

A18/S(HSS)/a

**2013/14 NHS STANDARD CONTRACT FOR
HEART AND LUNG TRANSPLANTATION SERVICE (ALL AGES)**

**PARTICULARS, SCHEDULE 2 – THE SERVICES, A –SERVICE
SPECIFICATIONS**

Service Specification No.	A18/S(HSS)/a
Service	Heart and Lung Transplantation Service (All Ages)
Commissioner Lead	
Provider Lead	
Period	12 months
Review	

1. Population Needs

1.1 National/local context and evidence base

Cardiothoracic transplantation is an established treatment for acute irreversible heart and/or lung failure. Clinical outcomes are monitored within the UK and as part of the International Society for Heart and Lung Transplantation. There are also active links to international colleagues, such as the US Pediatric Heart Transplant Study Group.

2. Scope

2.1 Aims and objectives of service

Aims

This specification describes the national cardiothoracic transplantation service for adults (16+) commissioned by NHS England.

The cardiothoracic transplantation service includes:

- Assessment of suitability of patients for transplantation
- Registration of appropriate patients with UK transplant authority
- Heart and/or lung transplantation including
 - pre-operative assessment,
 - hospital based care,
 - post-transplantation follow-up
 - long term follow up.

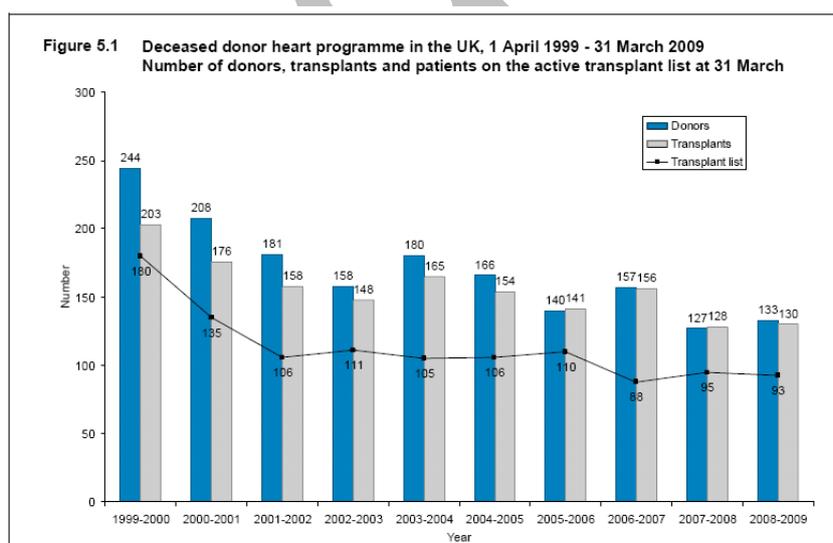
NHS England commissions the first three months of post transplant immunosuppression drugs and other associated drugs. Thereafter the financial responsibility for drugs is with the patient's Clinical Commissioning Group if the patient is resident in England or the relevant commissioner for patients resident elsewhere in the UK.

