A18/S(HSS)/b

2013/14 NHS STANDARD CONTRACT FOR VENTRICULAR ASSIST DEVICES (VADS) AS A BRIDGE TO HEART TRANSPLANTATION OR MYOCARDIAL RECOVERY(ALL AGES)

PARTICULARS, SCHEDULE 2 – THE SERVICES, A – SERVICE SPECIFICATION

Service Specification No.	A18/S(HSS)/b for Children see Appendix 1
Service	Ventricular Assist Devices (VADs) as a bridge to heart transplantation or myocardial recovery(All Ages)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Description

As the native heart fails, cardiac output deteriorates resulting in inadequate kidney perfusion and liver congestion. Significant renal and hepatic dysfunction results in renal failure, liver failure and bleeding and patients can become too high a risk for transplantation.

Left ventricular assist devices (LVADs) augment the circulation in these patients, not only saving their lives but also improving secondary organ function for transplantation, reducing pulmonary hypertension and allowing for improvement of nutritional status.

Heart failure management

Medical therapy with ACE inhibitors, β blockers, angiotensin 2 inhibitors and aldosterone antagonists together with resynchronisation therapy has improved the survival of many with heart failure, but there remain a subgroup of patients who, despite optimal medical therapy, progress to **New York Heart Association** (NYHA) Class III or IV heart failure. These advanced heart failure patients have a very poor prognosis which is worse than that for patients with myocardial infarction, carcinoma of the bowel, breast or prostate.

Heart transplantation is widely accepted as an effective surgical treatment for suitable patients with advanced heart failure. However, the number of heart

transplants is severely limited by the availability of suitable donor hearts. Over recent years, there has been a steady decline in donor numbers both nationally and internationally. Because of ever increasing waiting times for heart transplantation, an increasing number of patients deteriorate whilst waiting for a donor heart. The smaller numbers of useable hearts also means that this scarce therapeutic resource and often life-saving donation should be directed to those that will benefit most.

There have been important advances in both VAD technology and patient management over the last decade. VADs can broadly be divided into first, second and third generation devices. As the devices and patient management have improved over time, survival has increased and complications have decreased. This is evidenced by both UK and international data. Rapid evolution in VAD technology continues to occur.

First generation VADs

The first generation VADs are pulsatile volume displacement pumps. These pumps provide excellent haemodynamic support but have constraints, particularly their size (they are large hence needing extensive surgical dissection), the presence of a large diameter lead (which is more prone to infection), an audible pump, the need for medium-large body habitus and limited long-term durability as they were only designed for up to 1 year of support.

Second generation VADs

The second generation VADs are axial flow pumps that are smaller than the 1st generation VADs (for example the second generation *Heartmate II* is 1/7th the size and ¼ the weight of the first generation *Heartmate I* device). Surgical implantation requires less extensive dissection and therefore it is less traumatic for the patient. They are also easier to insert into patients with smaller body habitus. The smaller diameter drivelines appear to result in lower rates of driveline infection. These continuous flow pumps are quiet in operation and only have a single moving part, the rotor, and hence are expected to be more durable than 1st generation VADs and are now being widely used.

Third generation VADs

A number of third generation VADs are now also in clinical use or clinical trials. These are bearingless continuous flow pumps with an impeller that is either magnetic levitation or hydrodynamically suspended. Since there are no mechanical bearings inside these VADs, there is no mechanical wear and tear, and durability should be much longer. Although these third generation VADs are only just starting to be used they are anticipated to last for 5-10 years.

Evaluation of Ventricular Assist Device Programme in the United Kingdom

The independently led health technology assessment (HTA), the *Evaluation of Ventricular Assist Device Programme in the United Kingdom, EVAD UK*, followed the clinical and cost effectiveness of the use of VADs as Bridge to Transplant (BTT) or

Bridge to Recovery (BTR) in patients who were appropriate candidates for heart transplantation, or would be after a period of VAD support, evaluated seventy patients implanted with a VAD as a bridge to transplantation between April 2002 and December 2004 in Papworth Hospital (Cambridge), Harefield Hospital (London) and Freeman Hospital (Newcastle).

