SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	A10/S(HSS)/a
Service	Heart Transplantation Service (adults)
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Heart transplantation is an established treatment for advanced heart failure. Clinical outcomes are monitored within the UK and as part of the International Society for Heart and Lung Transplantation.

Patients are listed for heart transplant if there are no contraindications and when their quality of life and survival are likely to be improved by a transplant. Patients are categorised as urgent or non-urgent. The development of Ventricular Assist Devices (VADs) has enabled some people with end stage heart failure to be supported till such time as a suitable donor heart is identified. VADs may also be used to treat reversible complications of heart failure that are potential contraindications to heart transplantation (e.g. kidney dysfunction, high pulmonary vascular resistance). The overall demand for heart transplantation may therefore increase with the use of this technology.

Organ availability

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

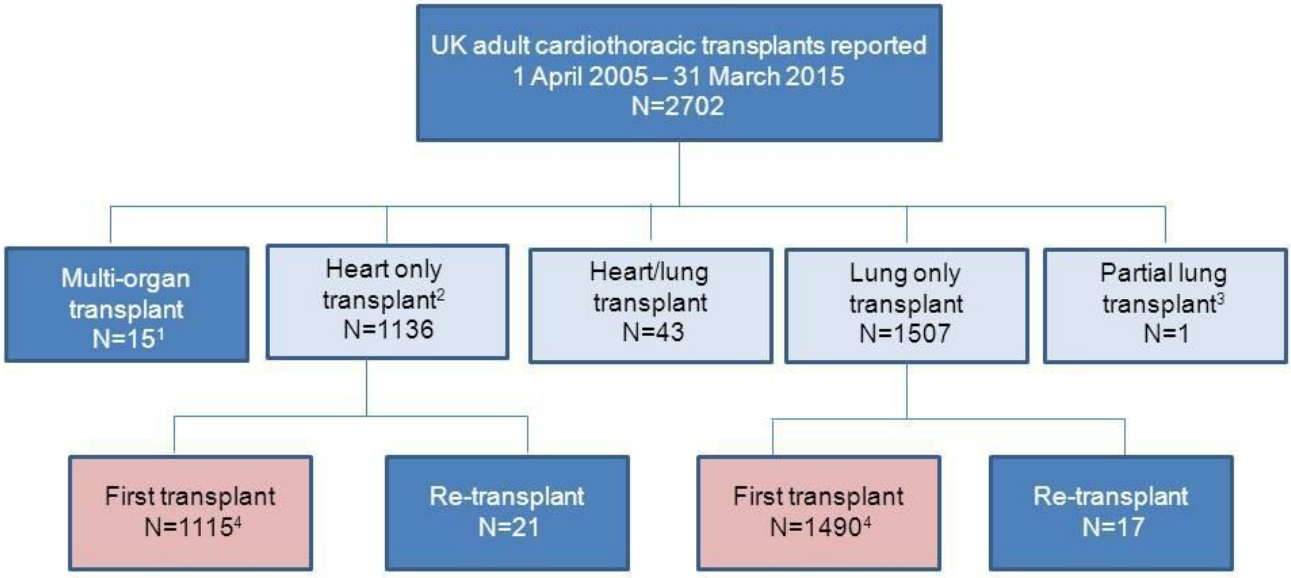
NHS Blood and Transplant matches donated organs to candidates on the waiting list. Centres must be able to respond without delay. It is expected that individual centres will have fluctuating levels of activity.

The acceptable cold ischemic time for donated hearts is short compared to most other donated organs. This currently makes long distance transport of hearts undesirable. This

service aims to transplant all suitable organs that are matched to recipients on the waiting list. The service will need to work with retrieval teams and respond to innovation in retrieval services.

The service provides life-long aftercare related to the functioning of the grafted organ. The total number of patients requiring follow-up has reached a steady state, with a balance between the recent decrease in the number of heart transplants and improvements in medical care of the allograft and co-morbid conditions. If an increase in the rate of transplantation is achieved with current initiatives this balance may be altered.

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



[1] Includes 11 heart and kidney transplants (1 of which was a retransplant), 1 lung and kidney and 3 lung and liver
[2] Includes 3 domino donor transplants and 1 DCD heart transplant
[3] Includes 1 partial lung transplant from a living donor
[4] 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

2. Outcomes

The service provides assessment; treatment and follow up for adults (16+) who need heart transplantation.

