

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

<b>Service Specification No.</b>	A04/S/a
<b>Service</b>	Specialised Vascular Services (Adults)
<b>Commissioner Lead</b>	Kathy Blacker
<b>Clinical Lead</b>	Professor Matt Thompson
<b>Period</b>	12 months
<b>Date of Review</b>	

#### 1. Population Needs

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

Vascular disease relates to disorders of the arteries, veins and lymphatics. Conditions requiring specialised vascular care include: lower limb ischaemia; abdominal aortic aneurysm (AAA); stroke prevention (carotid artery intervention); venous access for haemodialysis; suprarenal and thoraco- abdominal aneurysms; thoracic aortic aneurysms; aortic dissections; mesenteric artery disease; renovascular disease; arterial/graft infections; vascular trauma; upper limb vascular occlusions; vascular malformations and carotid body tumours.

The scope of the specialised service includes deep vein reconstruction and thrombolysis for deep vein thrombosis (DVT) but excludes varicose veins and inferior vena cava (IVC) filter insertion.

The prevalence of vascular disease increases with age. Average life expectancy continues to rise especially in males. This suggests that demand for vascular services is likely to increase over time. There are currently an estimated 3m people with diabetes mellitus in England, and prevalence is increasing. Vascular disease is the major cause of morbidity in diabetes and the risks of disease progression are higher, with an epidemic of diabetic foot disease expected in the next decade.

Smoking is a major cause of vascular disease and over 80% of vascular patients are current or ex-smokers. Around 20% of the population over 60 years of age have peripheral arterial disease, with about a quarter of these affected being symptomatic. Approximately 4% of men aged 65 have an enlarged aorta although not all go on to develop a significant aneurysm. The National AAA Screening Programme (NAAASP) is now fully operational in England. ~~will be fully instituted in the next year.~~

Historically the UK does not compare well internationally for certain vascular procedures. It had the highest mortality rates in Western Europe following elective abdominal aortic aneurysm surgery (7.9% UK vs 3.5% Europe (Vascunet 2008) and is among the slowest nations for uptake of new endovascular technology. Patients are not always treated by a vascular specialist and stay longer in hospital following their surgery than the rest of Europe. There are also significant gaps in the provision of emergency vascular interventional radiology services.

The Vascular Society of Great Britain and Ireland (VSGBI) and the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) have called for a reorganisation of vascular services for emergency and elective care to optimise outcomes for patients. The Abdominal Aortic Aneurysm Quality Improvement Programme (AAA QIP) was initiated after the UK's higher mortality was recognised.

A minimum population of 800,000 is considered necessary for an AAA screening programme and is often considered the minimum population required for a centralised vascular service. This is based on the number of patients needed to provide a comprehensive emergency service, maintain competence among vascular specialists and nursing staff; the most efficient use of specialist equipment, staff and facilities, and the improvement in patient outcome that is associated with increasing caseload.

Over the last few years there have been a number of changes in the structure of vascular services which will start to influence and improve service quality, efficiency and clinical outcomes. However more restructuring will be required to deliver high quality services on an equitable basis. A number of services are currently under active review with implementation plans delivering service changes which will all be completed during 2016/17-2017/18. Progress will need to continue on these reviews and the further reviews required, ensuring the appropriate service configuration is achieved in the next 2-3 years. The context of these reviews also needs to take into account changes in training and the service implications, for all the specialists involved in the delivery of vascular services. Vascular surgery became an independent specialty in 2012.

## **Local Context**

## **Evidence Base**

In outlining the level and nature of service expected from providers, this service specification is written in the light of the recommendations and published evidence of the Department of Health (DH), the VSGBI, the Royal College of Radiologists (RCR), NCEPOD and all relevant NICE Guidance.