The majority (81%) had first generation devices. Of the 70 VAD patients, survival after VAD implant was 74% at 30 days and 52% at 12 months. Forty one percent of patients were discharged from hospital with a VAD. One-year survival post-transplant was 84%. The study concluded that overall survival of 52% was an excellent clinical achievement for those young patients with rapidly failing hearts. It was decided that the UK VAD service should be maintained because of its clinical effectiveness for these young sick patients and to maintain and develop expertise for the future when wider use of these devices seemed likely. UK activity and results would be carefully monitored and the nationally commissioned service structured and managed to maximise understanding and skill-base for future patients.

UK experience after EVAD study

Since the EVAD study, the results of VAD implantation as BTT and BTR have significantly improved in the UK. The EVAD study analysed patients receiving VADs from May 2002 to December 2004. Since the completion of EVAD, post-VAD 1 year survival has improved significantly.

Importantly, the duration of support has also significantly increased over recent years, as shown in Table 1. Hence there is evidence of significant improvement in patient survival after long-term VAD implantation over time in the UK. Patients with long term VADs may be explanted undergo heart transplantation or die with a VAD.

Table 1: Median long-term VAD duration, by grouped financial years, 9 May 2002 to 31 March 2010

Financial year groups	N	Median	95% CI	Range
02/03 – 03/04	51	84 days	26 – 142	0 – 828 days
04/05 – 05/06	149	109 days	83 – 1335	1 – 1835 days
06/07 – 07/08	45	262 days	179 – 345	1 – 1341 days
08/09 – 09/10	83	319 days	160 – 478	0 – 691 days

Table 2: Long-term VAD outcome, by implant centre, 9 May 2002 to 31 August 2010

Outcome	N	%
Alive (post Tx)	64	26%
Alive (post Explant)	18	7%
Alive with VAD	58	24%
Died (post Tx)	18	7%
Died (post Explant)	2	1%
Died with VAD	85	35%
TOTAL	**246**	**100%**

International evidence

In the multi-centre evaluation of the first generation *HeartMate VE* device as a BTT, 71% of 280 patients survived to transplantation or device removal and in the Cleveland Clinic experience of 277 LVADs, 69% survived to transplantation. In other series, survival to transplantation ranged from 60% to 75%. However this data is all from the first generation VADs which are associated with higher mortality. Data from the second generation VADs, which would be expected to have a better outcome due to their smaller size, easier surgical implantation and lower complication rates is now becoming available.

More recently Miller *et al* published a prospective multi-centre study of 133 NYHA Class IV patients on a transplant waiting list who underwent implantation of the second generation *Heartmate II* LVAD as a BTT. All were on inotropic support (except 11% who were intolerant because of arrythmias) and 41% were also intra aortic balloon pump (IABP) dependent. After 180 days, 100 (75%) patients had reached the principal outcome of transplantation, recovery or survival on ongoing support with eligibility for transplantation.

INTERMACS

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) started recording the outcome of Food and Drug Amdinistration (FDA) approved devices in March 2006 in the USA. For the first two years, the INTERMACS dataset was confined to patients with first generation VADs as these were the only FDA approved devices In April 2008 the second generation *HeartMate II* axial flow pump *Thoratec*) received FDA approval for clinical use. The Second INTERMACS annual report provided data on LVAD patients (with either first or second generation devices) for the period June 2006-March 2009. The actuarial survival of the primary LVAD cohort, was 83% at 6 months, 74% at 1 year, and 55% at 2 years.

Data is beginning to emerge for the third generation devices.

- In the VentrAssist CE mark study, 33 patients received the VentrAssist as BTT with 83% of patients successfully transplanted or eligible for transplantation at 154 days post-implant.

- 35 patients have received the Duraheart VAD with a Kaplein Meir survival of 78% at 2 years and 86% of 1 month survivors have been discharged home.

Evidence for VADs as bridge to myocardial recovery

Unloading of the left ventricle with the use of a VAD is associated with structural reverse remodelling that can be accompanied by functional improvement or recovery of heart function. This can be sufficient in some cases to allow removal of the device so avoiding the need for transplantation. However the exact proportion of patients in which this is possible is unknown but has been reported to be only 5-24% in various series.

