Changes in this version

Section 6.2.2 – change to removal process for those suspended for more than 14 days from ULAS
Section 6.3.3 – change to removal process for those suspended for more than 14 days from SULAS

Policy

This policy has been created by the Cardiothoracic Advisory Group (CTAG) 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: August 2023

Approved by OTDT Care: August 2023

The aim of this document is to provide guidelines 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 patients receiving 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 **POL198***: NHS Blood and Transplant Organ Donation and Transplantation: Policy on Non-compliance with Selection and Allocation policies.*

It is acknowledged that these guidelines will require regular review and refreshment. Where they do not cover specific individual cases, patients should be referred to the Adjudication Panel.

Lung transplantation is an established treatment in patients who have a likelihood of poor survival or impaired quality of life secondary to end stage lung disease.

In selected patients, lung transplantation improves survival and quality of life. Current UK data (UK Transplant Registry) show that 1- and 5- year survival rates following DBD lung transplantation are 84% and 55% for adult patients and 80% and 66% for paediatric patients, respectively (*http://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/*).

The decision to recommend lung transplantation depends on a balance of the benefits, risks and alternatives. However, the scarcity of suitable donor lungs makes it necessary to also consider the population of potential lung 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 multidisciplinary 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 Referral for Assessment of Suitability for Transplantation

1.1. Adult Patients (aged 16 and above)

Most adult patients with lung disease are not managed in transplant centres. Patients referred for assessment for lung transplant will include those with the following broad categories of conditions:

- Diffuse Parenchymal Lung Disease including:
  - Idiopathic pulmonary fibrosis (UIP and NSIP)
  - Lung fibrosis in association with connective tissue disease
  - Occupational lung fibrosis
  - Drug / toxic lung fibrosis
  - Chronic hypersensitivity pneumonitis
  - Sarcoidosis
  - Lymphangioleiomyomatosis
  - Langerhan's cell histiocytosis

- Obstructive lung disease including:
  - Smoking related chronic obstructive pulmonary disease (COPD)
  - Alpha 1 antitrypsin deficiency
  - Obliterative bronchiolitis
  - Chronic asthma

- Pulmonary vascular disease including:
  - Idiopathic pulmonary arterial hypertension
  - Pulmonary arterial hypertension associated with connective tissue disease
  - Complex congenital heart disease with Eisenmenger's syndrome
  - Chronic thromboembolic pulmonary hypertension unsuitable for or unresponsive to pulmonary thrombo endarterectomy
  - Pulmonary veno-occlusive disease
  - Pulmonary capillary haemangiomatosis

- Suppurative lung disease including:
  - Cystic Fibrosis (CF)
  - Non-CF bronchiectasis

Patients not falling within these diagnostic categories will be also considered by the local transplant multidisciplinary team (MDT) on a case by case basis.

1.2. Paediatric Patients (aged less than 16 years)

There are a number of rare paediatric respiratory conditions which may not fall into the following broad diagnostic categories but will be considered by the local MDT on an individual case basis.

- Pulmonary vascular disease including:
  - Idiopathic pulmonary arterial hypertension
  - Pulmonary veno-occlusive disease
  - Complex congenital heart disease with Eisenmenger's syndrome
- Suppurative lung disease including:
  - Cystic Fibrosis
  - Non-CF bronchiectasis
- Children's Interstitial Lung Disease (ChILD) (will be considered on an individual basis)
- Obliterative bronchiolitis

2. Referral

Clinicians looking after potential transplant candidates should discuss referral with one of the lung transplant centres in the UK and, when appropriate, arrange for formal referral. Paediatric patients will be referred to one of the two designated paediatric lung transplant centres (Newcastle and Great Ormond Street, London). It is advisable that patients are discussed with transplant centres at an early stage so a combined approach can be formulated.

3. Assessment of Candidates for Transplantation

Patients should be fully assessed in one of the Lung Transplant Centres. Patients should be discussed at the MDT meeting and, if appropriate for transplantation, should be offered listing. Assessment of patients is outlined in **Appendix 1**.

4. Transplant Centres

There are six lung transplant centres in the UK: Birmingham, Great Ormond Street Hospital, Harefield, Manchester, Newcastle and Papworth. Newcastle transplant adult and paediatric patients, and Great Ormond Street transplant paediatric patients only. The remaining centres transplant adult patients only. Additionally, Newcastle offer lung transplant services to patients from Scotland as the transplant centre in Glasgow performs heart only transplants at present.

5. Lung Allocation Overview

There are three tiers of allocation; the Super-Urgent Lung Allocation Scheme (SULAS), the Urgent Lung Allocation Scheme (ULAS) and the Non-Urgent Lung Allocation Scheme (NULAS). 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 allocated donor lungs is outlined in **POL230***:* Lung Allocation Policy *(https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/).*

5.1. Adult Patients

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

5.2. 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.

5.3. Small Adult Patients

A Small Adult is defined as a patient aged 16 or above and of height less than or equal to 155cm (this is done automatically and does not rely on indication on the registration form) who is registered on the SULAS or ULAS. Patients meeting these criteria will generally receive offers of lungs available from paediatric donors before other adults, but after paediatric patients.

5.4. 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. The Small Adult patient category only applies to the Urgent and Super-Urgent schemes.