Needs

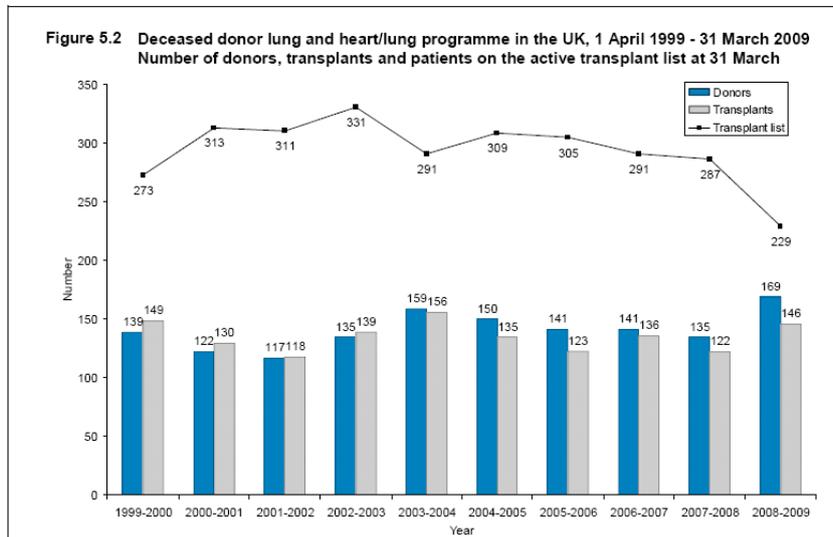
The demand for heart and lung transplant outstrips the supply of available organs. The Organ Donation Taskforce (2007-2012) implemented a number of recommendations intended to increase the overall number of actual donors by 2012-13. It is likely that the number of deceased non-heart beating donors (donors after circulatory death, DCD) will increase significantly, but that the number of deceased donors suitable to donate hearts and/or lungs (donors after brainstem death, DBD) is unlikely to change.

Patients are listed for heart transplant if it is believed there is a reasonable likelihood of a matched donor heart becoming available. Patients are categorised as urgent or non-urgent. The development of Ventricular Assist Devices has enabled some people with end stage heart failure to survive long enough for a suitable donor heart to be identified. This evolving technology has influenced the perceived likelihood of heart availability, and thereby has the potential to impact the overall level of demand for heart transplantation.

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.



From NHS Blood & Transplant Annual Report 2008-09, p26



From NHS Blood & Transplant Annual Report 2008-09, p26

Organ availability

NHS England does not commission organ retrieval. Organ retrieval and allocation is the responsibility for NHS Blood and Transplant (NHS Blood and Transplant).

NHS Blood and Transplant matches donated organs to candidates on the waiting list. Centres must be able to respond without delay. It is expected that individual centres will have fluctuating levels of activity.

The acceptable cold ischemic times for donated hearts and lungs are short compared to other donated organs; hearts having a shorter acceptable cold ischemic time than lungs. This currently makes long distance transport of hearts unfeasible, increasing the importance of good local organ retrieval logistics and local recipient management logistics.

This service aims to transplant all available cardiothoracic organs that are matched to recipients on the waiting list.

The service provides life-long aftercare related to the functioning of the grafted organ. The total number of patient requiring follow-up has reached a steady state, and there is a likelihood that numbers may adjust to changes in transplantation rates and improving medical care of comorbidities.

Objectives and Expected Outcomes

The service provides assessment, treatment and follow up for adults (16+) who need heart and/or lung transplantation.

All centres use real time sequential monitoring of 30 day and 90 day mortality rates following cardiothoracic transplantation. This monitoring is conducted by NHS Blood & Transplant in collaboration with the Royal College of Surgeons Clinical

Effectiveness Unit. Commissioners and providers are alerted to any trends that might indicate a significant increase in mortality rate.

Centres are compared to either a centre-specific or national average mortality rate depending on their past performance in relation to the national average. A centre whose mortality rate is below the national average is compared to their own past performance whereas a centre whose mortality rate is above the national norm is compared to the national average.

2.2 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 heart transplant and lung transplant assessment, surgery and life-long follow up for adults (16+). The service operates closely with the bridge to heart transplant service for adults and the cardiothoracic transplantation service for children.

A standard episode of care will include:

- pre-transplant assessment, immunology and tissue-typing of recipient;
- admission,
- transplant,
- routine follow-up for 12 months in outpatients, including re-admission if necessary.
- Subsequent follow-up will be on a defined frequency (not less than annually) and will depend on shared care arrangements with local cardiothoracic services.

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.

