LUNG DONOR DISTRIBUTION AND ALLOCATION

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

The policy has been considered and approved by 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.

Last updated: July 2014
Next review: [Month] 2015

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 transplant list. These criteria apply to all 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 policy*

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

1.1 Rational for allocation policy

The guidelines set out below are developed by the Cardiothoracic Advisory Group (CTAG) after discussion with patient groups and other stakeholders and are then approved by the Transplant Policy Review Committee on behalf of the Board of NHSBT. These policies are reviewed annually and revised as necessary

The guidance describes the mechanism by which donated lungs within the UK are distributed to individual transplant centres (donor distribution) and how they are allocated (organ allocation).

1.2 How allocation policy was developed

At present, there are five designated centres undertaking adult lung transplantation and two undertaking paediatric lung transplantation in the UK. The designated centres are

allocated organs from named hospitals within clearly defined zonal boundaries (the allocation zones). The National Organ Retrieval Service (NORS) provides a UK-wide service for organ retrieval and is described in the National Standards.

Allocation zones are regularly reviewed and revised by NHSBT to ensure equity of access.

1.2.1 Overview

Lungs are allocated to the transplant centre, in whose zone the donor originates. The clinicians in that centre will select the most appropriate recipient from their routine list. Should the organ not be suitable for any local zonal recipients the organ is offered in sequence nationally (see section 1.3.2).

Lung allocation policies in the UK remain under close and regular review. The rationale for two separate allocation processes reflects the conflicting needs:

- To prioritise those patients who are at greatest risk of death without a transplant (which favours a national allocation system)
- To keep cold ischemic times to a minimum
- The potential benefits of closer matching the donor and recipient characteristics
- The challenges in using a scoring system which may not reflect the varied needs of all those on the transplant list

1.3 Allocation policy

1.3.1 Donor and recipient definitions

1.3.1.1 Donor definitions

An adult lung donor is defined as a donor aged 16 years or over at the time of death.

A paediatric donor is defined as being a patient aged less than 16 years at the time of death.

1.3.1.2 Group 1 and Group 2 recipients

Recipients are categorised as Group 1 or Group 2 (as defined by Direction of the Secretary of State for Health: 1 October 2005 – The NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005 – Guidance). Nationals of a non-UK country may only be registered on a transplant waiting list after they have been accepted by a consultant as suitable for treatment. It is the responsibility of the consultant registering such a patient on the waiting list to confirm that the patient is Group 1.

Group 1 patients have priority for available organs above Group 2 patients. No organ should be offered to or accepted for a Group 2 patient in the UK or Republic of Ireland if there is a clinically suitable Group 1 patient in the UK.

1.3.1.3 Recipient definitions

Paediatric recipients are defined as patients either with a body weight of 40 kg or less or aged under 16 years at the time of offer. Paediatric recipients will receive priority within the offering sequence for any organs available from a paediatric

A centre may register a small adult, weighing 40 kg or less, on the paediatric list at their discretion. Such patients will have equal priority with paediatric recipients within the offering sequence.

1.3.2 Details of the policy

1.3.2.1 Adult lung allocation sequence

Offers will be made to centres in the following priority order for Group 1 patients:

- The designated zonal centre
- The Royal Hospital for Sick Children, Great Ormond Street (for paediatric recipients)
- Designated centres in the UK or Republic of Ireland
- Organ Exchange Organisations in EC and other Group 1 countries

Offers will then be made to centres in the following priority order for Group 2 recipients:

- The designated zonal centre
- Designated centres in the UK or Republic of Ireland
- Organ Exchange Organisations in Group 2 countries

1.3.2.2 Paediatric lung allocation sequence

All paediatric donor cardiothoracic organs in the UK or Republic of Ireland will be offered first to paediatric recipients, including registered small adults, and then to adults in the following priority order for Group 1 recipients:

- Designated paediatric transplant centres and those centres with small adults registered as paediatric recipients in the UK or Republic of Ireland
- The designated zonal centre for adult patients
- Designated centres in the UK or Republic of Ireland for adult patients
- Organ Exchange Organisations in EC and other Group 1 countries

Offers will then be made to centres in the following priority order for Group 2 recipients:

- Designated paediatric transplant centres and those centres with small adults registered as paediatric recipients in the UK or Republic of Ireland

- The designated zonal retrieval centre for adult recipients
- Designated centres in the UK or Republic of Ireland for adult recipients
- Organ Exchange Organisations in Group 2 countries

No paediatric organ should be offered to a Group 2 patient in the UK or Republic of Ireland if there is a clinically suitable Group 1 patient in the UK or Republic of Ireland.