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)**	**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, height ≤155cm	Small Adult	Small Adult	Paediatric

* Newcastle is counted as both an adult centre and a paediatric centre in the document

6. Listing of Patients

Transplant centres should request NHSBT to place eligible patients on the UK national lung transplant list. Patients who have not been registered should not be offered an organ. 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.

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: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1864/nhsbt_directions_2005.pdf.
It should nevertheless 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.

6.1. Non-Urgent Lung Allocation Scheme (NULAS)

6.1.1. Listing Criteria for NULAS Lung Transplantation

To ensure equity, patients listed for transplantation should meet agreed minimal listing criteria. Table 2 outlines guideline criteria for adult non-urgent lung registration.

Table 2: Guideline listing criteria for Adult Non-Urgent Lung Allocation Scheme registration

Patients listed for transplantation will:

- Be on maximal medical therapy
- Have a potential survival benefit from transplantation or a potential significant improvement in their quality of life as a result of transplantation
- Have projected post-operative survival >5 years with a quality of life acceptable to the patient

In addition, patients will also meet one or more of the disease-specific criteria listed below;

* Obstructive Lung Disease

- Forced expiratory volume (FEV1) of less than 20% predicted despite maximal medical therapy and either
  * diffusion capacity of the lungs for carbon monoxide (DLCO) of less than 20% predicted, or
  * homogenous distribution of emphysema
- History of hospitalisation and, in particular, an increasing frequency of this for exacerbations associated with acute hypercapnia (PaCO2 exceeding 6.5 KPa) and worsening hypoxia
- Pulmonary hypertension (defined as a mean pulmonary artery pressure of >25 mmHg in the presence of normal pulmonary capillary wedge/left atrial pressure) or cor pulmonale (evidence of right ventricular decompensation leading to fluid retention)
- BODE score greater than 7. BODE is a composite, multidimensional assessment tool which was derived in a large population of COPD patients. The score ranges from 0-10, a higher score indicating worse functional reserve and poorer prognosis.

* Cystic Fibrosis and bronchiectasis

- FEV1 below 30% predicted or a rapid and irreversible decline in FEV1
- Exacerbation of pulmonary disease requiring at least one intensive care unit (ICU)/high dependency unit (HDU) admission
- Pneumothorax in association with advanced disease
- Haemoptysis not controlled by embolization
- Progressive increase in medical therapy to maintain survival including an increased frequency of the need for intravenous (IV) antibiotics due to increased/worsening exacerbations

* Idiopathic pulmonary fibrosis

Histologic or radiographic evidence of IPF and any of the following:

- A 10% or greater decrement in forced vital capacity (FVC) during 6 months of follow-up
- DLCO of less than 40% with clinical deterioration and/or a greater than 15% decline in DLCO over 6-months of follow-up
- A rapid decrease in pulse oximetry below 88% during a 6-minute walk test

- Short rapid decline in symptoms pre-diagnosis

* Pulmonary arterial hypertension

- Presentation in or deterioration to World Health Organisation (WHO) functional class III or IV without an improvement on parenteral medical therapy over 3 months
- Declining 6-minute walk distance to less than 350 m despite maximal medical therapy
- Worsening refractory right heart failure as defined by increasing fluid retention despite optimal medical management with disease modifying therapy and diuretics
- Requirement for continuous intravenous (IV) inotropic support
- Recent (within 3 months) right heart catheter study showing right heart catheter evaluation of right atrial pressure >15mmHg and CI <2.0 L/min/m2 despite optimisation of therapy

Table 3 outlines guideline criteria for paediatric non-urgent lung registration.

Table 3: Guideline listing criteria for Paediatric Non-Urgent Lung Allocation Scheme registration

Patients listed for transplantation will:

- Be on maximal medical therapy
- Have a potential survival benefit from transplantation or a potential significant improvement in their quality of life as a result of transplantation
- Have projected post-operative survival >5 years with a quality of life acceptable to the patient

A complicating factor in paediatric practice is that some of the conditions affecting children are individually rare and decisions have to be based on general principles rather than condition-specific data. In general, listing for transplant is advisable when patients have a less than 50% 2-year predicted survival and a poor quality of life.

It is recognised that transplantation may be indicated for some adult or paediatric patients who do not meet these criteria. In such cases, the MDT should clearly document in the hospital records the reasons for their decision to list a patient who does not meet the agreed criteria and the case should be referred to the CTAG Adjudication Panel (Section 7). The use of transplantation for the rarer indications should be audited regularly by the MDT and new indications should be developed by consensus.

6.1.2. NULAS Registration Process

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

6.2. Urgent Lung Allocation Scheme (ULAS)

Urgent patients will be suitable transplant candidates in whom survival without transplantation is likely to be less than 90 days. Patients requiring re-transplantation will not have access to the ULAS. Patients should be removed from the list when the local MDT concludes the patient does not have a reasonable chance of intermediate survival; for example, 50% probability of surviving 3-5 years post-transplant.

6.2.1. Listing Criteria for ULAS Lung Transplantation

Table 4 outlines the criteria for urgent lung registration. These criteria are applicable for patients registering under the Adult, Paediatric and Small Adult patient categories (see Table 1); a patient must meet one of the urgent categories listed below to be registered (note that the category numbers are not sequential due to the way they are programmed into the electronic system), or be approved by the CTAG Adjudication panel (see Section 7). Some transplant candidates fulfilling the urgency criteria listed below will likely require ongoing inpatient treatment. In principle however, urgent candidates may remain ambulant at home but will require close monitoring as deemed necessary by the local transplant team.

