

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

<b>Service Specification No.</b>	A10/S(HSS)/b
<b>Service</b>	Lung transplantation service (Adults)
<b>Commissioner Lead</b>	
<b>Provider Lead</b>	
<b>Period</b>	
<b>Date of Review</b>	

#### 1. Population Needs

##### 1.1 National/local context and evidence base

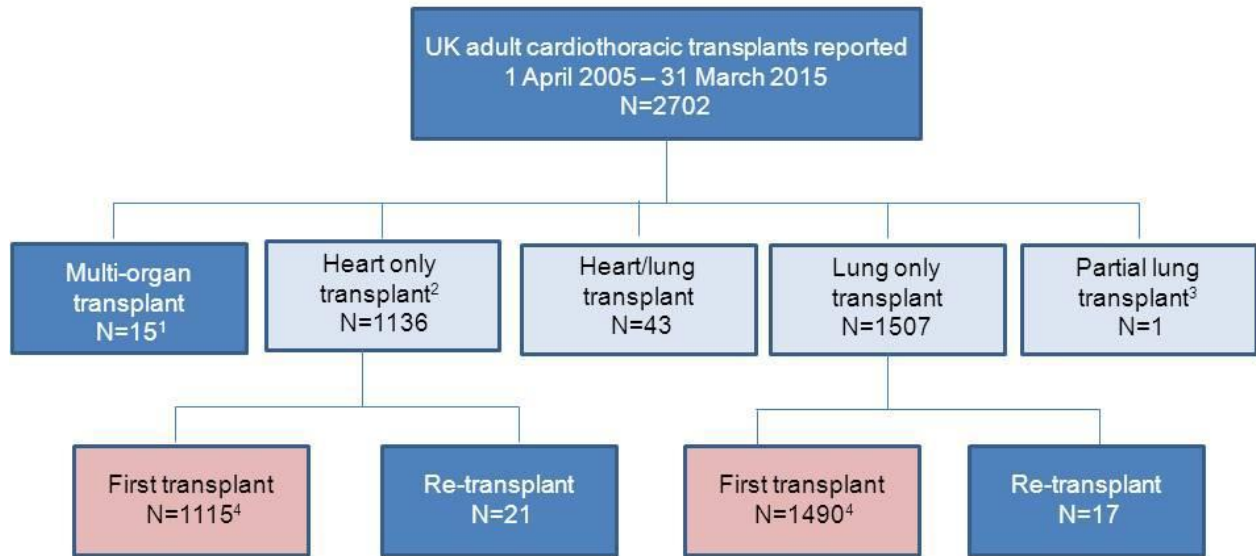
Lung transplantation is an established treatment for irreversible lung failure. It offers carefully selected individuals improvement in survival and quality of life. Clinical outcomes are monitored within the UK and as part of the International Society for Heart and Lung Transplantation.

##### Needs

The demand for lung transplant outstrips the supply of available organs. The Organ Donation Taskforce (2007-2012) implemented a number of recommendations intended to increase the overall number of actual donors by 2012-13. The number of deceased non-heart beating donors (donors after circulatory death, DCD) has increased significantly. The number of adult lung transplants performed in the UK has increased modestly over the last 5 years, but despite this the number of patients who remain on the waiting list has not fallen, Approximately 40% of those listed will either die on the waiting list or be removed due to worsening clinical status.

Technology improvements in organ reperfusion (*ex vivo* lung perfusion, EVLP) permit donated lungs with suboptimal gas exchange to be reconditioned. This has the potential to increase the number of lungs donated from deceased heart beating and non-heart beating donors, and thereby the perceived likelihood of lung availability.