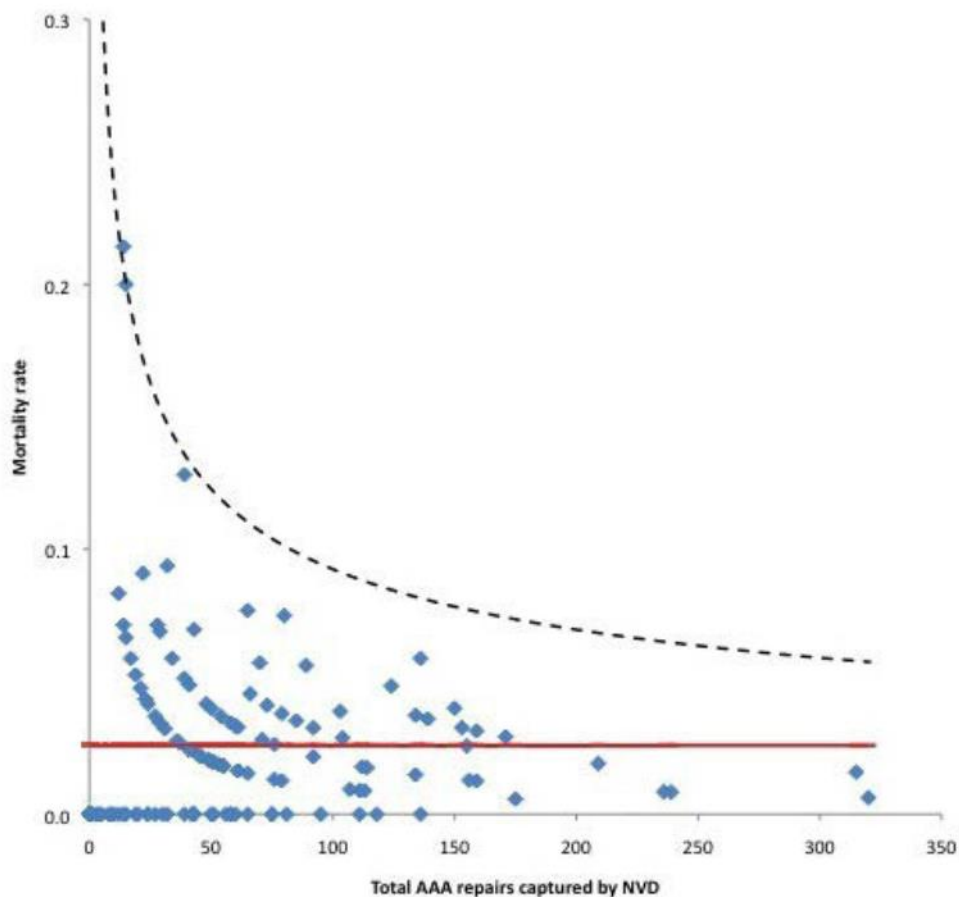
The NCEPOD Report 2005 into patient outcome and death following abdominal aortic aneurysm (AAA) found the overall mortality rate for elective surgery was 6.2%.

The VSGBI and NCEPOD guidance on the provision of emergency and elective vascular surgery services states that the best outcomes are achieved in specialist vascular units with dedicated vascular teams available 24 hours a day, seven days a week.

The VSGBI recommends fewer and higher volume units. The evidence supports minimum numbers of elective procedures that vascular units should undertake and links surgeon elective volume with outcome.

The evidence base concerning the relationship between patient outcome and the organisation of vascular services has become more extensive over the past few years. There is a strong evidence base that suggests that mortality from elective aneurysm surgery is significantly less in centres with a high caseload than in units that perform a lower number of procedures. A meta-analysis of the existing literature (Holt, Poloniecki et al. 2007) reviewed studies containing 421,299 elective aneurysm repairs and reported a weighted odds ratio of 0.66 in favour of higher volume centres dichotomised at 43 cases per year. This result echoes meta-analyses of most complex surgical interventions and should be regarded as definitive and highly informative.