1.3.2.3 Adult lung allocation

Transplant centre rota

Patients listed for a combined heart and lung transplant will be included on the heart waiting list.

The adult rota will include all UK designated lung transplant centres.

All deceased donors identified within the Royal Hospital for Sick Children, Great Ormond Street, will be offered initially to the Great Ormond Street Transplant Unit before reverting to the local zone.

Offers for adult lung recipients will be in accordance with the Lung Centre Rota current at the time of offer. This rota will be managed as follows:

- The offer sequence will be in reverse-chronological order of last transplant date when organs are accepted outside of their own retrieval zone. A centre does not move position on the rota should they accept an organ from within their own zone. As each centre carries out a transplant using an organ donated from within the UK or Republic of Ireland and imported from another zone, it will be placed at the bottom of the rota. However, a centre carrying out a heart-lung block transplant, will be rotated to the bottom of both the Heart and Lung Centre Rotas.
- The rota will be used to advise designated centres of the availability of donor organs regardless of whether or not a patient of the appropriate blood group is registered from their centre on the National Transplant Database at the time.

Exceptions will be made to the strict reverse-chronological rota in the following cases:

- An organ donated from within a designated centre's zone will be offered first to that centre regardless of that centre's current place on the rota. If the organ is used, that centre will retain its place and not be rotated to the bottom of the relevant rota.
- A centre transplanting an organ donated from outside the UK or Republic of Ireland will retain its former place and not be moved to the bottom of the rota.
- Where a heart-lung block is exported from a zone, and the exporting zonal retrieval centre receives back in exchange a domino heart, neither the zonal retrieval centre nor the centre importing the heart-lung block will be rotated on the Heart Centre Rota. However, the centre importing the heart-lung block will be rotated on the Lung Centre Rota.

- Where a centre transplanting an imported heart-lung block donates a domino heart to a centre, other than the zonal retrieval centre exporting the heart-lung block, the centre donating the domino heart will be rotated on the Lung Centre Rota only, and the centre receiving the domino heart will be rotated on the Heart Centre Rota.

1.3.2.4 Paediatric lung allocation

Transplant centre rota

The Paediatric Cardiac Centre Rota applies to all heart and heart-lung recipients and the Paediatric Lung Centre Rota for lung only recipients.

The paediatric rotas will comprise the designated paediatric transplant centres and designated adult transplant centres with small adults registered as paediatric recipients in the UK and Republic of Ireland.

All deceased donors identified within the Royal Hospital for Sick Children, Great Ormond Street, will be offered initially to the Great Ormond Street Transplant Unit and, if declined, offered according to the rota.

Paediatric donor organ offers for heart-lung recipients will be in accordance with the Cardiac Centre Rota current at the time of offer; offers for lung recipients will be in accordance with the Lung Centre Rota current at the time of offer.

The cardiac and lung rotas used for paediatric donor organs will comprise first paediatric recipients followed by adult recipients. These rotas will be activated as follows:

- The offer sequence will be in reverse-chronological order of last transplant date. As each paediatric centre or adult centre with a small adult registered as a paediatric recipient carries out a paediatric transplant using an organ(s) donated from within the UK or Republic of Ireland, it will be placed to the bottom of the appropriate paediatric rota. A centre carrying out a heart-lung block transplant will be rotated to the bottom of both the Cardiac and Lung Centre Rotas. An adult centre registering a small adult as a paediatric recipient will start at the bottom of the paediatric rotation
- As each adult centre carries out an adult transplant using an organ(s) donated from a paediatric donor within the UK or Republic of Ireland and imported from another zone, it will be placed to the bottom of the appropriate adult rota. However, a centre carrying out a heart-lung block transplant will be rotated to the bottom of both the adult Cardiac and Lung Centre Rotas
- Offers will be made to non-designated centres in accordance with the offer rota only if a suitable blood group recipient is registered from their centre on the National Transplant Database at the time

Exceptions will be made to the strict reverse-chronological rota in the following cases:

- A centre transplanting an imported organ donated from outside the UK or Republic of Ireland will retain its former place and not be moved to the bottom of the rota
- Where a centre transplanting a heart-lung block donates a domino heart to another centre, the centre donating the domino heart will be rotated on the Lung Centre Rota only, and the centre receiving the domino heart will be rotated on the Cardiac Centre Rota

1.3.2.8 Use of blood group O lungs

Compared with other blood groups, blood group O candidates wait significantly longer to be matched with suitable donor organs. To promote equity of access, blood group O donor lungs should be offered in the following priority order:

1. Blood group O patients locally
2. Blood group O patients nationally
3. Blood group A, B or AB patients locally
4. Blood group A, B or AB patients nationally

Non-compliance will be followed up by NHSBT according to the agreed protocol.