**Adult cardiothoracic organ transplants performed in the UK, 1 April 2005 to 31 March 2015**



<sup>1</sup> Includes 11 heart and kidney transplants (1 of which was a retransplant), 1 lung and kidney and 3 lung and liver

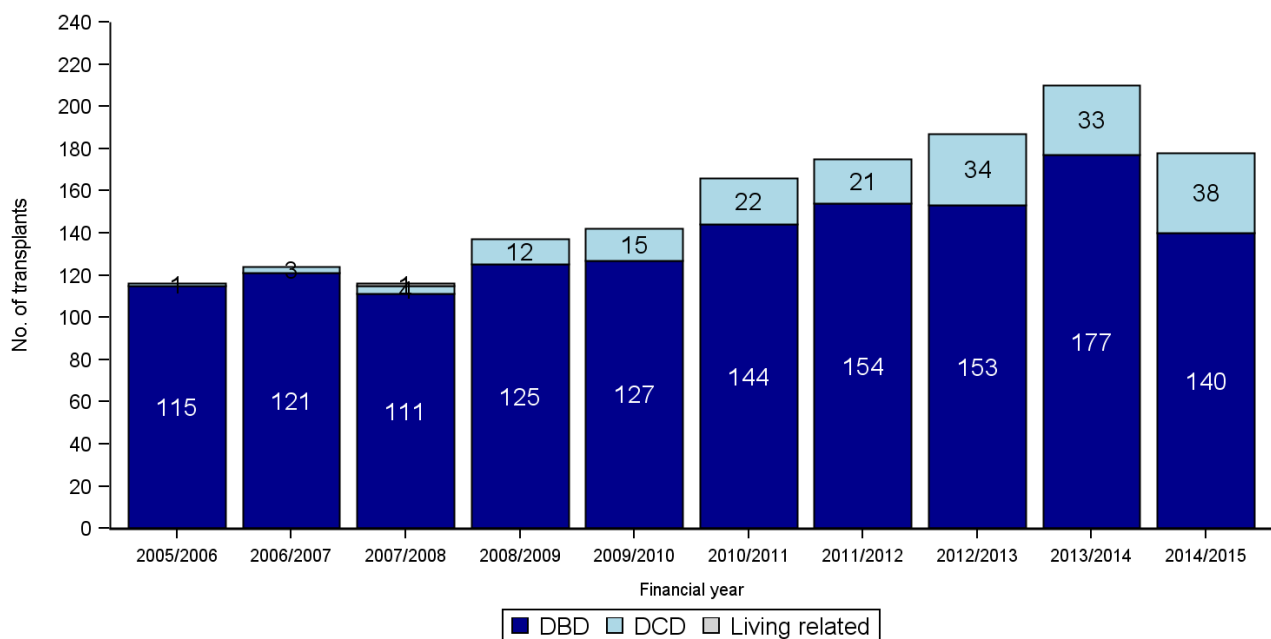
<sup>2</sup> Includes 3 domino donor transplants and 1 DCD heart transplant

<sup>3</sup> Includes 1 partial lung transplant from a living donor

<sup>4</sup> Survival sections are split into 1 April 2010 to 31 March 2014 for 30 day (heart) and 90 day post-transplant survival (lung)  
1 April 2006 to 31 March 2010 for 1 year and 5 year survival

**Number of transplants including adult lung transplants in the UK, by financial year, 1 April 2005 to 31 March 2015**

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## Organ availability

NHS England does not commission organ retrieval. Organ retrieval and allocation is the responsibility for NHS Blood and Transplant (NHS BT). NHS BT has produced a strategy which NHS England has signed up to achieving. The strategy "Taking Organ Transplantation to 2020" contains a series of recommendations which aim to enable the UK to match world-class performance in organ donation and transplantation. This means aiming for consent/authorisation rate above 80% from 57%, for 26 deceased donors per million population (pmp) from currently 19.1 pmp and a deceased donor transplant rate of 74 pmp from 49 pmp. For lungs this would mean increasing transplants from DBD donors to 35% from 30% and from DCD donors to 12% from 7%.

Individual cardio-thoracic transplant centres match organs offered by NHS BT to candidates on the waiting list. Centres must be able to respond without delay. Organ donation is inherently unpredictable in nature meaning that individual centres will have fluctuating levels of activity in response to organ availability.

This service aims to transplant all available lungs that are matched to a recipient on the waiting list. Despite this, a significant proportion of patients listed for lung transplantation will not be transplanted.

## Objectives and Expected Outcomes

The service provides assessment, treatment and life-long follow up for adults (16+) who need lung transplantation.

All centres use real time sequential monitoring of 30 day and 90 day mortality rates following lung transplantation. This monitoring is conducted independently by NHS Blood & Transplant.

Centres are monitored in real time using a CUSUM score on the basis of 90 day mortality. Pre-determined triggers are included in the algorithm and reported to the Cardio-Thoracic Advisory group (CTAG).