Table 4: Listing criteria for Urgent Lung Allocation Scheme registration

A patient who is suitable for acceptance on the transplant waiting list and displays or develops any one of the following characteristics. Many transplant candidates fulfilling the criteria listed below will likely require ongoing inpatient treatment. In principle, urgent candidates may remain ambulant at home but will require close monitoring as deemed necessary by the local transplant team.

1) COPD Patient

- Category 10 - Worsening hypoxia (PaO_2<7.5 kPa) and hypercapnia ($PaCO_2$>6.5 kPa) requiring increasing oxygen demand of >10 L/min despite continuous NIV
- Category 11 - pH persistently <7.30 despite optimal continuous NIV
- Category 12 - Refractory right heart failure despite all pharmacological interventions to support the right ventricle

2) CF patient

- Category 21 - Worsening hypoxia (PaO_2<7.5 kPa) and hypercapnia ($PaCO_2$>6.5 kPa) requiring increasing oxygen demand of > 10L/min despite continuous NIV
- Category 22 - pH persistently <7.30 despite optimal continuous NIV
- Category 23 - Refractory right heart failure despite all pharmacological interventions to support the right ventricle
- Category 24 - Ongoing episodes of massive haemoptysis despite bronchial embolisation

3) IPF Patient

- Category 31 - Persisting hypoxia (PO_2 <8 kPa) despite continuous O_2 at 10 L/min
- Category 32 - Refractory right heart failure despite all pharmacological interventions to support the right ventricle

4) PAH patient

- Category 41 - Worsening refractory right heart failure as defined by increasing fluid retention despite optimal medical management with disease modifying therapy and diuretics
- Category 42 - Requirement for continuous IV inotropic support
- Category 43 - Recent RHC RAP > 20 mmHg and CI < 2.0 L/min/m^2 despite optimisation of therapy. RHC data need to be recent, within 3 months of request to add to urgent list

6.2.2. ULAS Registration Process

Request for registration on the ULAS must be made by submitting a *Super-Urgent/Urgent Lung Recipient Registration Form* (**FRM5769**) to the Hub Operations by email. The centre

must specify the ULAS as the scheme they wish to register on to as well as the ULAS category.

Centres must register patients on the ULAS with gender-specific maximum and minimum donor heights they are willing to accept for that patient. Patients will subsequently not receive offers of donor lungs from donors that fall outside of these specified criteria. Centres must use their judgement when choosing these ranges and may update them whilst their patient is on the waiting list if necessary.

If there are any obvious errors or missing data, Hub Operations will call the centre immediately for clarification. If amendments to the form are needed, the centre must send through a new copy containing the amended details. When key information has been validated and it is confirmed that the patient is eligible, Hub Operations will place the patient on the ULAS and notify all lung transplant centres in the UK by email of an anonymised copy of the form to all lung transplant centres.

A summary of patients on the ULAS will be sent by email to all lung centres by Hub Operations each day. Centres wishing to seek clarification of the details of a patient on the ULAS must notify Hub Operations. 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, Hub Operations 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 Chair of CTAG who may refer the case to the CTAG Adjudication Panel (Section 7).

After a month waiting on the urgent list has elapsed, the centre must submit a Super-Urgent/Urgent Lung Recipient Monthly Update Form (**FRM5770**) to ODT Hub Information Services by emailing nhsbt.supplementary.allforms@nhs.net. This should occur for every month a patient waits on the list.

If a patient has been suspended from the ULAS waiting list for more than 14 days, the centre should remove the patient from the urgent lung list. If the patient needs to be re-activated on the ULAS waiting list after 14 days, a new registration form must be submitted, and they will not retain any waiting time from their previous urgent registration. If a patient has been suspended from the urgent heart-lung list for more than 14 days, the centre should contact Hub Operations to remove the patient from this list.

6.3. Super-Urgent Lung Allocation Scheme (SULAS)

Patients eligible for SULAS registration will usually be those already known to the local transplant team, having been fully assessed and deemed suitable transplant candidates, who are already registered on the urgent or non-urgent scheme and subsequently suffer acute deterioration requiring extracorporeal support to bridge them to donor organ availability. However, other suitable patients not already registered on the urgent or non-urgent scheme, may be considered.

Patients should be removed from the list when the local MDT concludes the patient does not have a reasonable chance of intermediate survival; for example, 50% probability of surviving 3-5 years post-transplant.

Patients requiring re-transplantation will not have access to SULAS.

6.3.1. Listing Criteria for SULAS Lung Transplantation

Table 5 outlines the criteria for Super-Urgent lung registration. These criteria are applicable for patients registering under the Adult, Paediatric and Small Adult patient categories (see Table 1); a patient must meet one of the super-urgent categories listed below to be registered.

Table 5: Listing criteria for Super-Urgent Lung Allocation Scheme registration
• Category 91 – Patient supported with VV-ECMO or iLA as a bridge to transplant and previously registered on the ULAS or NULAS • Category 92 – Patient outside the criteria listed above, but for whom the patient's transplant physicians believe super-urgent listing is justified. Agreement given by the CTAG (Lung) Adjudication Panel and evidence of agreement emailed to NHSBT

Registrations under Category 92 for Adult, Small Adult or Paediatric patients should be referred to the CTAG Adjudication Panel (Section 7).