Centres should assess all appropriate referrals and make a decision within 18 weeks on whether to list for a heart transplant. Patients anywhere in the country should have equal access to assessment for a transplant.

Centres should monitor patients on the waiting list and list for an urgent transplant or use mechanical circulatory support appropriately.

All centres use real time sequential monitoring of 30 day and 90 day mortality rates following heart 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. The national audit also provides 1 year, 5 year and ten year outcome for each centre. The International Society for Heart and Lung Transplantation publishes figures for these outcomes that can be used for benchmarking.

2.1 NHS Outcomes Framework Domains & Indicators

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

3. Scope

3.1 Aims and objectives of service

The national heart transplantation service aims to provide heart transplantation to improve

survival and quality of life for patients with advanced heart failure who meet the service inclusion criteria.

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

The 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 supply of post-transplant immunosuppressants from the transplant centre. Long-term prescribing of these drugs will come under the control and responsibility of the Centres.

3.2 Service description/care pathway

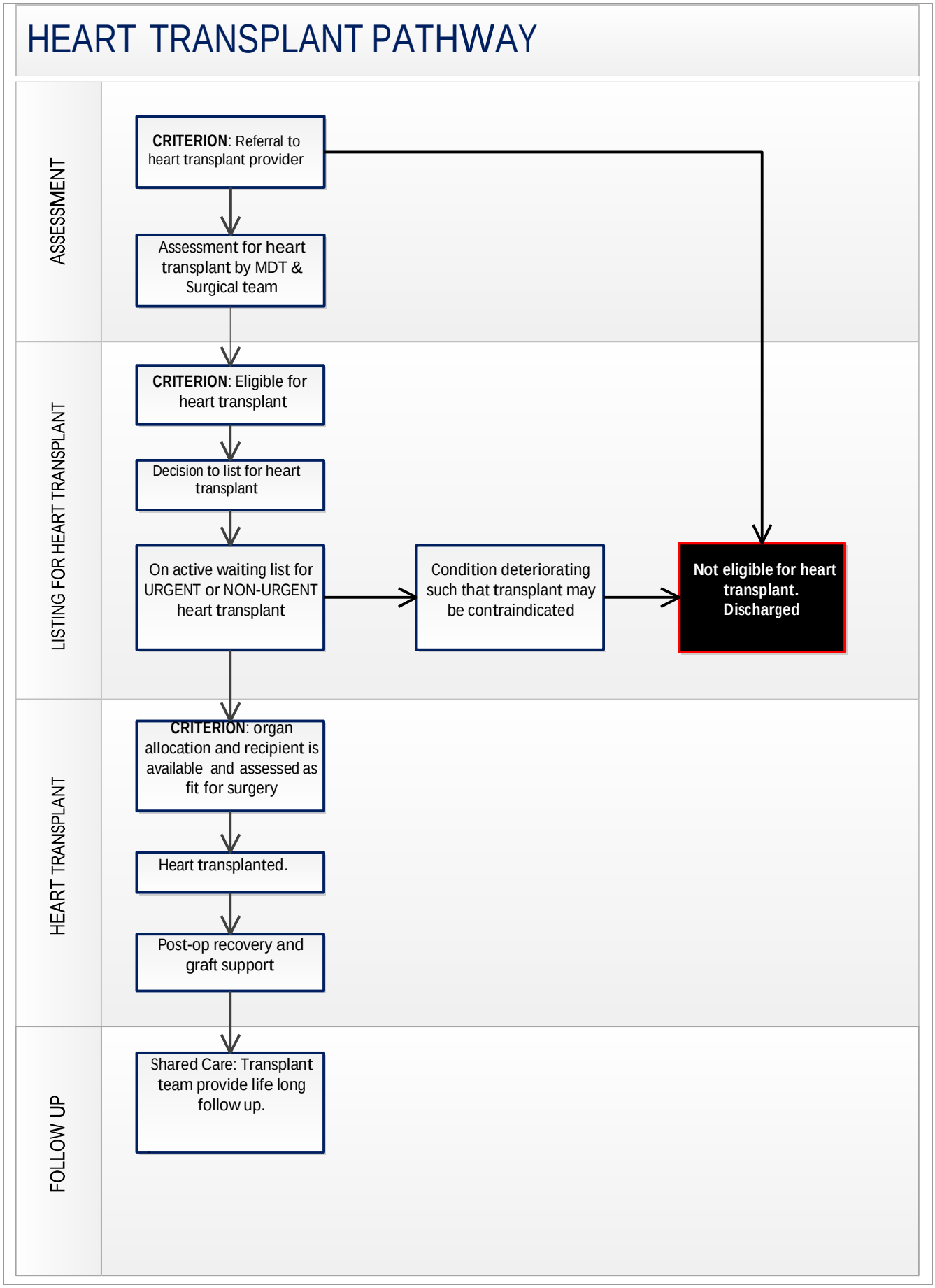
The service is responsive to the availability of organs and recipients, and is able to operate 24 hours per days, every day of the year.

