration. These criteria are applicable for patients registering under the paediatric patient category only.

Table 4: Listing criteria for paediatric Urgent Heart Allocation Scheme registration

- Category 51 - Paediatric with short-term MCSD: Mechanical circulatory support for acute haemodynamic decompensation using a short-term right, left or bi-ventricular device (including Berlin Heart), implanted as a specific bridge-to-transplantation
- Category 52 - Paediatric with MCSD with device-related complications: Mechanical circulatory support with objective medical evidence of significant device-related complications such as thrombo-embolism, device infection, mechanical failure and/or life-threatening ventricular arrhythmias. Panel reactive antibody sensitisation does not qualify for urgent registration in this criterion
- Category 54 - Paediatric with VA ECMO: Mechanical circulatory support using extra-corporeal membrane oxygenation as a specific bridge-to-transplantation
- Category 55 - Paediatric >15kg on high-dose inotropes: Patients >15kg on continuous central infusion of a high dose intravenous inotrope
- Category 56 - Paediatric ≤15kg on ventilation and inotropes: Patients ≤15kg who are ventilated and on inotropes.
- Category 59 - Paediatric patients outside the criteria listed above, but for whom the patient's transplant physicians believe urgent listing is justified using acceptable medical criteria not included above. For paediatric patients whereby a maximum acceptable donor size has been specified to be ≥160 cm in height and/or ≥60kg in weight, their eligibility for registering under this category must be discussed and agreed by a panel of representatives from each paediatric transplant centre and the CTAG Chair or his deputy. Evidence of this agreement must be emailed to NHSBT.

5.2.2 UHAS Registration Process

Request for registration on the UHAS must be made by submitting a *Super-Urgent/Urgent Heart Recipient Registration Form* (FRM4351) to the ODT Duty Office by fax or email. The centre must specify the UHAS as the scheme they wish to register on to as well as the UHAS listing category. Indication can be made on the form to request donor heart offers from 1) blood group identical donors only, 2) identical and compatible donors or 3) donors of any blood group (option available to paediatric patients only). Patients on the UHAS can also be registered with a maximum and minimum donor height and weight they are willing to accept, at the time of registration. These patients will subsequently not receive offers of donor hearts from donors that fall outside of these specified criteria.
If there are any clear errors or missing data, the ODT Duty Office will call the centre immediately for clarification. When key information has been validated and it is confirmed that the patient is eligible, the ODT Duty Office will place the patient on the UHAS and notify all heart transplant centres in the UK by facsimile of an anonymised copy of the form to all designated heart transplant centres.

A summary of patients on the SU/UHAS will be sent by facsimile or email to all designated centres by the ODT Duty Office each day. Centres wishing to seek clarification of the details of a patient on the UHAS must notify the ODT Duty Office by telephone. The clinician from the centre seeking clarification will make direct contact with the registering centre and discuss the case clinician to clinician. In cases where clarification has been sought, the ODT Duty Office will seek confirmation of the patient’s status from the registering centre 24 hours after a registration. Where there remains a dispute this should be discussed with the Chairman of CTAG who may refer the case to the Adjudication Panel (Section 7).

After a month waiting on the urgent list has elapsed, the centre must submit a *Super-Urgent/Urgent Heart Recipient Monthly Update Form* (FRM4352) to the ODT Duty Office by fax or email. This should occur for every month a patient waits on the list.

If a patient has been suspended from the UHAS waiting list for more than 14 days, the patient should be removed from the list. If the patient is to re-join the UHAS waiting list, a new registration form must be submitted and they will not retain any waiting time from their previous urgent registration.

5.3 Super-Urgent Heart Allocation Scheme (SUHAS)

Patients who have advanced heart failure and are placed on temporary mechanical circulatory support device (tMCSD) or are not suitable for tMCSD are prioritised by placing them on the Super-Urgent Heart Allocation Scheme (SUHAS).

5.3.1 Listing criteria for SUHAS heart transplantation

The Super-Urgent Heart Allocation Scheme (SUHAS) is available for patients in the adult patient category only. **Table 5** outlines the criteria for adult Super-Urgent heart registration.