A patient whose condition deteriorates to the point of becoming dependent on IPPV in an intensive care unit will not be included in the super-urgent scheme. If such patients are subsequently referred for consideration of suitability for lung transplantation, they need to complete treatment and undergo full rehabilitation before further consideration of their transplant candidacy by the local transplant team.

All super-urgent candidates will be receiving in-patient treatment and will continue to fulfil current transplant acceptance criteria; in particular, they must remain free of major sepsis and display no signs of other extrapulmonary organ failure. The daily clinical review process will also allow consideration of de-listing a patient who has deteriorated to a clinical status out with these guidelines.

6.3.2. Criteria for Bridging to Transplant

Patients should only be considered for bridging to lung transplantation if they have a good rehabilitation potential which usually means a relatively short duration of severe illness to minimise the risks of prolonged ITU stay and post-operative complications.

The decision in any transplant centre to place a rapidly deteriorating transplant candidate on a short-term device (iLA or ECMO) will be on a case by case basis. This is now a nationally commissioned process.

6.3.3. SULAS Registration Process

Request for registration on the SULAS must be made by submitting a *Super-Urgent/Urgent Lung Recipient Registration Form* (**FRM5769**) to Hub Operations by email. The centre must specify the SULAS as the scheme they wish to register on to as well as the SULAS category.

Centres must register patients on the SULAS with gender-specific maximum and minimum donor heights they are willing to accept, at the time of registration for that patient. Patients will subsequently not receive offers of donor lungs from donors that fall outside of these specified criteria. Centres must use their judgement when choosing these ranges and may update them whilst their patient is on the waiting list if necessary.

If there are any obvious errors or missing data, Hub Operations will call the centre immediately for clarification. If amendments to the form are needed, the centre must send through a new copy containing the amended details. When key information has been validated and it is confirmed that the patient is eligible, Hub Operations will place the patient on the SULAS and notify all lung transplant centres in the UK by email of an anonymised copy of the form to all lung transplant centres.

A summary of patients on the SULAS will be sent by email to all lung centres by Hub Operations each day. Centres wishing to seek clarification of the details of a patient on the SULAS must notify Hub Operations. 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, Hub Operations 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 Chair of CTAG who may refer the case to an Adjudication Panel (Section 7).

If a patient waits over a month on the Super-Urgent list, the centre must submit a *Super-Urgent/Urgent Lung Recipient Monthly Update Form* (**FRM5770**) to ODT Hub Information Services by emailing nhsbt.supplementary.allforms@nhs.net. This should occur for every month a patient waits on the list.

If a patient has been suspended from the SULAS waiting list for more than 14 days, the centre should remove the patient from the super-urgent lung list. If the patient needs to be re-activated on the SULAS waiting list after 14 days, a new registration form must be submitted and they will not retain any waiting time from their previous super-urgent registration.

6.4. Patients Requiring Heart-Lung Transplantation

This subject is covered in the **POL229**: Heart Selection Policy (https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/). Importantly, any request for urgent heart-lung transplantation needs to be referred to the CTAG Lung Adjudication Panel (Section 7).

6.5. Patients Requiring Combined Lung and Liver Transplantation

A patient can be registered on either the ULAS or NULAS while also registered to receive a liver, but not the SULAS. Patients should be assessed for both organs by the relevant mulit-disciplinary teams (MDT) and should meet minimal listing criteria for both organs. If they do not meet minimal listing criteria for either organ, the patient should be referred to the relevant Adjudication Panel(s) for approval before listing (see Section 7 and **POL195:** Liver Selection Policy https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/). The decision to urgent list a lung-liver patient who does not meet standard urgent listing criteria should be referred to the CTAG Lung Adjudication Panel (Section 7). Non-urgent registrations should be made via *Heart/Lung Recipient Registration Form (**FRM4847**)* and urgent registrations via the *Super-Urgent/Urgent Lung Recipient Registration Form (**FRM5769**).*The liver registration should be made via the elective liver registration form.

6.6. Patients Requiring Combined Lung and Kidney Transplantation

A patient can be registered on either the ULAS or NULAS while also registered to receive a kidney, but not the SULAS. Patients should be assessed for both organs by the relevant multi-disciplinary teams (MDT). The decision to urgent list a lung-kidney patient who does not meet standard urgent listing criteria should be referred to the CTAG Lung Adjudication Panel (Section 7). Non-urgent registrations should be made via *Heart/Lung Recipient Registration Form (**FRM4847**)* and urgent registrations via the *Super-Urgent/Urgent Lung Recipient Registration Form (**FRM5769**).*The kidney registration should be made via the kidney/pancreas recipient registration form.

7. Adjudication Panel

It is recognised that no system can describe every clinical situation where lung transplantation may be appropriate, and an equitable system must allow for consideration for individual cases in a fair and transparent way. For this reason, a centre may refer individual cases to the CTAG Adjudication Panel.

7.1. Adult Cases

The CTAG Lung Adjudication Panel is made up of the CTAG Chair plus one representative from each of the 6 designated lung transplant centres. The registering centre must provide the panel with relevant details. The patient may be registered if the majority agree on the case for listing but if the panel cannot reach a consensus, the CTAG Chair has the casting vote. A decision will endeavour to be made within 24 hours of receiving the request, however in

complex cases more time may be required. The decisions of the CTAG Lung Adjudication Panel will be presented annually at meetings of the CTAG.