2. Scope

2.1 Aims and objectives of service

Aims

The service is nationally commissioned to provide ventricular assist devices (VADs) as a bridge to heart transplantation, bridge to decision for heart transplantation or bridge to myocardial recovery within transplant centres for a particular group of adults (17+) with deteriorating advanced heart failure. The service can be accessed via elective and non-elective routes. Patients are eligible for referral to the service if they have deteriorating heart function and clearly would not survive long enough to be transplant recipients despite the provision of an *"urgent"* category nationally. Patients must be appropriate candidates for cardiac transplantation or will become appropriate for a transplant following a period of VAD support.

Objectives

The service is commissioned to:

- provide a high quality, patient focused, evidence-based service which represents good value and is responsive to national requirements, guidance and policy;
- work collaboratively between the VAD centres, with the acute sector, general practice and other primary care providers;
- prioritise training needs and support for established and developing VAD centres;
- work with commissioners to further develop high quality national services.

Expected outcomes: NHS England commission NHS Blood and Transplant, and the Royal College of Surgeons Clinical Effectiveness Unit to conduct 6 monthly audits of the VAD service activity and outcomes. In addition, all providers must meet the following expectations:

- Access available to patients with advanced heart failure (NYHA Class III or IV) as a bridge to transplant or recovery;

- Achievement of optimal health outcomes for patient cohort (e.g. improved mortality/ morbidity);
- Reduction in patients requiring heart transplantation as a result of bridge to recovery;
- Achievement of national access targets where applicable including 18 weeks;
- To have a process in place to ensure that patients, their carers and families have access to clear, accurate and up-to-date information and advice throughout the assessment, treatment and follow up;
- To have access to Multi Disciplinary Team (MDT) discussions at key stages throughout the care pathway.

2.2 Service description/care pathway

The service is always open.

The service is characterised by:

- secondary or tertiary care referral access only;
- provided by specialist centres only;
- specialist centre network model of care;
- multidisciplinary working;
- links to existing cardiothoracic transplant services;
- and providing services to adults who fit the eligibility criteria.

Service Requirements

Details of staffing requirements are set out in the service standards and updated as necessary. The NHS England commissions a service rather than posts, to allow providers flexibility in job design and team configuration.

VAD patients require a team of specialist staff very similar to that of a specialist cardiothoracic transplant service. The size of the team required will depend on the number of ongoing patients and the size of the programme.

The team will include cardiologists, surgeons and intensivists to assess the patient implant the pump and look after the patient post VAD insertion. Because of the level of technology and dependence of the patient's life on it, specialist VAD nurses or perfusionists are needed to train other nursing staff, teach the patient and their family and to monitor these patients. Patient education includes escorted visits out of the hospital and then with their family prior to discharge. In addition both social and psychological support is available to patients and their families.

The information below is a summary, and further details are given in the service standards.

Referral

Referrals are from secondary or tertiary services only. The service can be accessed via elective and non-elective routes. Patients are eligible for referral to the service if they have deteriorating heart function and clearly would not survive long enough to be transplant recipients despite the provision of an *"urgent"* category nationally (Urgent Listing Criteria are produced and updated by the Cardiothoracic Transplantation Advisory Group, CTAG). Patients must be either appropriate candidates for cardiac transplantation or will become appropriate for a transplant following a period of VAD support.

Assessment

Assessment is done by a multi-disciplinary team. On assessment, if the patient has contraindications to longer-term VAD implantation or urgent heart transplant, they may be considered as a candidate for bridge to decision. The outcome of the assessment will be: to proceed with bridge to heart transplant; that the patient has recovered sufficiently to no longer require a VAD or heart transplant; or that the patient in not eligible for heart transplant.

VAD insertion

Haemodynamic criteria for VAD insertion:

Haemodynamic measurements are made before inotropic/IABP support is started. Although haemodynamic parameters may improve dramatically with inotropic support there is no evidence that such treatment improves the prognosis and indeed may worsen it. Inotropic therapy should be regarded as a short-term measure while other treatment is implemented. The amount of support provided by an **Intra-aortic balloon pump** (IABP) in advanced heart failure is usually minimal. It should not unnecessarily delay the insertion of the VAD and may cause complications so its use is not mandatory prior to VAD insertion.

Either

- Low cardiac output (C.I. < 2.2l/min/m2) despite an adequate preload (CVP > 12 mmHg or PCWP > 16 mmHg) and require inotropic and/or IABP support for;
    - symptomatic hypotension (systolic BP < 90mmHg)
    - secondary organ dysfunction (especially renal and hepatic).