Table 5: Listing criteria for adult Super-Urgent Heart Allocation Scheme registration

- Category 11 - Adult patient on short-term mechanical circulatory support (MCSD)
- Category 12 - Adult patient at imminent risk of dying or irreversible complications. Meets criteria for urgent listing but is not suitable for long-term VAD and/or other exceptional circumstances. Agreed by CTAG Adjudication Panel (Section 7) and evidence of agreement emailed to NHSBT.

5.3.2 SUHAS Registration Process

Request for registration on the SUHAS must be made by submitting a *Super-Urgent/Urgent Heart Recipient Registration Form* (FRM4351) to the ODT Duty Office by fax or email. The centre must specify the SUHAS as the scheme they wish to register on to as well as the SUHAS listing category. Indication can be made on the form to request donor heart offers from 1) blood group identical donors only, 2) identical and compatible donors or 3) donors of any blood group (option available to paediatric patients only). Patients on the SUHAS can also be registered with a maximum and minimum donor height and weight they are willing to accept, at the time of registration. These patients will subsequently not receive offers of donor hearts from donors that fall outside of these specified criteria.

If there are any clear errors or missing data, the ODT Duty Office will call the centre immediately for clarification. When key information has been validated and it is confirmed that the patient is eligible, the ODT Duty Office will place the patient on the SUHAS and notify all heart transplant centres in the UK by facsimile of an anonymised copy of the form to all designated heart transplant centres.

A summary of patient on the SU/UHAS will be sent by facsimile or email to all designated centres by the ODT Duty Office each day. For cases where a centre wishes to seek clarification of the details of a patient on the SUHAS, the process is the same as for the UHAS (see Section 4.2.2).

After a month waiting on the super-Urgent list has elapsed, the centre must submit a *Super-Urgent/Urgent Heart Recipient Monthly Update Form* (FRM4351) to the ODT Duty Office by fax or email. This should occur for every month a patient waits on the list.

If a patient has been suspended from the SUHAS waiting list for more than 14 days, the patient should be removed from the list. If the patient is to re-join the SUHAS waiting list, a new registration form must be submitted and they will not retain any waiting time from their previous super-urgent registration.

6. Heart/lung transplantation

A patient who requires a heart-lung block can register on to the non-urgent heart-lung allocation scheme (NUHLAS). Any patient (paediatric, small adult and adult patient categories) has access to this scheme.

6.1 Non-Urgent Heart-Lung Allocation Scheme

In order to register a patient on the NUHLAS, the transplant centre must complete the '*Heart/Lung Registration Form*' (FRM4847) via ODT Online and select the option for 'Heart and Lung'.

6.2 Urgent Heart Patients

If an urgent heart patient also requires lungs, the centre must write to the CTAG Adjudication Panel (Section 7) for approval. If approved, the centre must inform the Duty Office at the time of offering. In such cases, the Duty Office will inform the requesting centre of all the centres above them on the lung rota and the decision as to whether the urgent heart patient may take the lungs must be determined between these centres.

7. Adjudication Panel

It is recognised that no system can describe every clinical situation and an equitable system must allow for consideration for individual cases in a transparent way. There are hence aspects of the UHAS, SUHAS and the UHLAS whereby the individual case is referred to the CTAG Adjudication Panel for approval.

7.1 Adult Cases

The CTAG Adjudication Panel is made up of the CTAG Chairman plus one representative from each of the 7 designated heart transplant centres. The registering centre must provide the panel with relevant details by email. The patient may be registered if the majority agree on the case for listing but if the panel cannot reach a consensus, the CTAG Chairman has the casting vote. In cases where the patient is from the same centre as the CTAG Chair, the process will be administrated by the Deputy CTAG Chair. A decision will be made within 24 hours of receiving the request. The decisions of the Adjudication Panel will be presented annually at meetings of the CTAG.