For cases where approval is granted, confirmation of approval by the CTAG Lung Adjudication Panel must be sent to Hub Operations via email at the same time as the *Super-Urgent/Urgent Heart Recipient Registration Form (**FRM5769)***. Such patients will not be registered until the confirmation documentation is received and the registering centre must immediately call Hub Operations to clarify that the information has been sent. Confirmation documentation should be sent either by email to: odthub.operations@nhsbt.nhs.uk and odthuboperations.shiftmanagers@nhsbt.nhs.uk.

7.2. Paediatric Cases

For paediatric patients, the case must be referred not to the CTAG Lung Adjudication Panel but to the CTAG Chair and a representative from the other paediatric centres for approval. A decision will be made within 24 hours of case referral, however in complex cases more time may be required. Again, for cases where approval is granted, confirmation of approval by the panel must be sent to Hub Operations via email at the same time as the *Super-Urgent/Urgent Lung Recipient Registration Form (**FRM5769)***. Such patients will not be registered until the confirmation documentation is received and the registering centre must immediately call Hub Operations to clarify that the information has been sent. Confirmation documentation should be sent either by email to: odthub.operations@nhsbt.nhs.uk and odthuboperations.shiftmanagers@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 Lung Registration

A centre can make a request for super-urgent listing of any patient (Adult, Small Adult or Paediatric) outside Category 91 in Table 5 to the relevant Adjudication Panel.

7.3.2. Urgent Lung Registration

A centre can make a request for urgent listing of any patient (Adult, Small Adult or Paediatric) outside the criteria outlined in Table 4 to the relevant Adjudication Panel. This includes patients requiring urgent lung listing with abdominal organs, if the patient does not meet standard urgent lung listing criteria.

7.3.3. Urgent Heart-Lung Registration

All requests for urgent heart-lung listing should be referred to the Lung Adjudication Panel, due to the high priority that these patients are given in the lung allocation sequence (see POL228: Heart Allocation Policy https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/policies-and-guidance/). In exceptional circumstances, a centre may request to list a patient for a super-urgent heart-lung transplant. Such cases need approval from both the Heart and Lung Adjudication Panels.

7.3.4. Disputes Over Existing Patient Registrations

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

8. Contraindications

Not all patients who meet criteria for transplantation are suitable for a variety of reasons. Concurrent extra-pulmonary comorbid medical, mental health and social conditions are relevant to whether to list a patient for transplantation if, despite full supportive therapy, these factors will affect the patient's prospect for

survival post-transplant, quality of life, or likelihood of compliance with medical treatments and clinic follow-up.

In complex cases and where uncertainty remains, discussion between centres to share opinion across the UK is encouraged.

8.1. Absolute Contraindications

- Solid organ and haematological malignancies within 5 years of listing for transplantation with the exception of cutaneous squamous and basal cell tumours and selected paediatric malignancies

- BMI>35 kg/m^2

- Untreatable advanced dysfunction of any other major organ system that may impact the chances of the patient surviving the operative and peri-operative process, and will affect 5-year survival (e.g., heart, liver or kidney), unless considered for a combined multi-organ transplant. This includes coronary artery disease not amenable to percutaneous intervention/bypass grafting or associated with significant impairment of left ventricular function. However, heart-lung transplantation could be considered in highly selected cases where the MDT considers that the patient is appropriate Unstable critical clinical condition (such as active septicaemia, shock, unstable condition on mechanical ventilation or extra-corporeal membrane oxygenation)

- Significant chest wall/spinal deformity impeding adequate surgical access at implantation or preventing optimum ventilation post-operatively

- Uncontrolled extra-pulmonary manifestations of a systemic disease (e.g. vasculitis, oesophageal dysmotility and severe skin involvement with ulceration in systemic sclerosis) that will prevent a successful outcome after transplantation

- Substance addiction or misuse (e.g., tobacco, alcohol or narcotics) that is either currently active or was active within the last 6 months
    - Those who continue to smoke will not be accepted for listing as smoking has many deleterious effects on the peri-operative course of a patient and will reduce lung graft function and survival. Active smokers will be supported to quit and to remain abstinent, with involvement from their GP, the referring respiratory physician and the local smoking cessation services, as appropriate. Those who achieve abstinence should be reassessed and may be listed as clinically indicated. Patients must undertake to continue abstinence after transplantation.
    - Excessive alcohol use and dependency is associated with medical problems and poor compliance. Illicit drug use is also associated with medical complications and non-compliance that affects patient and graft survival. Patients with evidence of alcohol and illicit substance abuse should be assessed by a healthcare professional expert in substance abuse and offered treatment. When treatment goals are achieved, the patient should be re-considered for listing. Those with a high likelihood of return to alcohol or substance abuse, despite support, are not suitable transplant candidates.
    - Patients must be off weaning therapy, such as nicotine replacement, before listing

- Documented non-adherence or inability to comply with medical therapy, outpatient follow up, or both

- Mental health or a psychological condition that fails to respond to treatment and is associated with poor outcomes, poor quality of life or the inability to cooperate or comply with medical therapy

- Absence of consistent or reliable social support that cannot be organised, despite attempts to, that would affect post-transplant survival or quality of life as indicated above

8.2. Relative Contraindications

The importance of potential contraindications should be discussed openly between all members of the transplant team and interpreted with clinical judgement on a case by case basis:

- Patients over 60 years of age will need careful evaluation but age per se is not a contraindication to listing. Age, however, is an independent risk factor for peri-operative morbidity and mortality, and evidence exists that older patients have worse short- and medium-term survival, likely due to comorbidities. The presence of other relative contraindications can combine to increase the risks of transplantation above a safe threshold. Individual cases will be assessed on their merit, but patient age will be a factor in candidate selection. The International Society for Heart and Lung Transplantation proposed a guideline of less than 65 years of age, but this does not obviate the need for assessment of each patient and a decision based on that individual.