Pre-transplant assessment

The service follows the *National Protocol for Assessment of Cardiothoracic Transplant Patients*. 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).
- Assessment stages:
 - Referral letter and proforma with details

- Pre-assessment outpatient clinic when appropriate
- In patient assessment
- Decision
- Waiting List

Objectives of assessment procedures:

- To assess the patient's clinical, social and psychological suitability as a transplant recipient
- To impart factual information to the patient and his/her family concerning all aspects of transplantation
- 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 aftermath
- The general condition of the patient is such that transplantation of the heart/lungs or lungs alone allows the patient a realistic chance of prolonging a good quality of life.

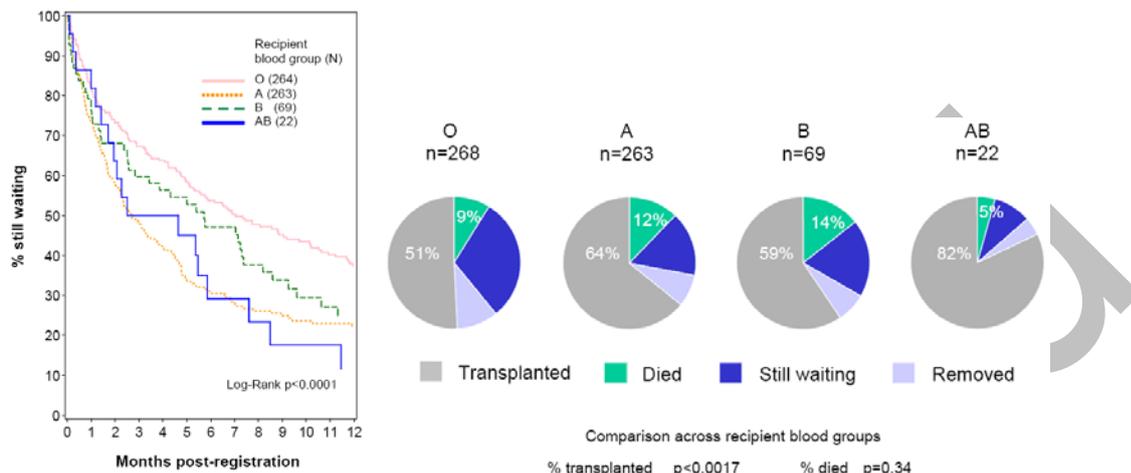
Assessment outcome:

- If the patient decides to go forward for transplantation, he or she is then registered with NHS Blood & Transplant 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.

Waiting times

- This Service Specification does not cover care received by the patient whilst waiting for a suitable organ to become available. This may involve a period of intensive care unit (ICU) inpatient care (often on inotropes, and/or balloon pump care).
- NHS Blood and Transplant has operated an urgent heart allocation scheme since 1999. This enables centres to register patients with a rapidly deteriorating condition as a higher priority than patients with a stable condition.
 - The NHS Blood and Transplant study of cases between 1999 and 2003 showed that the majority of adult cases were elective, with only around 10% being urgent. In recent years, the Urgent Heart Allocation Scheme has accounted for approximately 40% of heart transplants.
- Waiting times are influenced most significantly by a patient's body size, blood group and primary diagnosis (NHS Blood and Transplant presentation to International Society for Heart and Lung Transplantation).
 - Patients over 81kg waited a median of 271 days to transplant compared with those under 70kg who waited 95 days.
 - Blood groups A and AB patients had more than twice the chance of transplant compared with group O patients; they waited a median of 93, 97 and 230 days, respectively.

- Patients with cardiomyopathy had an increased chance of transplant compared with those with coronary heart disease while those with diseases other than congenital heart disease had a reduced chance; they waited a median of 127, 166, 251 days, respectively.



From NHS Blood and Transplant (2005) *Relevance of blood group to waiting time for heart transplantation in the UK: implications for equity of access*

Admission

- It is the patients' 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,
 - and 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,
 - or the necessary clinical resources (e.g. staff, operating theatres) are unavailable.