For cases where approval is granted, confirmation of approval by the Adjudication Panel must be sent to the ODT Duty Office via email or fax at the same time as the *Super-Urgent/Urgent Heart Registration Form*. Such patients will not be registered until the confirmation documentation is received and the registering centre must immediately call the ODT Duty Office to clarify that the information has been sent. Confirmation documentation should be sent either by fax or by email to: duty.office@nhsbt.nhs.uk and ODTOperationsDutyOfficeManagers@nhsbt.nhs.uk

7.2 Paediatric Cases

For paediatric patients, the case must be referred not to the CTAG Adjudication Panel but to the CTAG Chairman and a representative from each of the two paediatric centres for approval. A decision will be made within 24 hours of case referral. Again, for cases where approval is granted, confirmation of approval by the CTAG Chair must be sent to the ODT Duty Office via email at the same time as the *Super-Urgent/Urgent Heart Registration Form*. Such patients will not be registered until the confirmation documentation is received and the registering centre must immediately call the ODT Duty Office to clarify that the information has been sent. Confirmation documentation should be sent either by fax or by email to:
duty.office@nhsbt.nhs.uk and ODTOperationsDutyOfficeManagers@nhsbt.nhs.uk

7.3 Types of referral

The following cases can be referred to the relevant panel to obtain a decision over patient registration.

7.3.1 Super-Urgent Heart Registration

For an adult to be registered on to the SUHAS under Category 12, the case must be accompanied by proof of approval from the CTAG Adjudication Panel.

7.3.2 Urgent Heart Registration

The following cases must be accompanied by proof of approval from the relevant panel:

- an adult or small adult to be registered on to the UHAS under Category 22 or 23
- a paediatric patient to be registered on to the UHAS under Category 59

7.3.3 Urgent Heart Patients who also require lungs

An Urgent Heart patient who also requires lungs must be discussed and approved by the relevant panel before the centre is able to request donor lungs (Section 6.2).

7.3.4 Small adult registrations

The CTAG Adjudication Panel is also used to make decisions over whether a patient between 30 kg and 40 kg in weight should be registered as a small adult (Section 4.3). In such cases, the registering centre must provide the panel with relevant details and the Panel will respond with their decision within 24 hours. Small adult patients have access to the NUHAS and the UHAS.

7.3.5 Disputes over existing patient registrations

For cases where a centre has sought clarification over the details of a patient on either the SUHAS or the UHAS and disputed the registration of such patient with the registering centre, the case may be referred to the CTAG Adjudication Panel.

8. Contraindications, risk factors and comorbidities

Not all patients who meet criteria for transplantation are suitable for a variety of reasons. Patients need full evaluation by a discussion at an MDT meeting. Some contraindications are absolute and others are relative. The team needs to take a balanced decision based on need and avoiding futility.

A full discussion of the contraindications, risk factors and comorbidity is available in *Reference 2*.

The factors below need to be considered, although the list is not exhaustive

- Cardiorenal syndrome and other causes of renal dysfunction
- Liver dysfunction
- Pulmonary hypertension caused by heart failure and other factors
- Age (since older age is associated with co-morbidities)
- Previous cardiac surgery
- Diabetes mellitus
- Obesity
- Vascular disease
- Infection that is resistant to treatment
- Pulmonary embolism
- Immunosuppression
- Current and previous malignancy
- Autoimmune disease
- Social factors that, despite full support, will result in poor outcomes
- Substance use and alcohol abuse
- Smoking
- Non-adherence to treatment, despite support, that is likely to result in graft failure
- Mental capacity that, despite support, will result in poor outcomes
- Mental illness that, despite full assessment and treatment, will result in poor outcomes
- Other comorbidity

9. Selection for re-transplant
A small number of patients may require and be suitable for a second heart transplant. They will need to be assessed in a similar way to other potential recipients and a decision made based on the risks and benefit for that individual, relative to other potential recipients. Patients that have had a previous transplant may not be registered on to the SUHAS or the UHAS until three months have elapsed.

10. Follow up on list and de-listing
Patients who are listed for transplantation should be monitored at appropriate intervals to ensure their suitability for transplantation; maintain current clinical and other data; address any concerns of the patient and their carers; and ensure consent continues to be current. Some patients waiting on the list may deteriorate to the point where they need urgent or Super-Urgent listing, or mechanical circulatory support. Occasionally it may be appropriate to de-list patients and palliate appropriately. This must be done with tact and sensitivity. In these circumstances, patients are entitled to a second opinion.

References

1. Taylor DO, Stehlik J, Edwards LB, *et al*. Registry of the International Society for Heart and Lung Transplantation: twenty-sixth official adult heart transplant report 2009. *J Heart Lung Transplant* 2009;**28**:1007e22.

2. Banner NR, Bonser RS, Clark AL et al. UK guidelines for referral and assessment of adults for heart transplantation. Heart 2011;97:1520-1527