Or

- Patients whose haemodynamics are better than these criteria, but are deteriorating so rapidly that they are unlikely to survive until transplantation.

Bridge to decision:

A short-term VAD can be used as a *bridge to decision* in extremely sick or "moribund" patients who have contraindications to the implantation of a long-term VAD or urgent transplantation at the time of presentation if these contraindications are considered acute and potentially reversible, prior to deciding if a more expensive device or transplant should be used.

Such patients often have end-stage organ failure and/or uncertain neurological

status and are often ventilated. Using short term low cost devices in this setting is very effective in stabilising the haemodynamic state, improving the end organ function, extubating the patient to assess neurological status and provides an opportunity to further assess their clinical condition. Short term low cost devices that can be inserted with minimal surgical invasiveness in such sick patients often with coagulopathy, provide immediate haemodynamic stability and recovery for future assessment of these patients either for bridge to heart transplantation, bridge to myocardial recovery or a long term device.

Bridge to heart transplant:

The Ventricular Assist Device (VAD) works by supporting the pumping action of the failing heart until a donor heart becomes available for transplantation – a technique known as “bridge to transplant” (BTT).

Bridge to myocardial recovery:

Occasionally, the use of a VAD enables the heart to recover sufficiently for the device to be removed; this is termed “bridge to recovery” (BTR).

Destination therapy (long term device) excluded:

NHS ENGLAND does not commission the implantation of a VAD as a bridge to destination or chronic support. Whilst there is evidence suggesting that VADs may be effective as long-term treatments for chronic heart failure in patients who are not transplant candidates (destination therapy) this would require further evaluation of the cost effectiveness of the intervention.

Discharge

Patients with a VAD remain under the care of the specialist centre. This includes the period of time spent awaiting a heart transplant (bridge to heart transplant) or spent awaiting a decision on eligibility for heart transplant (bridge to decision).

Patients who have a VAD inserted but later become ineligible for heart transplantation will need to receive life-long care from the specialist centre (unintended destination therapy). This is not covered by this Service Specification. Patients who have recovered sufficiently to no longer require a heart transplant will be discharged to their local services (bridge to myocardial recovery).

Patients with a VAD who receive a heart transplant will have the VAD explanted, and be discharged from the VAD service to the heart transplant service.

Risk management

Service providers are responsible for managing the logistical arrangements for on-call teams, clinical resources, and recipient coordination.

When surgical teams treat patients who have, or are at risk of having transmissible spongiform encephalopathy's (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 http://www.dh.gov.uk/ab/acdp/tseguidance/index.htm. 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.