However, although robust, meta-analyses can be criticised due to publication bias, heterogeneity and the predominance of data from certain countries, additional information may be gathered by analysing national administrative data. HES data for elective aneurysm repair in the UK between 2000-2005 (Holt, Poloniecki et al. 2007) demonstrated that the mean mortality for an elective repair was 7.4%, and that 80% of all aneurysm repairs were carried out in units performing less than 33 cases annually. Importantly, the mortality rate in the units with lowest caseload was 8.5% as compared to the 5.9% reported by units with a higher workload. Even more worrying were the many small volume centres where the elective mortality may often exceed 20%. A similar pattern was seen in a recent report from the Vascular Society – Outcomes after Elective Repair of Infra-Renal AAA 2012, and it remains noticeable that some low volume units have mortality rates vastly in excess of the national average:



Recent data have demonstrated that the early mortality difference observed between low and high volume units is maintained in the long term (Holt, Karthikesalingam et al. 2012).

With regard to ruptured AAA, the absolute mortality differences between hospitals in the lowest and highest volume quintiles reached 24% (Holt, Karthikesalingam et al.). Data on operative mortality in isolation, only tells part of the story, as case mix and patients considered “unfit” for surgery must also be considered. In these areas there is evidence to suggest disparate practices, with no surgical intervention being offered to over 50% of emergency patients with ruptured AAA in low volume units as compared to approximately 20% in the highest volume centres (Holt, Karthikesalingam et al.).

Two recent studies have investigated the effect of endovascular repair on the volume-outcome relationship for elective aneurysm surgery. The studies demonstrated that:

- Hospital volume was significantly related to elective aneurysm mortality for open repair, endovascular repair and the combined (open + endovascular) group (Holt, Poloniecki et al. 2009). There was a significant difference between endovascular mortality between the lowest and highest quintile providers (6.88 vs. 2.88%), and a 77% reduction in mortality was observed for every 100 endovascular repairs performed.

- Higher volume hospitals were more likely to adopt endovascular therapy (44% in high volume hospitals vs. 18% in low volume hospitals)(Dimick and Upchurch 2008).
- Hospital volume was an independent predictor of mortality.
- Results were defined by the total aneurysm caseload rather than either endovascular or open cohorts alone i.e. hospitals with a large, predominantly endovascular, caseload also reported better than average results from open aneurysm repair.

Screening for men over the age of 65 for AAA has been introduced: National Abdominal Aortic Aneurysm Screening Programme (NAAASP) with full roll out **has now been achieved. to be achieved by 2013.** It is hoped that there will therefore be an increase in activity for elective aneurysms and a gradual decrease in emergency aneurysm activity.

The use of endovascular and minimally invasive techniques is a rapidly developing area within vascular services and there is likely to be a further shift towards endovascular repair of aneurysm over coming years.

The evidence for volume-outcome relationships has been described for abdominal aortic aneurysms. However, there is evidence that similar relationships affect the performance of other vascular procedures including lower limb arterial reconstruction and carotid endarterectomy (Karthikesalingam et al 2010;Moxey et al 2012)

- Dimick, J. B. and G. R. Upchurch, Jr. (2008). "Endovascular technology, hospital volume, and mortality with abdominal aortic aneurysm surgery." J Vasc Surg 47(6): 1150-1154.
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- Moxey PW, Hofman D, Hinchliffe RJ, Poloniecki J, Loftus IM, Thompson MM, Holt PJ. Volume-outcome relationships in lower extremity arterial bypass surgery. Ann Surg. 2012 Dec;256(6):1102-7.

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	Target
	Unit overall elective AAA in hospital mortality	≤3.5%
	Delay from symptom to treatment for suitable patients for carotid intervention	<7 days
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	
	LOS for elective AAA repair	<7d
	Number of AAA repairs total – elective and emergency	>60
	All cause mortality AAA elective repair at 1 year	≤15%
	% of subjects with AAA ≥ 5.5cm deemed fit for intervention operated on by vascular specialist within eight weeks	≥80%
	Carotid Intervention stroke rate 30 days after surgery	<2%
	Peripheral Arterial Disease – Lower Limb Bypass (PAD) Death 30 days after surgery	<5%
	Amputation free survival 1 year post surgery	
	In hospital mortality following lower limb amputation	5%
	Ratio of below to above knee amputation in unit	>1
Domain 4	Ensuring people have a positive experience of care	
	Patients should undergo surgery for lower limb amputation on day time lists (between 0800 and 2000)	90%
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	
	Reduction in rate of amputation revision to higher level	<10%

### **3. Scope**

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

Vascular services are commissioned to provide diagnostics and treatment for vascular disease. The principal specialities involved are vascular surgery and interventional vascular radiology.