These rules do not apply for fast track lung offers.

1.3.2.9 Allocation within centres

Currently there is no universal allocation tool nationally or within centres describing which patients, matched for blood group and size, will receive the first available donor.

Most centres will allocate the lungs to the patient with the greatest need, but other factors will also need to be considered to obtain optimal outcomes. Donor factors include age, smoking history, double or single lung offer and graft quality; recipient factors include their respiratory diagnosis, age, height and blood group (which together influence the chance and speed of identifying matched donors) and projected cold ischaemia time.

Discussions are necessary with all patients concerning varying risk associated with some donors. Patient preferences should be considered and appropriate consent must be obtained.

1.3.2.10 Fast track lung offer scheme

Fast track offers from the UK and Republic of Ireland

Designated cardiothoracic centres may register with the NHSBT Duty Office to receive offers of lungs that are available at short notice from another centre in the UK and the republic of Ireland. The scheme will come into effect for any lungs referred to NHSBT that are:

- To be removed within 90 minutes of the referral to NHSBT
- Already removed or in the process of removal

Lungs offered on the fast track offer scheme may be accepted for blood group compatible or identical patients: the usual blood group O priority (section 1.3.2.8) will be waived.

The scheme will operate as follows:

- Offers of lungs meeting the fast track offer scheme criteria will be made only to centres registered in the Scheme.
- Offers will be made by NHSBT by simultaneous facsimile and/or electronic message to pager transmission of donor information. Full donor information should be viewed via the electronic offering system (EOS or EOS Mobile).
- In all cases, centres must respond by telephone to all fast track offers within 30 minutes of the facsimile offer whether they wish to accept or decline the offer. If a centre does not respond to a fast track offer, the ODT Duty Office will assume that the offer has been declined.
- If an organ is accepted by more than one centre, it will be allocated to the centre placed highest on the rota at the time of offering the organ.
- Group 1 patients will be allocated organs before Group 2 patients. Centres accepting for Group 2 patients must wait until the 30 minutes and follow up have lapsed to ensure no centre is accepting for a Group 1 patient.
- Within 45 minutes of receiving the referral, NHSBT will advise the offering centre of the outcome.

Fast track offers from Europe

Designated Cardiothoracic Units may register with the ODT Duty Office to receive offers of organs that are available from other centres in Europe. The scheme will come into effect for all offers of hearts and lungs from European Organ Exchange Organisations.

The scheme will operate as follows:

- Offers of cardiothoracic organs meeting the fast track offer scheme criteria will be made only to centres registered in the scheme.

- Offers will be made by NHSBT by simultaneous facsimile and/or electronic message to pager transmission of donor information.
- For all cases, acceptance will be on a first come first served basis. Centres not responding will be deemed to have declined the offer.
- Within 45 minutes of receiving the referral, NHSBT will advise the offering European Organ Exchange Organisation of the outcome.

1.3.3 Organs unsuitable for offering

If the retrieval team consider the cardiothoracic organs to be not suitable, the organs must be offered to two more cardiothoracic transplant centres (not including Great Ormond Street) before they are deemed untransplantable. Suggested criteria for non-retrieval are listed in Appendix 1.

2. Acceptance of offered organs

2.1 Offering time and acceptance of offered organs

Offers will be made in accordance with the cardiothoracic centre rotation for offering donor lungs, on the basis of a firm offer to the first centre and a provisional offer to the second in line.

For all cases, centres to which a firm offer has been made must advise NHSBT within 45 minutes whether they wish to accept or decline the offer. If the organ is declined, it will be offered to the second in line as a firm offer and to the third in line as a provisional offer, and so on throughout the rotational sequence.

For firm offers made to a centre previously advised provisionally, NHSBT must be advised within 30 minutes whether they wish to accept or decline the firm offer.

An offer will be withdrawn by NHSBT after 60 minutes if a response is not made.

In all cases, centres must respond by telephone to all *fast track offers* within 30 minutes of the offer whether they wish to accept or decline the offer.