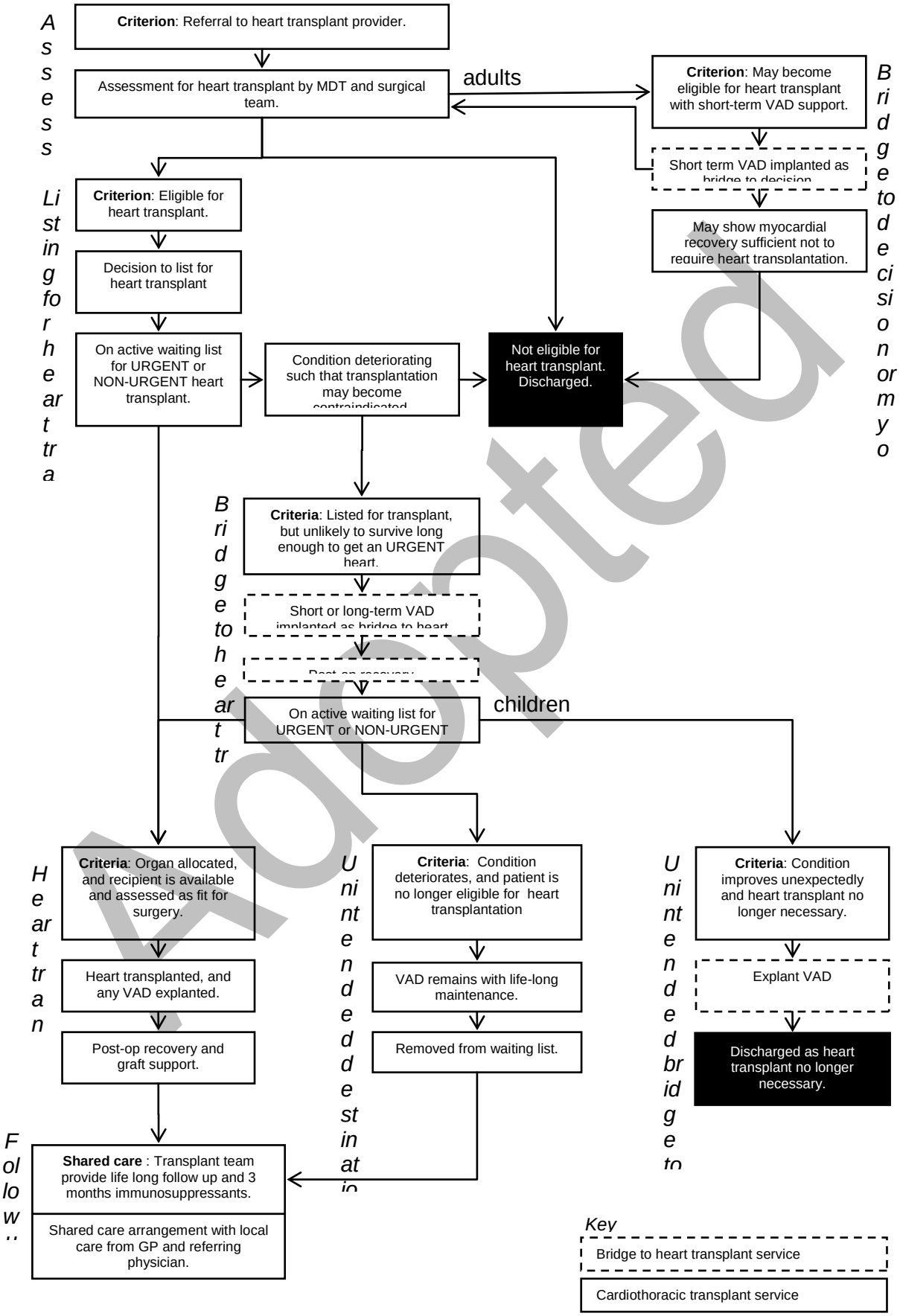
All providers offering a service to under 18 years of age should ensure they are compliant with the requirements to safeguard children, and follow current guidance on obtaining consent from children.

Discharge criteria

Possible discharge pathways for VADs patients are shown on the care pathway chart.

Patients are discharged when they are no longer eligible for heart transplant (due to either improvement or decline in clinical condition), or when they receive a heart transplant.

Heart transplant and bridge to heart transplant care-pathway



3. Applicable Service Standards

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

VAD centres are required to submit data to NHS Blood and Transplant as part of a continuous evaluation and audit. Age, sex, diagnosis, intention to treat, survival following VAD implantation, VAD type, whether transplanted or explanted and survival post transplant or explant are continuously monitored. Data requirements may be varied by agreement.

The UK VAD Forum consists of expert VAD representatives (VAD cardiologists and surgeons) from each centre, representatives of the NHS England and NHS Blood and Transplant. It currently meet twice a year to review and monitor audit data and clinical practice.

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 annual written reports for NHS England commissioners that demonstrate 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 service.

4. Key Service Outcomes

Quality Performance Indicator	*Threshold*	*Method of measurement*	*Consequence of breach*	*Report Due*
Length of Wait	In line with heart availability / urgency	Waiting list analysis	Review & action plan	NHS Blood and Transplant report every 6 months
Mortality	As agreed with NHSBT	CUSUM	Review & action plan	NHS Blood and Transplant report every 6 months, plus exception reporting
Outcomes		VAD database	Review & action plan	NHS Blood and Transplant report every 6 months
Bridge to heart transplant in adults (ventricular assist devices) For (a) longer-term VADs and (b) short-term VADs): • Transplanted alive • Transplanted died • Explanted alive • Explanted died • VAD alive • VAD died Actuarial survival after long-term VADs implantation at: • 30 days • 90 days • One year • Two years • Three years	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	NHS ENGLAND Annual report (September of contract year)

5. Location of Provider Premises

There are no sub-contractors for the provision of this service. The provider shall inform commissioner of any intention to sub-contract part or all of the services provision contracted to deliver outlined within this service specifications.