Transplantation

- The service is delivered in accord with the latest NHS England service standards.
- Individual centres should provide assurance that individual surgeons are working at safe and sustainable levels, avoiding risks associated with excessive hours and with occasional practice.
- Mechanical support of the graft post-transplant is considered to be commissioned by NHS England within the existing recurrent investment.

Initial follow-up

- There should be arrangements for direct 24 hour emergency access after discharge.
- The follow-up process must run for the period of time agreed with the referring clinician.

Long-term follow-up

- Subsequent follow-up will be on a defined frequency (not less than annually) and will depend on shared care arrangements with local cardiothoracic services and patient need.
- 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 without specialist centre (see clinical standards);
 - And if necessary, a patient may need to be reassessed for transplantation.
- Clear arrangements should be in place for the safe planned transition from child to adult follow-up services.
- 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.
- NHS England commissions 3 months post-transplant immunosuppressants, after which time the originating Clinical Commissioning Group (CCG) takes financial responsibility.

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 cardiothoracic transplant services is an area for further development in 2011-12.

Risk Management

- Service providers are responsible for managing the logistical arrangements for on-call teams, clinical resources, and recipient coordination. UK units to work towards a minimum of 5 consultant surgeons capable of undertaking heart or lung transplantation and at least 3 involved as part of a left ventricular assist devices (LVAD) programme. A department may have different surgeons in each team but must have a sufficient number to publish a robust on-call rota. (Standard 2.2)
- International evidence demonstrates that high heart transplant mortality is seen in units with low activity (between 9 and 12 heart transplants per year). UK units agreed to work towards a minimum of 25 heart transplants and 25 lung transplants per year.
- The staff and facilities covered by the baseline investment for cardiothoracic 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.

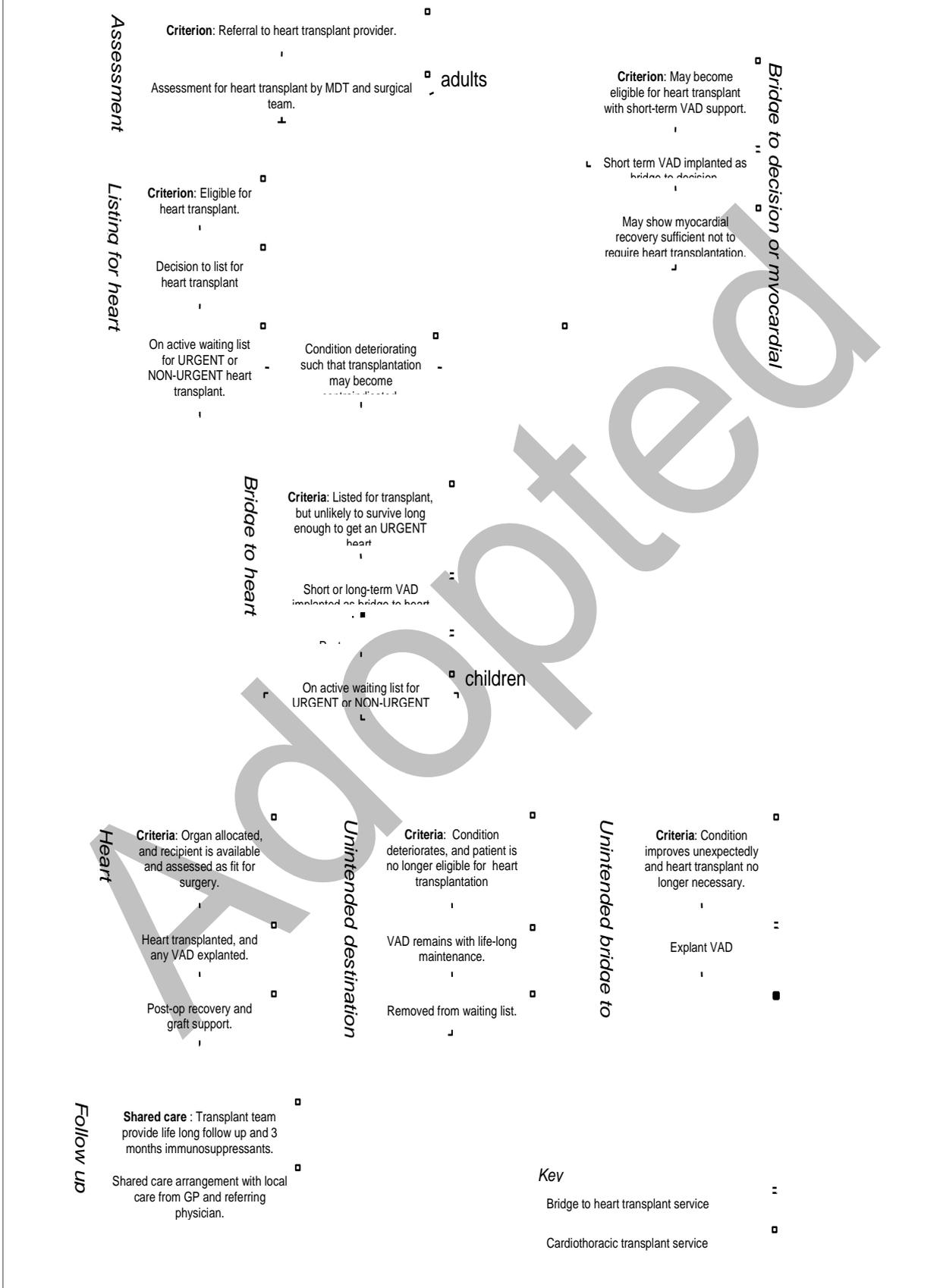
- This service specification does not limit the pharmacological treatment options available with regard to transplant care, provided they are met within the existing level of investment. This includes desensitisation due to graft-recipient mismatch.
- All providers offering a service to patients under 18 years of age should ensure they are compliant with the requirements to safeguard children, and follow current guidance on obtaining consent from children.