The overarching aim of elective and 24/7 emergency vascular services is to provide evidence-based models of care that improve patient diagnosis and treatment and ultimately improve mortality and morbidity from vascular disease.

The service will deliver this aim by:-

- Improving the patient experience, providing equality of access to the full range of vascular diagnostics and interventions and ensuring that patients are receiving a high quality of service, with access to the most modern techniques.
- Developing and sustaining the resilience of vascular services and the workforce providing those services.
- Improving mortality and morbidity rates for people with vascular disease and improving survival rates following hospitalisation.
- Improving complication rates following a vascular admission (short and long term).
- Reducing mortality rates by preventing death from ruptured abdominal aortic aneurysm, stroke, lower limb ischaemia and vascular trauma.
- Providing early intervention and treatment to achieve regional reductions in the incidence of stroke due to carotid artery disease and leg amputation due to peripheral arterial disease.
- Supporting other services to control vascular bleeding and manage vascular complications.
- Working jointly with the diabetic and podiatry service to optimise care, minimise tissue loss and prevent amputation.

Although care for varicose veins is often provided by vascular teams this specification excludes these procedures as they are not included in the specialised definition.

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

This service comprises the following elements:-

- Diagnosis and assessment of vascular disease (including the input of the vascular laboratory and diagnostic imaging).
- Outpatient management of patients with peripheral arterial disease.
- Inpatient spells, emergency and elective activity.
- Day case activity.
- Outpatient follow-up of patients receiving vascular surgery/endovascular interventions.
- Rehabilitation services particularly for post amputation care.

## Service Model

Vascular services need to be organised to allow reasonable volumes of elective activity to exist alongside an acceptable consultant emergency on call rota thus ensuring appropriate critical mass of infrastructure and patient volumes.

There are two service models emerging which enable sustainable delivery of the required infrastructure, patient volumes, and improved clinical outcomes. Both models are based on the concept of a network of providers working together to deliver comprehensive patient care pathways centralising where necessary and continuing to provide some services in local settings.

One provider network model has only two levels of care: all elective and emergency arterial vascular care centralised in a single centre with outpatient assessment, diagnostics and vascular consultations undertaken in the centre and local hospitals.

The alternative network model has three levels of care: all elective and emergency arterial care provided in a single centre linked to some neighbouring hospitals which would provide non arterial vascular care and with outpatient assessment, diagnostics and vascular consultations undertaken in these and other local hospitals.

The network model adopted will follow the principles and governance set out in the national guidance on Operational Delivery Networks.

## Vascular Networks

All Trusts that provide a vascular service must belong to a vascular provider network.

The network arrangements must be clearly documented and have clearly articulated governance arrangements. As well as the weekly multi-disciplinary team meetings there will be regular business meetings to ensure an inclusive and coherent approach to audit, education and training.

To avoid any misunderstanding, it is envisaged that all arterial surgery will be provided at a vascular centre, with the facilities outlined below.

Leg amputations should be undertaken in the arterial centres due to the need to improve/reduce the current perioperative mortality rate. It is recognised that, at present, due to capacity pressures, in the short-term, leg amputations may need to continue to be undertaken out-with the centres in designated units. Provider networks **will ensure that work towards the aim of** all leg amputations being undertaken in arterial centres by 2016<sup>65</sup> and develop a robust implementation plan to achieve this.

In circumstances where leg amputations are undertaken outside the arterial centre the patient must be under the care of the arterial network and the procedure undertaken by a vascular specialist. All patients considered for leg amputation including those operated on locally should be discussed by the vascular multi-disciplinary team and will be given the same opportunities for limb salvage as those treated in the arterial centre. All leg

amputation patients/procedures will be included in the network audit and recorded on the National Vascular Register.