The providers have varying experience using long and short-term VADS, and work collaboratively to ensure patients from all areas have appropriate access

Provider
The Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital, High Heaton, Newcastle upon Tyne. NE7 7DN
Papworth Hospital NHS Foundation Trust Papworth Everard, Cambridge CB23 3RE
Royal Brompton & Harefield NHS Foundation Trust Sydney Street, London SW3 6NP
University Hospital of Birmingham NHS Foundation Trust Selly Oak Hospital, Raddlebarn Road, Selly Oak, Birmingham, B29 6JD
University Hospital of South Manchester NHS Foundation Trust Wythenshawe Hospital, Southmoor Road, Manchester M23 9LT

Appendix 1

2013/14 NHS STANDARD CONTRACT
FOR VENTRICULAR ASSIST DEVICES (VADS) FOR CHILDREN AS A BRIDGE TO HEART TRANSPLANTATION

PARTICULARS, SCHEDULE 2 – THE SERVICES, A – SERVICE SPECIFICATION

Service Specification No.	A18/S(HSS)/b Appendix 1
Service	Ventricular Assist Devices (VADs) for children as a bridge to heart transplantation
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Description

As the native heart fails, cardiac output deteriorates resulting in inadequate kidney perfusion and liver congestion. Significant renal and hepatic dysfunction results in renal failure, liver failure and bleeding and patients can become too high a risk for transplantation.

The service is for infants and children referred to the national service for acute cardiac failure, who are listed for heart transplantation, and whose condition necessitates the use of a ventricular assisted device (VAD).

Left ventricular assist devices (LVADs) augment the circulation in these patients, not only saving their lives but also improving secondary organ function for transplantation, reducing pulmonary hypertension and allowing for improvement of nutritional status.

The devices work by supporting the pumping action of the a failing heart until a donor heart becomes available for transplantation – a technique known as “bridge to transplant” (BTT).

Evidence base

This service was original developed using cardiac extracorporeal membrane oxygenation (ECMO). ECMO can only be used for about a month and using the ECMO pump only will extend usage for another month. This time is insufficient for many patients awaiting heart transplants due to the limited availability of donor hearts. The Berlin Heart devices were introduced to extend the period for which a patient could be bridged to transplant. Berlin Hearts are used for all heart transplant patients who are likely to wait longer than one month for a donor heart. Heartware devices are used in teenagers when possible as the risk of cerebral infarction is significantly less.

Choice of VAD is at the discretion of the clinician and should be evidence based. The VAD Forum should routinely review the range of devices and outcomes and, where possible, make clinical recommendations on device use.

More than 80% of children who are bridged to transplant, survive and receive a heart. A small number of children who are bridged to transplant make an unanticipated recovery, such that a heart transplant is no longer required and the VAD can be explanted (unintended bridge to recovery).

2. Scope

2.1 Aims and objectives of service

Aims

This service is provides a comprehensive service for infants and children (under the age of 17years) referred for acute cardiac failure, who have failed to respond to maximum conventional treatment and who are candidates for mechanical support as a bridge to heart transplant. The service can be accessed via elective and non-elective routes. Patients are eligible for referral to the service if they have deteriorating heart function and clearly would not survive long enough to be transplant recipients despite the provision of an *"urgent"* category nationally. Patients must be appropriate candidates for cardiac transplantation.

Objectives

The service ensures patient survival and minimal morbidity until a suitable donor heart becomes available. More than 80% of children who are bridged to transplant, survive and receive a heart. This is a critical adjunct to the nationally commissioned cardiothoracic transplantation service and the two services are highly interwoven. Providers will submit data to the NHS Blood and Transplant VAD database.

2.2 Service description/care pathway

The service is available 365 days a year 24 hours a day**.** The service is characterised by:

- secondary or tertiary care referral access only;
- provided by specialist centres only;
- specialist centre network model of care;
- multidisciplinary working;
- links to existing cardiothoracic transplant services;
- and providing services to infants and children who fit the eligibility criteria.

The information below is a summary, and further details are given in the service standards.