In addition to monitoring of mortality rates, the efficiency of the assessment pathway assessed by monitoring of the time from referral to first decision (eligibility for the transplant waiting list) to ensure achievement of the 18 weeks target.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

<b>Domain 1</b>	<b>Preventing people from dying prematurely</b>	✓
<b>Domain 2</b>	<b>Enhancing quality of life for people with long-term conditions</b>	✓
<b>Domain 3</b>	<b>Helping people to recover from episodes of ill-health or following injury</b>	✓
<b>Domain 4</b>	<b>Ensuring people have a positive experience of care</b>	✓
<b>Domain 5</b>	<b>Treating and caring for people in safe environment and protecting them from avoidable harm</b>	✓

#### **Domain 1: Preventing People from Dying Prematurely**

*Reducing premature mortality from the major causes of death:* reviewing survival figures on an annual basis on a whole service basis with international comparisons and on an individual centre basis.

#### **Domain 2: Enhancing Quality of Life for People with Long Term Conditions**

*Improving functional performance in people with long term conditions:* reviewing change in functional performance post transplantation and assessing proportion of patients who are well enough to return to work.

Report length of time spent on waiting list.

#### **Domain 3: Helping People to Recover from Episodes of Ill Health or Following Injury**

*Reducing the time from referral to diagnosis and streamlining the patient pathway:* reviewing delay from receipt of adequate dataset (generally completed transplant proforma) to initial consultation, and delay from receipt of adequate dataset (generally completed transplant proforma) to listing decision.

Report the number of patients receiving an annual review at transplant centre.

#### **Domain 4: Ensuring that People have a Positive Experience of Care**

*Improving people's experience of outpatient care*: assessment of patient feedback by regular audit using agreed tool. Annual audit.

### **Domain 5: Treating and Caring for People in a Safe Environment and Protecting them from Avoidable Harm**

*Reducing the incidence of avoidable harm*: assessment of incidence of hospital related venous thromboembolism (VTE), and assessment of incidence of healthcare associated infection (HCAI)

## **3. Scope**

### **3.1 Aims and objectives of service**

The aim of the service is to deliver high quality and consistent care of patients with advanced lung disease by providing access to lung transplantation, and so improving mortality, functional capacity, quality and length of life.

The service will deliver these aims for adults with advanced lung disease by:

- undertaking timely assessment of suitability of patients for lung transplantation
- registration of appropriate patients with UK transplant authority
- delivery of lung transplantation including
- provision of post-transplantation follow-up
- providing patient-centred care with appropriate support for patients and their families
- supporting care closer to the patient's home by delivering care through shared care centres and outreach clinics
- ensuring effective communication with patients, their families and carers, as well as with referring clinicians and other services
- ensuring smooth and managed transition between services, including shared care centres and providers of specialist respiratory care (CF, pulmonary hypertension).

### **3.2 Service description/care pathway**

The service is responsive to the availability of organs and recipients, and is able to operate 24 hours per days, every day of the year.

The service provides lung transplant assessment, surgery and life-long follow up for adults (16+).

A standard episode of care will include:

- pre-transplant assessment, immunology and tissue-typing of recipient
- transplantation
- routine life-long follow-up in outpatients for transplant related condition, including re-admission if necessary
- Assessment and treatment of long term complications of immunosuppression in particular Hypertension, Diabetes, Renal disease and Malignancy.

The service must be delivered in accord with the latest NHS England service standards. The provider will work with the NHS England to ensure sufficient considerations are given to communications.

### **1. Pre-transplant assessment**

The service follows the *National Protocol for Assessment of Cardiothoracic Transplant Patients and the National PEER Review Standards*. A summary is given below:

- Multi-disciplinary involvement: The assessment should involve a whole spectrum of healthcare professionals, including physicians, surgeons, radiologists, nurses, transplant co-ordinators, pharmacists, occupational therapists, dieticians, physiotherapists, social workers, psychologists (if indicated psychiatrists) and anaesthetists.
  - Assessment stages:
    - Receipt of completed National Assessment Proforma plus referral letter
    - Pre-assessment outpatient clinic when appropriate
    - In patient assessment
    - Decision
    - Waiting List
  - To ensure prompt and most appropriate utilisation of resources, referrals are expected to be made by specialist units where such units exist (Cystic Fibrosis, Pulmonary Hypertension, Interstitial Lung Disease)
- ### **2. Objectives of assessment procedures:**
- To assess the patient's clinical, social and psychological suitability as a transplant recipient
  - To start the education of the patient and their family concerning all aspects of transplantation
  - Detailed explanation of the risks and benefits of transplantation including donor choices
  - 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 to be informed about the procedure and its aftercare
  - To ascertain that the general condition of the patient is such that transplantation of the lungs allows the patient a realistic chance of a prolonged and good quality of life.
- ### **3. Assessment outcome:**
- If the patient is offered listing and decides to go forward for transplantation, he or she is then registered with NHS BT and placed on the waiting list.
  - If the patient is not deemed suitable and/or declines the option of transplantation the clinician explains to the patient and their family the options available to them.
  - The GP and referring clinicians are informed of the outcome of the assessment
- ### **4. Surveillance of patients on the waiting list**
- This Service Specification does not cover clinical care received by the patient whilst waiting for a suitable organ to become available
  - Independent of any clinical care required, patients should continue to be reviewed regularly

by the transplant centre to assess urgency and confirm on-going suitability for transplantation; if this is not practical, the referrer should provide regular clinical updates to the transplant centre

## **5. Waiting times**

- Waiting times are influenced by several factors including by patient's height, blood group, antibody status and primary diagnosis.

## **6. Admission**

- It is the patient's responsibility to make themselves available to be contacted by the transplant centre at anytime.
- Once an available organ has been matched to a recipient:
  - The relevant centres should respond to the offer within one hour
  - The patient is alerted and asked to make their way to the transplant centre.
- Every effort should be taken to minimise the occasions on which a patient is admitted but a transplant operation does not proceed because:
  - The patient is not medically fit
  - The necessary clinical resources (e.g. staff, operating theatres) are unavailable.
  - The patient chooses not to go ahead

## **7. Transplantation.**

- Centres should provide assurance that individual surgeons are working at safe and sustainable levels, avoiding risks associated with excessive hours and with occasional practice (national standards from the peer review)
- Mechanical support of the graft post-transplant.

## **8. Initial follow-up**

- There should be arrangements for direct 24 hour emergency access after discharge.
- Patients are offered life-long follow up at a centre of their choice.

## **9. Long-term follow-up**

- Subsequent follow-up will be on a defined frequency (not less than annually) Routine follow-up is intended to identify and manage any emerging problems of graft function:
  - Shared care arrangement may be developed for routine investigations which may be administered away from the specialist centre.
- Each centre should ensure that patients are offered a choice of transplant centre at which to receive routine follow-up care, and this will be important to review if a patient changes their home address. Where patients change centre, the funding for post transplant follow up will move with the patient.
- NHS England commissions the supply of post-transplant immunosuppressants from the transplant centre. (Homecare arrangements)
- Consideration needs to be given to the availability of generic immunosuppressants and the importance of maintaining consistent supply of the same "brand". Hence, immunosuppressants (both the innovator brand and branded generics) will be prescribed by brand and referred to by that brand in all correspondence (see Medicines and Health products Regulatory Agency guidance).

## **10. Transition**

- Patients transition from child to adult services between 16 and 18 years of age, when considered appropriate by the patient, family and clinical team.
- Transition from child to adult lung transplant will occur in a staged fashion, with the timing and pace to be tailored to the needs of each individual patient.
- Each centre must have a transition policy in keeping with the national peer review standards.