In-patient arterial surgery and vascular interventional radiology will be available 24/7 within the arterial centre with a vascular on call rota for vascular emergencies covered by on site vascular surgeons and vascular interventional radiologists to ensure immediate access for emergency procedures and post-operative care. In practice that means a vascular medical team of a minimum of 6 vascular surgeons and 6 vascular interventional radiologists to ensure comprehensive out of hours emergency cover.

Each surgeon will need to have an appropriate arterial workload (e.g in the region of 10 AAA emergency and elective procedures per surgeon per year and commensurate numbers of lower limb and carotid procedures), which will necessitate an appropriate catchment area to generate sufficient case volume. A minimum population of 800,000 would be appropriate but for a world class service a larger catchment area will be required.

A 24/7 vascular interventional radiology rota may need to be organised on a network wide basis to ensure that interventional radiology services for other specialties, in local hospitals, are not destabilised. All participants in the rota must have the appropriate skills and competencies to undertake the full range of vascular interventional radiological procedures. Emergency access to vascular interventional radiology must be within 1 hour from initial consultation to intervention.

Where appropriate, day case and first line diagnostics procedures will be provided locally.

The network may also agree that low risk peripheral vascular interventions can be undertaken locally, to utilise local skills and local interventional vascular radiology capacity. The scope of this local provision must be clearly defined and the activity must be included in the network audit arrangements. (See appendix A).

With regard to services for patients with chronic vascular conditions arising from venous insufficiency and diabetes, local models of care will be developed.

Each vascular network will have a formalised description of where inpatient, day case and outpatient services are provided in the network.

Local protocols will be agreed to provide high quality specialist care at any non-arterial hospitals in the network. Clear written arrangements will exist for cover of inpatients and the transfer of emergencies out of hours. Formal arrangements will also exist to enable vascular-specialists working predominately at a spoke hospital to support out-patient clinics, ward work and non-arterial surgery on appropriate sites across the network.

The provider network will nominate a lead vascular clinician and a lead manager with responsibility for ensuring and maintaining implementation of the standards set out in this service specification and locally agreed policies/protocols.

All patients with vascular disease or vascular complications cared for outside the main arterial centre must have access to the same high quality of care and the same opportunities/choices of care as those patients who are in the arterial centre hospitals.

The vascular service will provide a diagnostic and treatment service through a multidisciplinary team model.

### **Specialist Vascular Team**

Patients with vascular disorders will be cared for by specialist vascular teams. These teams will include vascular surgeons, consultant anaesthetists, interventional vascular radiologists, vascular scientists, nurses, radiographers, physiotherapists, occupational therapists and rehabilitation specialists.

The vascular multidisciplinary team will be hosted by the arterial centre. Clinicians providing emergency care will be part of the vascular services multi-disciplinary team and be delivering both in and out of hours care in the network arterial centre.

Care of patients will be managed through regular multi-disciplinary team meetings which will occur at least once a week. The membership requirements for the multi-disciplinary team meeting will include a range of clinical disciplines and be formalised. The documentation will include statements on minimum levels of attendance for individuals and quoracy. It is expected that all clinicians will attend multi-disciplinary team meeting on a regular basis.

Emergency procedures will be reviewed at the next multi-disciplinary team meeting.

Discussion at the multi-disciplinary team meeting will precede elective vascular procedures being undertaken, although protocols will be developed to ensure that urgent cases are not delayed inappropriately.

The specialist vascular team will also support the care of patients under the management of other specialties.

### **Infrastructure/Facilities**

With regard to the whole vascular service across the network there will be access to the following:

- Outpatient Clinics – will include access to nurses experienced in ulcer and wound dressing. Doppler ultrasound machines should be available. There will be access to Doppler machines in the clinic.
- Vascular Laboratory – the vascular laboratory service will be available for the diagnosis and assessment of arterial and venous disease. (Service availability does not necessarily have to be within the confines of a vascular laboratory).
- Vascular Ward – patients with vascular disease will have access to dedicated vascular beds. There will be sufficient dedicated beds to accommodate the routine elective work and emergency admissions. Beds will be staffed by an appropriate skill mix of nurses who have been trained in the care of vascular patients. Doppler investigation will be available on the ward.
- Interventional radiology suite with access to nursing staff who have been trained in vascular procedures.
- Operating Theatres – a 24 hour NCEPOD emergency theatre will be accessible at

all times to undertake emergency vascular procedures.