- Severely limited functional status with poor rehabilitation potential

- Colonisation with Burkholderia cenocepacia

- Chronic infection with highly resistant virulent bacteria, mycobacteria, fungi or viruses

- Obesity defined as a body mass index (BMI) exceeding 30 kg/m^2

- Malnutrition with BMI less than 17 kg/m^2

- Severe or symptomatic osteoporosis (defined as bone mineral density > 2 SD less than predicted for the patient's age with or without low impact fractures)

- Mechanical ventilation – carefully selected candidates on mechanical ventilation/extracorporeal support without other acute or chronic organ dysfunction, who are able to actively participate in a meaningful rehabilitation program, may be successfully transplanted

- Limited coronary artery disease without ventricular impairment, if the patient is considered for lung transplantation only. Patients with an isolated single vessel coronary artery lesion may undergo percutaneous intervention before transplantation or coronary artery bypass grafting concurrent with the procedure

- Chronic renal impairment with glomerular filtration rate (GFR) <50 ml/min, unless the patient is a candidate for combined lung-renal transplant

- Poorly controlled diabetes mellitus with end organ damage (e.g. nephropathy, neuropathy, proliferative retinopathy)

- Other medical conditions that have not resulted in end organ damage, such as diabetes mellitus, systemic hypertension, active peptic ulcerative disease, gastroesophageal reflux or diverticulitis should be optimally treated before transplantation

- Regular chronic high-dose oral corticosteroids, defined as >15 mg per day

- Very extensive pleural disease, with or without previous thoracic surgery
- A high burden of lung cavities with aspergillomas
- Human immunodeficiency virus (HIV) infection is a relative contraindication to transplantation, and the decision to list will depend on factors such as CD4 count, effectiveness of therapy, history of HIV-related infections and other co-morbidities
- Patients with viral Hepatitis B and C may be considered for transplantation in light of recent advances in treatment and after consideration of the degree of liver and other organ damage.

9. Selection for Re-transplant

Patients requiring re-transplantation will not have access to the Super-Urgent or Urgent Lung Allocation Scheme.

Re-transplants on the NULAS will need special consideration dependent on the circumstances that gave rise to the need for re-transplant, as results after re-transplant are worse than for first transplants (JHLT. 2015 Oct; 34(10): 1264-1277) and only limited benefit may be achieved. Re-transplants are only undertaken when there is evidence of irreversible graft failure and the risk of mortality from that exceeds the significantly increased post-operative mortality after re-transplantation.

NULAS re-transplantation should not be performed within the first 90 days of the initial transplant.

Registrations for second or subsequent NULAS transplants are subject to the same selection criteria for the first transplant: candidates must have minimal contraindications with no other untreatable major organ system dysfunction and must retain good post-operative rehabilitation potential.

10. Follow-up on List and De-listing

All patients will need to be regularly reviewed to ensure they continue to meet the selection criteria and have not improved or become too sick to benefit from transplantation. Patients who are initially assigned non-urgent status can be upgraded on to the urgent list at subsequent reviews should they deteriorate to meet the criteria and the reverse is true. The same principal applies to patients moving up to or down from the super-urgent scheme. When the clinical situation alters such that a patient no longer meets the criteria for any of the three schemes, the patient's name must be removed from the transplant list.

Patients remaining on the transplant list will be re-assessed at intervals by the local respiratory physicians and/or the transplant centre, during their wait for a donor organ match. Suggested management on the waiting list is discussed in **Appendix 2**.

APPENDIX 1

Assessment of patients

Adult Patients
It is essential for the patient's family/carers to be involved in the assessment process. These initial assessment procedures often follow outpatient consultation and are undertaken over several days.
A decision not to recommend transplantation can be made at any stage of the process.
A number of factors are used to inform decisions around the appropriateness of transplantation in each patient context and these must all be made explicit to the patients and their relatives.

Stages of assessment
1 Referral
2 Pre-assessment outpatient clinic when appropriate
3 In-patient assessment where appropriate
4 Listing decision
5 Follow up on the waiting list where appropriate

If the patient is considered suitable and decides to proceed to transplantation, he or she is then registered with NHS Blood & Transplant (NHSBT) and placed on the waiting list. It is the responsibility of the healthcare professional to ensure that the registration details are correct, and they are accountable for the accuracy of the information provided.

If the patient is not deemed suitable and/or declines the option of transplantation, the clinician should explain to the patient and their family the options available to them. The family doctor and referring clinicians should be informed of the outcome of the assessment.

Patients who have not been registered with NHSBT should not be offered an organ. Patients will be placed on the transplant list on the day on which all required details are received by NHSBT. Discrepancies or missing information will be followed up with the local centre and might cause a delay.