## **11. Pregnancy**

- Pregnancy following lung transplantation is not uncommon in younger lung transplant recipients
- Such patients require assessment and/or management from highly specialist tertiary maternity care delivered within a dedicated multi-disciplinary service staffed by a maternal medicine specialist, a physician, and supporting multi-disciplinary team with extensive experience of managing the condition in pregnancy.
- In view of this, nationally commissioned condition-specific services must have outreach arrangements with highly specialised tertiary maternity units with access to appropriate tertiary medical, surgical, fetal medicine, clinical genetics and level 3 Neonatal Intensive Care services. These specialised maternity services must have a critical mass of activity to maintain expertise, ensure best practice, training opportunities and for the organisational infrastructure, staffing, facilities and equipment to be clinically and economically efficient. They should have robust risk management and performance monitoring processes.
- All such women must receive personalised pre-pregnancy and maternity care planning from specialised tertiary maternity services to allow optimal management in the context of the pregnancy. This will reduce avoidable morbidity, mortality and unnecessary intervention for mother and baby.
- All such women must be referred immediately once they are pregnant to plan their care. This must include access to termination of pregnancy and specialist advice re contraception. The individualised care plan must cover the ante natal, intrapartum and postnatal periods. It must include clear instructions for shared care with secondary services, when appropriate including escalation and transfer protocols and clear guidelines for planned and emergency delivery.

## **12. Palliative care**

- Patients and their carers will receive a palliative approach whenever appropriate during their journey through the lung transplant pathway, involving symptom control, psychological, social and spiritual support, and where necessary, referral to specialists in palliative care.

## **13. Risk Management**

- Service providers are responsible for managing the logistical arrangements for on-call teams, clinical resources, and recipient coordination. Centres must work towards a minimum of 5 consultant surgeons capable of undertaking lung transplantation, and must have a sufficient number to publish a robust on-call rota.
- Adequate physician time needs to be allocated to the care of transplant patients. For centres performing up to 30 transplant per year a minimum of 2 WTE physicians are



recommended. For centres performing upto 50 transplants per year a minimum of 3 WTE are recommended. The staff and facilities covered by the baseline investment for lung transplantation should not be used to cross-subsidise local services.

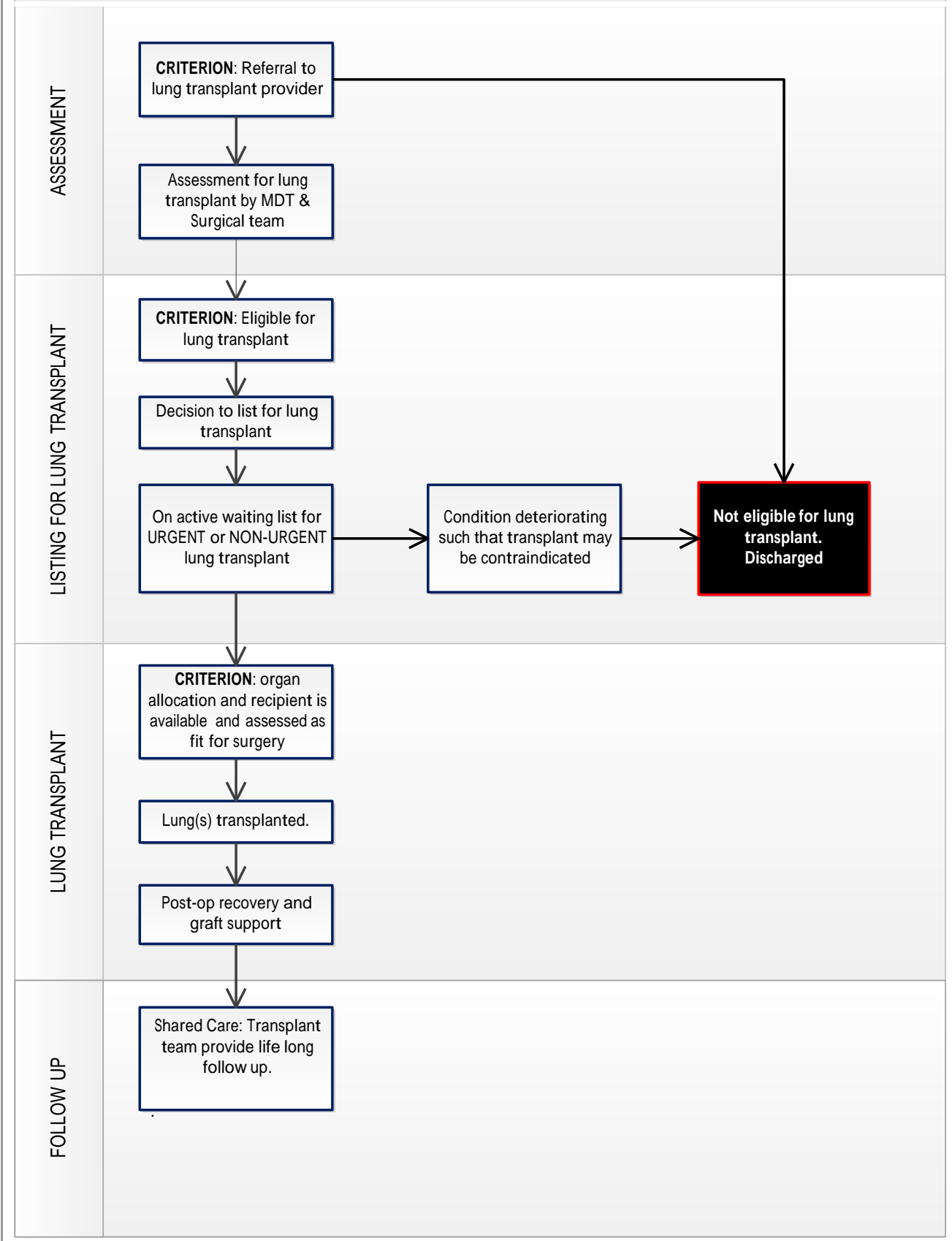
- When surgical teams treat patients who have, or are at risk of having transmissible spongiform encephalopathies (including variant Creutzfeld-Jakob disease, vCJD), there is a risk of contaminating the instruments used during their surgery and hence transmitting the infection to subsequent patients in whom the same instruments are used. Special decontamination measures are required by Department of Health policy. Some instruments cannot be fully decontaminated, in which case policy requires destruction of the instrument. The full guidance is set out at. Patients with or at risk of vCJD present to all parts of the NHS and the same precautions are needed. Hence costs of treating patients with this condition, including destruction of surgical instruments where necessary, are included in average costs.
- This service specification does not limit the pharmacological treatment options available with regard to transplant care, provided they are met within the existing level of investment. This includes desensitisation due to graft-recipient mismatch.
- All providers offering a service to patients under 18 years of age should ensure they are compliant with the requirements to safeguard children, and follow current guidance on obtaining consent from children.