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.

Patients may be discharged from routine follow-up at a cardiothoracic transplantation service with the agreement of their local cardiothoracic services.

Heart transplant and bridge to heart transplant care-pathway



Lung transplant care-pathway

Assessment

Criterion: Referral to lung transplant provider.

Assessment for lung transplant by MDT and surgical team.

Listing for lung transplant

Criterion: Eligible for lung transplant.

Decision to list for lung transplant

On active waiting list for URGENT or NON-URGENT lung transplant.

Condition deteriorating such that transplantation may be contraindicated.

Lung transplant

Criteria: Organ allocated, and recipient is available and assessed as fit for surgery

Lung (s) transplanted.

Post-op recovery and graft support.

Follow up

Shared care : Transplant team provide life long follow up and 3 months immunosuppressants.

Shared care arrangement with local care from GP and referring physician.

Key

▣ Cardiothoracic transplant service

2.3 Population covered

NHS England commissions the service for the population of England. Commissioning on behalf of other devolved administrations is reviewed annually, and a current list is available from NHS England commissioners.

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.

With regard to S2, the mechanism for recovery of costs has been via the Department for Work and Pensions Overseas Healthcare Team. They are responsible for agreeing reconciliation and recovery of costs with European administrations. These arrangements were implemented in October 2009, though a similar process existed previously. The financial flows are therefore back into the Treasury rather than back to Trusts.

2.4 Any acceptance and exclusion criteria

All centres must be able to respond to the offer of a suitable organ within 1 hour.

Acceptance criteria

See the National Protocol for Assessment of Cardiothoracic Transplant Patients.

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.

Evidence suggests that age, gender, height, body mass index, year of registration and cytomegalovirus status were not significant in determining waiting times once someone had been accepted on to the transplant list.