- Operating theatres – a vascular operating theatre with experienced vascular theatre staff should be available for elective activity.
- Operating theatres – facilities for endovascular aneurysm repair should be available with facilities as described by the Joint Working Group to produce guidance on delivering an Endovascular Aneurysm Repair Service
- Anaesthesia – elective vascular services will have dedicated vascular anaesthetic input into elective services, from anaesthetists experienced in dealing with the vascular patient and with a special interest in this area.
- Intensive Treatment Unit (ITU) and High Dependency Unit (HDU) – Facilities with full renal support must be available on-site to support the vascular service. Bookable HDU/ITU with sufficient beds will be available for elective patients.
- Limb Fitting Service – the vascular service must ensure its patients have access to a local limb fitting service, which meets the standards set by The British Society of Rehabilitation Medicine.

## Care Pathways

The following care pathways will be documented by each vascular network:

- Management of acute rupture of AAA
- Investigation and management of unruptured AAA
- Investigation and management of carotid disease (link to stroke care pathway)
- Management of acute limb ischaemia
- Investigation and management of chronic vascular insufficiency
- Management of vascular access for renal patients, if undertaken by vascular specialists
- Management of vascular injury (including complications of angiography)

The following pathways are published by the Map of Medicine:

- Abdominal Aortic Aneurysm Screening
- Peripheral Arterial Disease Pathways including suspected disease, secondary care investigations, surgical revascularisation and shared care
- Venous thromboembolism pathways (VTE) risk assessment and prophylaxis and diagnosis and management

## Highly Specialised Interventions

Some interventions/treatment are complex, rare or require other specialist input such as cardiothoracic surgeons e.g. thoraco-abdominal aneurysms. These procedures will only be carried out in arterial centres with the required skills and clinical linkages.

There needs to be a close relation between vascular services and cardiology/cardiac surgery services and whilst colocation is desirable it is not essential.

The introduction of new technologies will need to be managed and developed in line with commissioning policies. This may mean that only a small number of centres nationally are identified as a provider, with a greater catchment population than general arterial centres.

The use of fenestrated and branched endovascular stents for repairing aneurysmal disease of the aorta is an area of developing practice in vascular surgery. A separate commissioning policy will describe the appropriate patient group to receive this treatment and the service provision requirements in order to deliver this treatment.

Commissioners will need to judge whether or not there is a need to develop capacity to meet population need, taking into account existing case series.

### **3.3 Population covered**

Patients will experience varied contact with the service depending on the nature and severity of their condition. Patients will fall outside the scope of this specification when discharged from the care of the specialist vascular team.

The service outlined in this specification is for patients ordinarily resident in England\*, or otherwise the commissioning responsibility of the NHS in England (as defined in “*Who Pays?*”<sup>1</sup>: *Establishing the responsible commissioner* and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

Emergency admissions ambulance coverage will reflect the network footprints. Bypass arrangements will operate to ensure arterial emergencies are taken directly to the arterial centre.

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

The service will accept all patients who have been referred via their GP or other health care professional to a vascular specialist within secondary or tertiary care, or who have presented as an emergency in secondary care and identified as a vascular emergency. There will also be referrals from the National AAA Screening Programme.

This specification excludes the care of varicose veins as these procedures are outside the scope of the specialised service definition.

Vascular services for children are covered in the specialist paediatric surgery service specification.