#### **14. Discharge planning**

Patients may be removed from the waiting list if their clinical status has changed and transplantation is no longer the appropriate treatment. Patients may also be removed from the waiting list if they no longer wish to be considered for transplantation. The clinician would explain to the patient and their family the options available to them. The GP and referring clinicians would be informed.

The management of the patient's immunosuppression should be directed by the transplant physician. This will include a regular review of their immunosuppressive therapy which will be tailored to prolong the life of their transplant whilst minimising the risk of drug related side effects.

# LUNG TRANSPLANT PATHWAY



### **3.3 Population covered**

NHS England commissions the service for the population of England. Commissioning on behalf of other devolved administrations is reviewed annually.

NHS England contract includes provision for the service to treat eligible overseas patients under S2 [Under EU regulations, patients can be referred for state funded treatment to another European Economic Area (EEA) member state or Switzerland, under the form S2 (for EU member states) or the form E112 (for Iceland, Norway, Liechtenstein and Switzerland)] referral arrangements. Providers are reimbursed for appropriately referred and recorded activity as part of NHS England contract.

Trusts performing procedures on EU-based patients outside of S2 arrangements will need to continue to make the financial arrangements directly with the governments involved, separately from their contract with NHS England.

### **3.4 Any acceptance and exclusion criteria and thresholds**

All centres must be able to respond to the offer of a suitable organ within agreed protocols.

#### **Acceptance criteria**

See the UK Guidelines for Lung Transplantation Referral (available via NHS BT)

The Provider has a duty to co-operate with the commissioner in undertaking Equality Impact Assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation

All patients must be biologically fit, regardless of age. In practice, most recipients are less than 60 years of age as there is an increase in co-morbidity with the ageing process.

An audit of geographical access will be completed no less than once per year.

#### **Exclusion criteria**

See the UK Guidelines for Lung Transplantation Referral (available via NHSBT).

Patients aged 16 or older may be accepted by the adult lung transplantation service.

Post transplant patients over the age of 16 may have responsibility for their care transferred from child to adult lung transplantation providers.

### **3.5 Interdependencies with other services/providers**

The Cardiothoracic Transplant Advisory Group in NHS Blood and Transplant provides a forum for clinical innovation to be championed, as well as advising on the standards applied across all centres.