Referral

All *VADs for Children as a Bridge to Heart Transplant Service* patients are initially referred to the Heart Failure team either from within the two Trusts or directly from consultants in other hospitals.

Assessment

The Heart Failure team undertake an assessment of the suitability of patients with end-stage heart failure for heart transplantation. If they are suitable and require mechanical support they are placed on the *VADs for Children as a Bridge to Heart Transplant* programme and listed as awaiting organ donation with the UK Transplant Authority.

VAD insertion

Bridging to transplant involves the:

- Operative insertion of the Left VAD/BiVad or provision of ECMO support depending on clinical assessment and Intensive Care.
- Immediate post-insertion care and management of LVAD, BiVad, ECMO.
- Long term care and management of LVAD and BiVad on the Cardiology ward until transplantation
- Support services for the child and family, psychosocial, school, dieticians, play therapists
- The provider will work with the NHS England to ensure sufficient considerations are given to communications.
- Work with families who have been supported by the service to improve service design.
- The service works closely with the risk management team.

High cost coagulation products and anti-fungal drugs are excluded from the service designation.

Bridge to heart transplant

Patients with a VAD remain under the care of the specialist centre for the period of time spent awaiting a heart transplant (bridge to heart transplant).

There is a dedicated multiprofessional paediatric team skilled in the management of patients requiring Bridging to Heart Transplantation**.** Clinical Nurse Specialists are also available to prepare the patient and family for Bridging to Heart Transplantation and Heart Transplantation. They also run the competency based education and training programme for staff, patients and families. The service is delivered in the Cardiac Intensive Care unit while the child requires intensive care support. Once support has been established acutely the patient is transferred to the high dependency unit on the cardiology ward

If the patient dies while being bridged then the Bridge to Transplant team will undertake bereavement support with the family including telephone support and organising a bereavement meeting, the timing to be determined by the family.

Discharge

The patient is discharged from the *VADs for Children as a Bridge to Heart Transplant* care-pathway when the VAD is removed, either during a heart transplant or because of an unanticipated recovery. From transplantation onwards the patient is managed as part of the NHS England commissioned *Cardiothoracic Transplantation Service*.

Risk Management

Service providers are responsible for managing the logistical arrangements for on-call teams, clinical resources, and recipient coordination.

When surgical teams treat patients who have, or are at risk of having transmissible spongiform encephalopathy's (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 http://www.dh.gov.uk/ab/acdp/tseguidance/index.htm. 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.