Only once all centres have declined a donor for a Group 1 patient will Group 2 patient requirements be considered.

A centre to which an offer has been made will retain its place on the centre rota while a decision is pending. A centre declining an offer will retain its place on the rota.

In exceptional circumstances (i.e. extreme weather conditions), should the retrieval team be unable to retrieve organs, an offer could be made to a nearby cardiothoracic centre before being offered via the national offering sequence.

If a single lung is to be offered to cardiothoracic centres via the national offering sequence, the offering centre must state which lung is to be offered.

As of March 2006, Manchester would receive the first national offer of lungs declined by Birmingham from the northern part of Birmingham's retrieval zone in an attempt to redress apparent lung shortages at Manchester. Lungs are offered using this arrangement from donors in the following hospitals/intensive therapy units (ITUs):

- HM1601 - Birmingham, City Hospital
- HM1301 - Birmingham, Heartlands Hospital
- HM1202 - Birmingham, Queen Elizabeth Hospital
- HM1501 - Birmingham, Selly Oak Hospital
- HM0501 - Shrewsbury, Royal Shrewsbury Hospital
- HM0701 - Stoke, North Staffs Royal Infirmary
- HM0540 - Telford, Princess Royal Hospital
- HM2102 - Walsall, Walsall Manor Hospital
- HM2203 - Wolverhampton, New Cross Hospital
- HW1241 - Wrexham, Maelor General Hospital

3. Allocation policies for multiple organs

3.1 Heart-lung block

For adults and paediatrics, when a heart-lung block is available for donation, the organs will first be offered using the Cardiac Centre Rota. If part of a block is accepted for transplant, the remainder will be offered on, using the rota appropriate to the remaining organ(s). When a block is offered, either the whole block, heart only or lungs only can be accepted at any time during offering, however if a block is accepted this should be with the intention of being used for a block transplant for one patient not to be split and used as a heart only and lung only transplant for two separate patients.

3.2 Renal

A kidney can be accepted with a cardiothoracic organ and has primacy over any kidney allocation scheme. The acceptance of a kidney with a cardiothoracic organ must be made in the original 45 minute offering time.

1. Refere

APPENDIX 1

Suggested criteria for non-retrieval

In September 2007 it was proposed that all potential lungs (donor age <65 years, consent to lung donation) should be considered for lung retrieval by the local centre. A decision not to proceed with offering would be based on a documented PaO_2 <25kPa (187 mmHg) on FiO_2 1.0 and PEEP 5cmH_2O provided that:

- Endotracheal tube malposition had been excluded by CXR or bronchoscopy
- Rigorous attempts had been made to recruit atelectatic segments by ventilator adjustment and physiotherapy
- There are bilateral pathological changes on CXR
- A clear cause for hypoxaemia has been established e.g. bilateral pulmonary contusion or other trauma, documented aspiration, CXR evidence of major pulmonary consolidation
- In the presence of PaO2 <25kPa on FiO2 1.0 and PEEP 5cm.H_2O and unilateral CXR changes only, the possibility of single lung transplantation should be considered (pulmonary venous sampling during attempted organ retrieval is recommended)

APPENDIX 2

Donor acceptance criteria

These are at the discretion of the recipient centre and should be in line with patient wishes

Donor lung acceptance criteria

- Age up to 65 years
- No or minimal chest trauma
  - Pneumothorax and/or a chest drain are not a contraindication
  - No previous chest surgery on the retrieval side
- Ventilated less than 10 days
  - Tracheostomies are acceptable
- Normal chest x-ray (CXR) appearance reported on retrieval day
  - Normal cardiac silhouette, normal lung fields
  - Normal cardiothoracic ratio (i.e. less than 50% on standard chest X-ray)
  - Borderline gases with a unilateral abnormality on CXR may mask a perfectly usable contralateral lung
- No evidence of respiratory infection as demonstrated on CXR or the presence of purulent sputum and isolated pathogens
  - Purulent secretions do not necessarily rule out lung donation. Multiple organisms on gram stain may indicate normal flora and are unlikely to lead to infection. No donor should be rejected based on history of purulent sputum without bronchoscopic evidence of infection (i.e. injected mucosa)
  - Heavy fungal contamination of the bronchial tree may exclude donation. Candida infection should be treated with an azole
- No systemic sepsis (i.e. white cell count >20,000/mL or pyrexia > 38°C of unknown origin)
- Acceptable arterial blood gases (ABG):
  - On FiO_2 100%, $pO_2 \geq 300$ mmHg and on
  - FiO_2 of 40%, $PO_2 \geq 120$
  - PO_2 (mmHg) should preferably be 3 x FiO_2
  - PO_2 of 2.5 x FiO_2 may be considered at the discretion of the senior implanting surgeon
- Normal ventilatory parameters with normal compliance
  - The addition of 5 cm of positive end-expiratory pressure (PEEP) is recommended
- Mild asthma is acceptable (but may be transmitted)