Lung transplant is an intervention for irreversible end stage lung failure. The national service has interdependencies with cardiothoracic services, as well as other solid organ transplant services

(multi-organ transplantation). The increasing number of lung transplant survivors creates interdependencies between the adult and child programmes for life-long follow-up.

Patient and survivor groups include:

- British Lung Foundation
- Cystic Fibrosis Trust
- IPF foundation
- Alpha 1 Alliance
- Patient groups at each hospital

Ventricular Assist Devices (VADs) as a bridge to heart transplantation or myocardial recovery (All Ages) services are described in a separate service specification published on the NHS England website.

## **4. Applicable Service Standards**

### **4.1 Applicable national standards e.g. NICE**

- All providers will meet standard NHS governance requirements.
- All providers will comply with transplantation guidance and policies as agreed by the NHS Blood and Transplant Cardiothoracic Transplant Advisory Group.
- There is a requirement to hold national audit meetings involving all designated centres on an annual basis.
- HTA licencing.
- Participation in the National Transplant PEER Review audit process

Each centre must assure that:-

1. All practitioners participate in continuous professional development and networking
2. Patient outcome data is recorded and audited across the service
3. All centres must participate in the national audit commissioned by NHS England. Audit meetings should address:
  - Clinical performance and outcome
  - Process-related indicators e.g. efficiency of the assessment process, prescribing policy, bed provision and occupancy, outpatient follow-up.
  - Stakeholder satisfaction, including feedback from patients, their families, referring clinician and General Practitioners doctors and GPs.
4. Clinical teams are expected to participate actively in clinical networks to improve the national lung transplantation service

5. The National Institute for Health and Clinical Excellence (NICE) has issued full guidance regarding living donor lung transplantation for end-stage lung disease (IPG70).

#### **4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)**

There are no current guidelines related to lung transplantation published by the British Royal colleges.

Relevant National and International Guidelines on lung transplantation are:

1. UK Guidelines for Lung Transplantation Referral (available via NHSBT).
2. International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update—A Consensus Report from the ISHLT Pulmonary Scientific Council (Consensus Document) (J Heart Lung Transplant 2006;25(7):745-755)
3. A Review of Lung Transplant Donor Acceptability Criteria (Consensus Document) (J Heart Lung Transplant 2003;22(11):1183-1200)

### **5. Applicable quality requirements and CQUIN goals**

#### **5.1 Applicable quality requirements (See Schedule 4 Parts A-D)**

#### **5.2 Applicable CQUIN goals (See Schedule 4 Part E)**

To be agreed with the Commissioner.

### **6. Location of Provider Premises**

#### **The Provider's Premises are located at:**

The following five centres are designated to provide lung transplantation services for adults.

- Royal Brompton & Harefield NHS Foundation Trust (Harefield Hospital)
- Papworth Hospital NHS Foundation Trust
- The Newcastle upon Tyne Hospitals NHS Foundation Trust (Freeman Hospital)
- University Hospital of South Manchester NHS Foundation Trust (Wythenshawe Hospital)
- University Hospitals Birmingham NHS Foundation Trust (Queen Elizabeth Hospital Birmingham)

### **7. Individual Service User Placement**

Not applicable

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## Appendix Two

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
<b>Domain 1: Preventing people dying prematurely</b>			
Lung transplant (adults) <ul style="list-style-type: none"> <li>30-day mortality</li> </ul>	CUSUM trigger	CUSUM analysis by NHS BT	Agreed escalation process for CUSUM triggers
<b>Domain 2: Enhancing the quality of life of people with long-term conditions</b>			
Length of wait on waiting list	In line with lung availability	Waiting list analysis NHS Blood and Transplant report every 6 months	To be addressed in annual service audit meeting
<b>Domain 3: Helping people to recover from episodes of ill-health or following injury</b>			
Proportion of patients receiving annual review at transplant centre	80%	Trust data	To be addressed in annual service audit meeting
<b>Domain 4: Ensuring that people have a positive experience of care</b>			
Yearly audit of patient experience questionnaire	Significant decline on previous year	Trust survey	To be addressed in annual service audit meeting
<b>Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm</b>			
SUI and never events	Zero	STEIS	Root cause analysis