The service provides 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;
- follow- up of patients on the waiting list with repeat assessments as required
- admission,
- transplant,
- routine follow-up in outpatients for transplant related condition, including re-admission if necessary.
- Long-term lifelong follow-up at varying intervals (not less than annually); the frequency will depend on shared care arrangements with local cardiothoracic services. Readmission for allograft complications as required.

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*. 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/or proforma with details
- Pre-assessment outpatient clinic when appropriate
- In patient assessment (including management of advanced heart failure)
- Decision
- Waiting List

Objectives of assessment procedures:

- To assess the patient's clinical, social and psychological suitability as a transplant recipient
- To modify therapy as appropriate.
- 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 heart transplantation will allow 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.

2. 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). Others will require outpatient visits and repeat assessments depending on their clinical condition**.**

NHS BT 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 BT 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.

3. 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.

4. Transplantation.

- 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

5. 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 but will need to be lifelong in most patients as expertise in managing immunosuppression is not normally available at referring centres.

6. **Long-term follow-up**
   - The management of the patient's immunosuppression is ideally done by the transplant cardiologist;
   - 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 and complications associated with immunosuppression:
   - Shared care arrangement may be developed for routine investigations which may be administered without specialist centre input(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 the supply of post-transplant immunosuppressants from the transplant centre. Long-term prescribing of these drugs will come under the control and responsibility of the heart transplant centre.
   - 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 t**o** by that brand in all correspondence (see Medicines and Health products Regulatory Agency guidance).

7. **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 heart transplant will occur in a staged fashion, with the timing and pace to be tailored to the needs of each individual patient.

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

9. **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 an 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.

- Units should work towards a minimum of 25 heart transplants per year
- The staff and facilities covered by the baseline investment for heart 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 encenphalopathies (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 https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group. 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 less than 18 years of age should ensure they are compliant with the requirements to safeguard children, and follow current guidance on obtaining consent from children.

10. 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 will be informed.

3.3 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.

3.4 Any acceptance and exclusion criteria and thresholds

All centres must be able to respond to the offer of a suitable organ in line with agreed protocols.
Transport of patients to the transplant centre is not funded as part of this service.

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

Patients aged 16 or older may be accepted by the service.
All patients must be biologically fit, regardless of age. In practice, most recipients are less than 65 years of age as there is an increase in co-morbidity with the ageing process.

Evidence suggests that age, gender, 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 every two years.

Exclusion criteria
See the National Protocol for Assessment of Cardiothoracic Transplant Patients.

Patients aged 16 or older may be accepted by the heart transplantation service for adults. The heart 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 will, over a transition period, may have responsibility for their care transferred from child to adult heart transplantation providers.

3.5 Interdependencies with other services/providers

Heart transplant is an intervention for the treatment of end stage heart 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 Society of Heart Failure
- British Cardiovascular Society
- 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

- Providers will meet standard NHS governance requirements.
- Providers will comply with the agreed transplantation policies and guidance of NHS Blood and Transplant and the Cardiothoracic Transplant Advisory Group.
- There is a requirement to hold national audit meetings involving all designated centres on an annual basis.
- Each centre must ensure 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:

  Ÿ Clinical performance and outcome

  Ÿ Process-related indicators e.g. efficiency of the assessment process, prescribing policy, bed provision and occupancy, outpatient follow-up etc.