- Current pulmonary oedema if associated with CXR changes and borderline ABG excludes donation. May consider if treated and resolved. Fluid overload should be avoided
- No evidence of aspiration. The presence of a positive history, poor gases and abnormal CXR and bronchoscopic findings suggesting aspiration will preclude donation. In cases of history suggesting inhalation, donors should have abnormal bronchoscopy before being turned down.
- CMV mismatches are acceptable unless specified in high risk recipients
- Carbon monoxide poisoning is acceptable with caution as long as there is no smoke inhalation
- Smoking history should not be the sole reason for refusal of a well-functioning organ. Acceptable up to 30 pack years (i.e. 1 pack per day for 30 years). If greater than this, other factors should be considered in conjunction with smoking history as reasons for refusal

Donor heart-lung acceptance criteria
In addition to the above, heart acceptance criteria should apply. These are covered within the heart allocation policy document.

Contraindications to donation
With the increasing disparity between supply of donors and patients registered for a transplant, as well as evolving experience with donors previously considered to be unsuitable, the absolute criteria contraindicating donation changes with time. All donors carry some risks which should be perceived as a continuous spectrum of risk.

To maximise the potential for organ donation, every potential organ donor should become an actual donor where appropriate. However, to prevent families being approached needlessly, it is important to define those characteristics of potential donors that preclude donation in any circumstance.

It should be recognised that it is the responsibility of the recipient surgeon to decide whether to accept an organ and this decision will depend on both donor and recipient factors. Organs from all donors will carry some degree of risk and the risks associated with transplantation must be balanced against both its potential benefits and also the risks of awaiting a further, conceivably better quality, donor offer.

The criteria listed below were drawn up by a group of transplant surgeons, physicians, intensive care clinicians and specialist nurses in organ donation and are based on past experience. Each Advisory Group has developed contraindications for donation for each organ.

As with all guidelines, these should be used with clinical judgement and, if a clinician feels that a person excluded by this list, should be offered the opportunity to donate, then the family should be approached for consent/authorisation.

Contraindications to lung donation after brain death are:

- Age >65 years
- Cancer with evidence of spread outside affected organ (including lymph nodes) within 3 years of donation (however, localised prostate, thyroid, *in situ* cervical cancer and non-melanotic skin cancer are acceptable)
- Active melanoma
- Choriocarcinoma
- Active haematological malignancy (myeloma, lymphoma, leukaemia)
- Definite, probable or possible case of human transmissible spongiform encephalopathies (TSEs), including Creutzfeldt–Jakob disease (CJD) and variant (v)CJD, individuals whose blood relatives have had familial CJD, other neurodegenerative diseases associated with infectious agents
- Major systemic sepsis
- Tuberculosis (TB): active or within 6 months of start of treatment*
- Malaria: if not fully treated*
- Meningoencephalitis for which no infection has been identified*
- HIV disease (but not HIV infection)
- Hepatitis B and C*: Individuals known to be infected with hepatitis B/C or at significant risk of transmitting hepatitis B/C (hepatitis B surface antigen, hepatitis B core antibody, hepatitis C antibody positive donors may be offered by the ODT Duty Office and the final decision to accept the organ lies with the transplant surgeon and the potential recipient. The recipient must be made aware of the long term risks.

**In exceptional cases donation may be considered*

Contraindications to lung donation after circulatory death are:

- As above
- A proposed donor must achieve asystole within 60 minutes of withdrawing mechanical ventilatory and inotropic support to minimise warm ischaemia injury to the lung(s).

The transplant surgeon must ensure all potential recipients are aware of any special risk of infection involved in the particular transplant procedure.

Neither donor centres nor the ODT Duty Office will offer lungs from donors who have NOT been tested for Hepatitis B surface antigen, Hepatitis C antibody or HIV antibody.

Where a donor is found to fall into any of the risk categories defined as contraindications to donation for organ transplantation, the ODT Duty Office will actively seek, record and pass on all donor information for the transplant centre to make the decision on the suitability of the donor organ.