Consent process
When a patient is considered a suitable candidate for transplantation, the transplant team will obtain consent for the procedure. NHSBT and the British Transplantation Society have provided advice on consent in **POL191***: Guidelines for consent for solid organ transplantation in adults.*

This process will include:

1. The approved hospital consent form for surgical intervention: listing the nature of the procedure, potential benefits to the patient and frequent or serious complications. It is good practice to supplement the consent with written information.

2. Donor acceptance consent form: candidates should be presented with a list of nationally agreed criteria for organs routinely used for lung transplantation and will be asked to give prior written consent to accept donor organs from these categories. Candidates may choose to decline certain types of donor organs (such as lungs from smokers) after appropriate counselling outlining the consequences of their choice. Their views must be clearly documented and respected.

3. In exceptional circumstances, a donor with criteria and/or associated risks outside the previous consent, may be offered to a potential patient following further discussion. In such cases, the discussions and outcome should be clearly recorded in the hospital notes.

   It is important for a potential transplant patient and their family/carer to be offered full information on donor risks and the procedures relating to donor organ selection. They should be reassured all donors are fully characterised by the Specialist Nurses in Organ Donation, according to local and international guidelines, and assessed very carefully by the Intensive Care Consultants, the retrieval team and the implanting team for suitability for transplant. This process ensures an appropriate balance of risk and benefit for the patient.

Consent, if appropriate and where given, for participation in Research and Development (R&D) Ethics Committee approved clinical studies (local or national).

4. Consent to obtain and store photographic images of candidates for the benefit of the MDT, depending on local practices, where appropriate.

The waiting list
The patient should receive detailed, consistent explanations, and key information pertaining to the waiting period for transplantation, which is recorded in line with standard practice (see **Appendix 2**).

Paediatric patients
Paediatric patients (aged <16 years) undergo a similar assessment process involving a multidisciplinary team approach with full family involvement. Patients will undergo most of the investigations and assessments listed in the adult section, but they will not usually be seen in a pre-assessment clinic.

Suggested process for assessment of patients for lung transplantation

General guidelines for lung transplantation referral
In general, referral for transplant assessment is advisable when patients have a <50% 2-year predicted survival in the absence of transplantation or they persist in New York Heart Association (NYHA) class III or IV level of function despite maximal medical therapy, or both. When a patient is accepted, survival to transplantation depends on the waiting time governed by donor lung availability and the underlying disease. Waiting time tends to be variable and based on many factors such as height and blood group. The overriding principle in allocating a compatible organ to a patient is based on clinical need, benefit, utility, transparency and avoidance of futility.

Appropriate and timely referral for consideration of transplant is essential. It allows an orderly process of assessment, the management of areas of concern to optimise the candidate's condition, and patient education before active listing. An experienced multidisciplinary team, attending to the details of the underlying disease and any associated comorbidities, can lead to improved patient outcomes regardless of whether the patient receives a transplant. It is important to stress that the decision to refer should not be based on a single factor, because no simple, single-point determinant is sufficiently predictive of early mortality. Rather, it is recommended to rely on a variety of clinical (e.g., rate of infection, ICU hospitalisation, oxygen need, weight loss), laboratory (e.g. PaO2 and PaCO2) and functional findings (e.g. pulmonary function tests, echocardiography, exercise capacity).

Pre-assessment outpatient clinic
Most new referrals for consideration of suitability for lung transplant assessment require a pre-assessment outpatient clinic consultation conducted in the transplant centre or agreed satellite clinics. The pre-assessment outpatient clinic appointment should be offered within three months of referral unless the patient is clearly unsuitable, on account of documented clear contraindications, and a consultant physician or surgeon has made this decision. Every effort will be made to run these unsuitable cases by the local transplant MDT to ratify this decision. The decision not to offer this appointment should be communicated promptly in writing to the referral source. The purpose of this pre-assessment consultation is attention to detail and the avoidance of extensive inpatient investigations if the patient is clearly unsuitable for transplantation at initial clinic review.

Inpatient assessment
Potential transplant candidates usually undergo initial investigations in their local hospital. The results of investigations are requested from the referring hospital, but some lung transplant centres also opt to admit such patients for detailed assessment over a 2–4-day period. During their admission patients will undergo repeated investigations depending on their primary disease and individual need. At all stages of the assessment, the patient and family are offered opportunities to meet as many members of the transplant MDT as appropriate and are encouraged to ask questions and engage in all discussions.

Objectives of assessment procedures

- To assess the patient's clinical, social and psychological suitability as a transplant patient the transplant MDT must reach the conclusion that the general condition of the patient is such that lung transplantation allows the patient a realistic chance of increased survival and a good quality of life
- To impart factual information to the patient and his/her family concerning all aspects of transplantation. Patients will need to be given extensive information about the reason for their assessment for transplantation, the risks associated with the transplant procedure and post-operative immunosuppression, as well as the perceived benefits in their clinical context both in terms of survival gains and quality of life improvements. This information must be in an easily understandable format commensurate with their ability to assimilate and understand the information given
- To meet hospital staff and transplant patients
- To provide an opportunity for the patient, and his or her family, to begin to come to terms with the prospect of transplantation and its subsequent management

Investigations conducted

The multidisciplinary team

The importance of multidisciplinary involvement in the assessment of the patient and the care received is paramount. The assessment should involve a whole spectrum of healthcare professionals where everyone has a key role to play including:

- Respiratory physicians
- Cardiologists
- Cardiothoracic surgeons
- Anaesthetists
- Radiologists
- Microbiologists
- Transplant co-ordinators
- Transplant nurses
- Dieticians
- Physiotherapists
- Occupational therapists
- Social workers
- Psychologists (if indicated, psychiatrists)
- Pharmacists
- Histocompatibility & Immunogenetics (H&I) Scientists

Clinical assessment

Potential candidates are put through a full history and examination which may include the following:

Past/Concurrent History

- Unresolved pulmonary infarction/infection or consolidation
- Cardiac condition: cause, previous cardiac surgery and current therapy
- Peripheral or cerebrovascular disease
- Malignancy
- Diabetes mellitus
- Hypertension
- Renal disease
- Liver disease
- Gastro-oesophageal reflux, peptic ulceration, gastrointestinal (GI) bleeding
- Diverticular disease, GI sepsis
- Unresolved sepsis in any site
- Metabolic bone disease, previous fractures
- Herpes virus infection (active or past)
- Past surgical history
- Previous blood transfusion

Social history

- Social support network
- Housing
- Employment
- Social care benefits received
- Smoking, past and current
- Drugs/alcohol use

Routine observations
- Temperature
- Heart rate
- Blood pressure
- Height
- Weight and nutritional status

Pulmonary assessment
- Detailed lung function test including flow volume loop, lung volumes, gas diffusion and plethesmography
- 6-minute walk test with oximetry
- Arterial blood gases
- Respiratory muscle function tests

Cardiac function assessment
- Electrocardiography (ECG)
- Transthoracic echocardiography (occasionally transoesophageal)

Additionally, patients may undergo any or a combination of the following tests as per local protocols:
- Ejection fraction assessment by locally validated nuclear cardiology technique
- Cardiac catheterisation: coronary angiogram and left ventricular (LV) gram
- Right heart catheter
- Cardiac computerised tomography (CT)
- Cardiac magnetic resonance imaging (MRI)

Microbiology assessment
- Sputum culture and sensitivity
- Midstream specimen of urine (MSU) for urinalysis, Culture Sensitivity
- Nose swab
- Methicillin-resistant staphylococcus aureus (MRSA) screen

Radiology
- Chest x-ray
- Thoracic CT scan
- Ventilation/perfusion scan in single lung transplant candidates
- Abdominal Ultrasound Scan
- Dual-energy X-ray absorptiometry (DEXA) bone density scan

Dental assessment
- Full dental examination including orthopantomogram (OPG)
- Advice on dental hygiene
- Restorative work and extractions as necessary

Haematology blood tests
- Blood group
- Antibody screen
- Full blood count
- APTT
- PT, INR

- Fibrinogen

Biochemistry blood tests
- Urea and electrolytes
- Creatinine
- Uric acid
- Calcium phosphate
- Liver function tests
- Thyroid function tests
- Fasting blood glucose
- Fasting blood lipids
- Alpha 1- antitrypsin (if indicated)

Serology blood tests
- HIV
- Hepatitis B and C
- Syphilis
- Rubella
- Toxoplasma
- Epstein Barr Virus
- Varicella-Zoster
- Herpes simplex
- Cytomegalovirus

Immunology blood tests
- Auto-immune screen
- Aspergillus serology
- Human leucocyte antigen (HLA) typing and antibody screen

Psychosocial assessment
- Letter from GP confirming compliance with past therapy
- Interview with social worker/psychologist

If there is a history of prior psychiatric disease, the advice of a psychiatric team, preferably the patient's own team, should be sought to assess the potential impact of such diagnoses on compliance and outcomes.

Other
- Creatinine clearance or GFR (radio-isotope clearance, according to local practice)
- Dietician review
- Physiotherapy assessment

Final decision
The decision to place a patient on the waiting list is discussed, agreed and documented at a multi-disciplinary meeting as soon as the results of the inpatient assessment become available. A shared MDT decision card is being developed between the five adult lung transplant centres. This will capture the decision to accept or decline a patient to the lung waiting list and the category to which they are accepted, setting out the criteria used by the local MDT to assign super-urgent vs. urgent vs. elective status to a candidate and any deviations or variations from these criteria (see **POL230***: Donor Lung Distribution and Allocation Policy)*.

The patient and relatives will be informed of the outcome and given the opportunity to discuss it with a representative of the transplant team. A number of factors are used to inform decisions around the appropriateness of transplantation in each patient context and these must all be made explicit to the patients. Such discussions should always be undertaken in a private area.

APPENDIX 2

Suggested management on the waiting list

At all stages the patient is encouraged to ask questions. The following key areas must be discussed with the patient as appropriate:

- Reliable contact numbers for the patient and next of kin (a combination of landlines and mobile phone numbers is preferable)
- The patient's responsibility to make him/herself available to be contacted by the transplant centre at any time. This is discussed with the transplant co-ordinator
- Patients are requested to inform the transplant centre of any changes in their circumstances, for example:
  - If they become unwell
  - If they are admitted to hospital
  - Any changes in medication
  - Holidays

An information booklet should be provided to the patient. This will explain:

- Preparation for admission for surgery
- Maintenance of regular contact
- Reporting changes in circumstances
- What to do when called for surgery
- The operation
- Wards and departments after the operation
- Accommodation for partners
- Publicity and the media

During the waiting period the transplant centre will maintain contact with the patient and his/her family to offer support, information and guidance according to their needs. Patients on the waiting list will be reviewed as clinically indicated.