  Ÿ Stakeholder satisfaction, including feedback from patients, their families, referring clinician and General Practitioners doctors and GPs.

  Ÿ Equity of access to services
- Individual centres are expected to actively participate in clinical networks to improve

the national heart transplantation service.

- NICE guidance CG108 (August 2010) Chronic heart failure: Management of chronic heart failure in adults in primary and secondary care sets out the recommendations for the treatment of patients in heart failure, including referral for cardiac transplantation.
- NICE guidance QS9 (June 2011) Chronic heart failure quality standards set out the pathway for treatment of chronic heart failure patients and the importance of multidisciplinary team decision making.
- NICE guidance IP177 (June 2006) Short-term circulatory support with left ventricular assist devices as a bridge to cardiac transplantation or recovery identifies the importance of continuing evaluation of mechanical assist in urgent cases ahead of heart transplantation.

All providers will meet standard NHS governance requirements. All providers will comply with transplantation guidance and policies as agreed by the NHS BT Cardiothoracic Transplant Advisory Group. Clinical teams are expected to participate actively in clinical networks to improve the national heart transplantation service.

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

There are no current guidelines relating to cardiac transplantation published by the Royal Colleges of Surgeons, Physicians or Anaesthetists in the United Kingdom.

Relevant National and International guidelines on cardiac transplantation include:

Costanzo, M.R., et al., The International Society of Heart and Lung Transplantation Guidelines for the care of heart transplant recipients. J Heart Lung Transplant, 2010. **29**(8): p. 914-56.

Gronda, E., et al., Heart rhythm considerations in heart transplant candidates and considerations for ventricular assist devices: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates--2006. J Heart Lung Transplant, 2006. **25**(9): p. 1043-56.

Jessup, M., et al., Optimal pharmacologic and non-pharmacologic management of cardiac transplant candidates: approaches to be considered prior to transplant evaluation: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates--2006. J Heart Lung Transplant, 2006. **25**(9): p. 1003-23.

Mehra, M.R., et al., Rationale and process: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates--2006. J Heart Lung

Transplant, 2006. **25**(9): p. 1001-2.

Mehra, M.R., et al., Listing criteria for heart transplantation: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates--2006. J Heart Lung Transplant, 2006. **25**(9): p. 1024-42.

ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. Eur J Heart Fail 2012;**14**:8 803-869

Banner NR et al . UK guidelines for referral and assessment of adults for heart transplantation. Heart 2011;**97**:1520–7.

Hunt S ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): Developed in collaboration with the American College of Chest Physicians and the International Society for Heart and Lung Transplantation: endorsed by the Heart Rhythm Society." *Circulation* 112.**12** (2005): e154-e235.

Francis GS et al. ACCF/AHA/ACP/HFSA/ISHLT 2010 Clinical Competence Statement on Management of Patients With Advanced Heart Failure and Cardiac Transplant: A Report of the ACCF/AHA/ACP Task Force on Clinical Competence and Training. *J Am Coll Cardiol.* 2010;56(5):424-453.

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 Newcastle upon Tyne Hospitals NHS Foundation Trust Papworth Hospital NHS Foundation Trust Royal Brompton & Harefield NHS Foundation Trust University Hospital of Birmingham NHS Foundation Trust University Hospital of South Manchester NHS Foundation Trust Sheffield Teaching Hospitals NHS Foundation Trust – follow up only
7. Individual Service User Placement
Not applicable

Appendix Two

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Heart transplant (adults) Ÿ 30-day mortality	CUSUM trigger	CUSUM analysis by NHS BT	Agreed escalation process for CUSUM triggers
Domain 2: Enhancing the quality of life of people with long-term conditions			
Length of wait on waiting list	In line with heart availability	Waiting list analysis NHS Blood and Transplant report every 6 months	To be addressed in annual service audit meeting
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Proportion of patients receiving annual review at transplant centre	80%	Trust data	To be addressed in annual service audit meeting
Domain 4: Ensuring that people have a positive experience of care			
Yearly audit of patient experience questionnaire	Significant decline on previous year	Trust survey	To be addressed in annual service audit meeting
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
SUI and never events	Zero	STEIS	Root cause analysis