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

Exclusion criteria

See the National Protocol for Assessment of Cardiothoracic Transplant Patients.

Patients aged 16 or older may be accepted by the cardiothoracic transplantation service for adults.

The cardiothoracic transplantation service for children accepts patients up to the age of 17 at the point of transplantation.

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

2.5 Interdependencies with other services

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.

Heart transplant is an intervention for the treatment of end stage heart failure. Lung transplant is an intervention for irreversible end stage lung failure. The national service has interdependencies with cardiothoracic services, ventricular assist device services. The increasing number of paediatric heart and/or lung transplant survivors creates interdependencies between the adult and child programmes for life-long follow-up.

Patient and survivor groups include:

- British Heart Foundation
- British Lung Foundation
- British Thoracic Society
- Cystic Fibrosis Trust
- Patient groups at each hospital

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

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. In addition, all centres are reviewed at least annually, and are expected to produce a written annual report for NHS England commissioners that demonstrates compliance with the current service standards and requirements for equity of access. Clinical teams are expected to

participate actively in clinical networks to improve the national cardiothoracic transplantation service.

4. Key Service Outcomes

<i>Quality Performance Indicator</i>	<i>Threshold</i>	<i>Method of measurement</i>	<i>Consequence of breach</i>	<i>Report Due</i>
Numbers waiting	In line with heart availability	Waiting list analysis	Review & action plan	NHS Blood and Transplant report every 6 months
Length of Wait	In line with heart availability	Waiting list analysis	Review & action plan	NHS Blood and Transplant report every 6 months
30 day mortality	As agreed with NHS Blood and Transplant	CUSUM	Review & action plan	NHS Blood and Transplant report every 6 months, plus exception reporting
Heart and lung transplant (adults) <ul style="list-style-type: none"> • 30-day mortality • 90-day mortality • 30-day mortality with risk-adjustment • One-year survival • Three-year survival • Five-year survival 	Significant variation from the national average or, in services with one or two national centres, significant variation from the outcomes achieved in the previous three years	Annual report (September of contract year) with data from previous financial year April to March	Performance notice as set out in Clause 32.4 Review & action plan	NHSE Annual report (September of contract year)

<p>Minimum levels of activity</p> <ul style="list-style-type: none"> • Past 12 months heart transplants • Past 12 months lung transplants per unit • Robust on-call arrangements 	<p>No less than 9 heart transplants for the unit in the past 12 months; aspiring to a minimum of 25 heart transplants and 25 lung transplants per unit annually.</p>	<p>Copy of on-call rota for the past 12 months.</p> <p>Report identifying surgeons joining and leaving the heart transplant rota and lung transplant rota in the past 12 months.</p> <p>Report of heart transplants and lung transplants performed by each surgeon in the past 12 months.</p>	<p>Review & action plan</p>	<p>NHSE every 6 months, and NHSE Annual report (September of contract year)</p>
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5. Location of Provider Premises

Provider	Adult	Child
Great Ormond Street Hospital for Children NHS Foundation Trust Great Ormond Street, London, WC1N 3JH	No	Yes
The Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital, High Heaton, Newcastle upon Tyne. NE7 7DN	Yes	Yes
Papworth Hospital NHS Foundation Trust Papworth Everard, Cambridge CB23 3RE	Yes	No
Royal Brompton & Harefield NHS Foundation Trust Sydney Street, London SW3 6NP	Yes	No
University Hospital of Birmingham NHS Foundation Trust Selly Oak Hospital, Raddlebarn Road, Selly Oak, Birmingham, B29 6JD	Yes	No
University Hospital of South Manchester NHS Foundation Trust Wythenshawe Hospital, Southmoor Road, Manchester M23 9LT	Yes	No
Sheffield Teaching Hospitals NHS Foundation Trust Northern General Hospital, Herries Road, Sheffield S5 7AU	Yes Assessment and follow up only	No

Adopted

End.