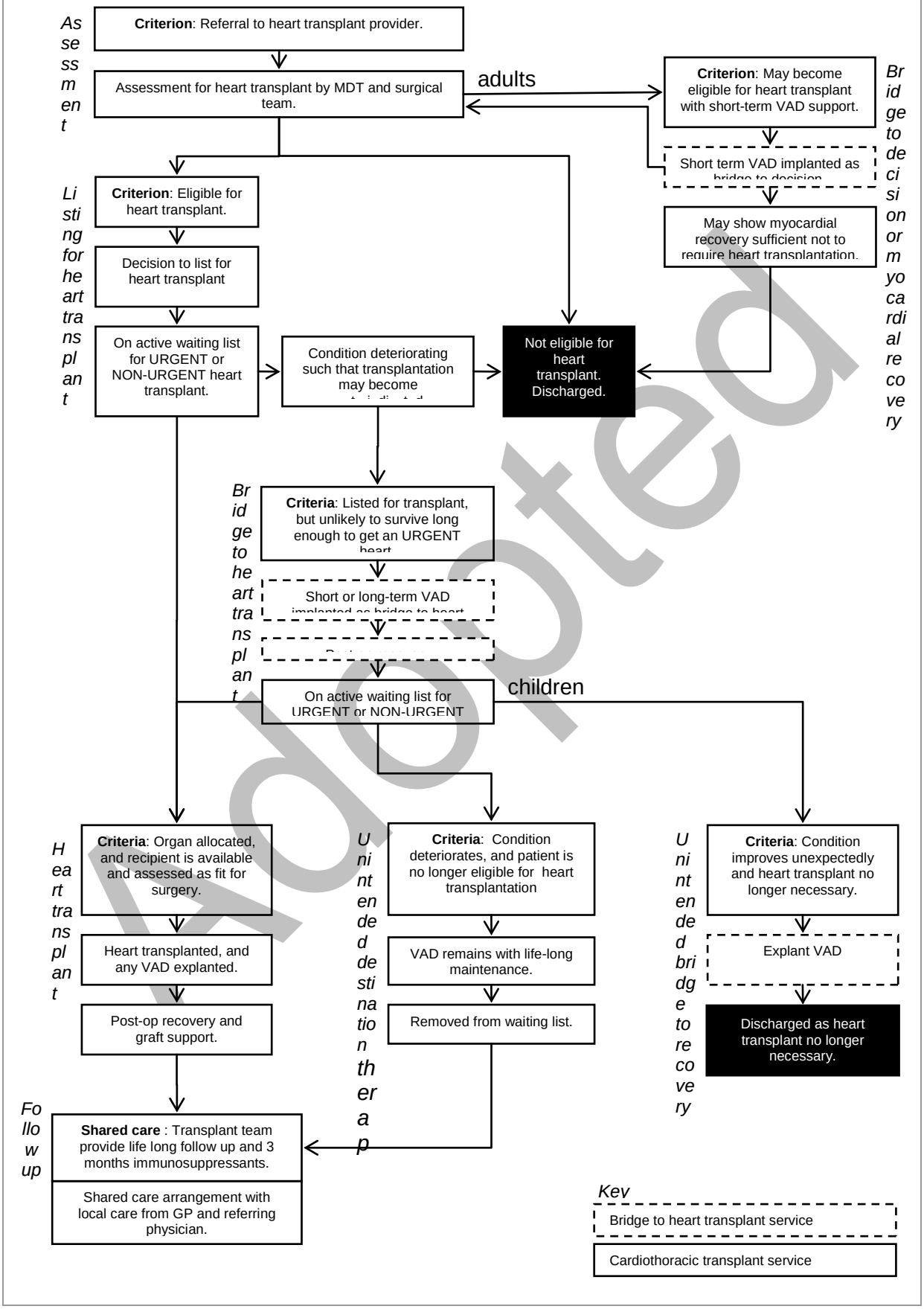
This service specification does not limit the pharmacological treatment options available with regard to transplant care, provided they are met within the existing level of investment. This includes desensitisation due to graft-recipient mismatch.

All providers offering a service to 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 are transitioned to the *Cardiothoracic Transplantation Service* once the child has received a heart transplant. The *Cardiothoracic Transplantation Service* then manages the discharge planning for the patient.

Heart transplant and bridge to heart transplant care-pathway



3. Applicable Service Standards

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

There are regular morbidity and mortality meetings with the whole cardiothoracic team in addition to critical incident reporting. Results are benchmarked nationally via NHS Blood and Transplant and CUSUM monitoring is performed by the Royal College of Surgeons Clinical Effectiveness Unit. If there is a breach of early mortality trends then an immediate internal review is held, commissioners are informed, and this is followed by external review as necessary.

The *VADs for Children as a Bridge to Heart Transplant* has agreed service standards and is supported by detailed clinical practice guidelines. All centres are reviewed at least annually, and produce a written annual report for NHS England commissioners that demonstrates compliance with the current service standards and requirements for equity of access.

4. Key Service Outcomes

Quality Performance Indicator examples	*Threshold*	*Method of measurement*	*Consequence of breach*	*Report Due*
Mortality	As agreed with NHS Blood and Transplant	CUSUM	Review & action plan	NHS Blood and Transplant report every 6 months, plus exception reporting
Outcomes	As agreed with NHS Blood and Transplant	VAD database	Review & action plan	NHS Blood and Transplant report every 6 months

Bridge to heart transplant: • Successful transplants when ECMO (or VAD) is used as bridge to transplant • Successful transplant following bridge to transplant, survival to discharge	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	NHS England Annual report (September of contract year)

There is an UK VAD Forum to share learning from audits and agree clinical guidelines and service standards.

5. Location of Provider Premises

There are no sub-contractors for the provision of this service

Provider
Great Ormond Street Hospital for Children NHS Foundation Trust Great Ormond Street, London, WC1N 3JH
The Newcastle upon Tyne Hospitals NHS Foundation Trust Freeman Hospital, High Heaton, Newcastle upon Tyne. NE7 7DN