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

Vascular services link to a range of other clinical specialties and services:

#### **Co-located services**

- Intensive care
- Interventional vascular radiology

#### **Interdependent services**

- Stroke surgery and vascular opinion on stroke management
- Limb salvage surgery

- Diabetes specialist hospital services and diabetic community services
- Renal inpatient units
- Interventional cardiology
- Cardiac surgery
- Thoracic surgery
- Major trauma centres and trauma units

#### Related services

- Rehabilitation services
- Limb fitting service

#### Relevant networks and screening programmes include:-

- Cardiac/Stroke networks
- Renal networks
- Critical Care networks
- Trauma networks
- AAA screening programme

## 4. Applicable Service Standards

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

There is a range of guidance available covering vascular services which set out the required service standards. The most significant are:-

- VSGBI: The Provision of Services for Patients with Vascular Disease 2012.
- NHS Abdominal Aortic Aneurysm Screening Programme Guidance for Public Health and Commissioners, July 2009.
- Royal College of Radiologists – Setting the Standards of Providing a 24 hour Interventional Radiology service, September 2008.
- Royal College of Radiologists – Standards in Vascular Radiology – 2011.
- NCEPOD Report 2005 – Abdominal Aortic Aneurysm – A service in need of surgery.
- VSGBI and the Royal College of Surgeons – Training in Vascular Surgery and Standards for Vascular Training – 2011.
- Medicines and health products Regulatory Agency (MHRA) Joint Working Group to produce guidance on delivering the Endovascular Aneurysm Repair (EVAR) Service (RCR, BSIR, VSGBI, Vascular Anaesthesia Society of Great Britain and Ireland(VASGBI), MHRA Committee on the Safety of Devices) – December 2010.

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

The core standards which ultimately shape the configuration of vascular services include:-

- As the new specialty of vascular surgery is established provision will need to be made for the separation of vascular and general surgery with vascular surgeons only treating patients with vascular disease, this will be required at both consultant and trainee level.
- Patients with a vascular emergency will have immediate access to a specialist vascular team at the arterial centre with on-site vascular surgery and interventional vascular radiology.

The arterial centre in the network will perform a high volume of vascular procedures per year. There is debate about the minimum/ideal volume of procedures. However, 6 surgeons, each with around 10 AAA procedures per surgeon per year would indicate at least 60 AAA procedures per centre. There would be a commensurate number of lower limb procedures.

The arterial centre will also perform a high volume of carotid endarterectomy procedures. A minimum number of 50 is indicated.

All vascular consultants working in vascular networks must routinely enter data onto the following databases/audits:-

- The National Vascular Database
- The Carotid Endarterectomy Audit (CEA)
- National Vascular Registry (when functional)
- The British Society of Interventional Radiology BIAS databases

Endovascular aneurysm repair (EVAR) will only be performed in specialist centres by clinical teams experienced in the management of AAAs. These teams will have appropriate expertise in all aspects of patient assessment and the use of endovascular aortic stent-grafts including the necessary expertise to manage complications encountered during these procedures.

Vascular centres providing post screening AAA repair must meet all the standards set out by the NAAASP

**NB: The AAA and CEA volumes quoted are currently indicators but over time as services are reconfigured will become the minimum.**

NICE guidance of significance to elective and emergency vascular services, exists as follows:-

- CG10 Type 2 diabetes footcare – (January 2004)
- CG66/87 Diabetes – type 2 (update): (May 2008/May 2009)
- CG68 Stroke - (July 2008)
- CG92 Venous thromboembolism – reducing the risk (January 2010) o CG119 Diabetic foot problems-inpatient management – (March 2011)
- CG127 Hypertension – (August 2011)
- CG147 Lower limb peripheral arterial disease – (August 2012)
- TA167 Endovascular stent-grafts for the treatment of abdominal aortic aneurysms – (February 2009)

- TA210 Vascular disease – clopidogrel and dipyridamole – (December 2010)
- IPG52 Endovenous laser treatment of the long saphenous vein - (March 2004)
- IPG60 Thrombin injections for pseudoaneurysms - (June 2004)
- IPG74 Balloon angioplasty with or without stenting for coarctation or recoarctation of aorta in adults and children - (July 2004)
- IPG79 Stent placement for vena caval obstruction - (July 2004)
- IPG127 Endovascular stent-graft placement in thoracic aortic aneurysms and dissections – guidance (June 2005)
- IPG163 Stent-graft placement in abdominal aortic aneurysm – Guidance (March 2006)
- IPG229 Laparoscopic repair of abdominal aortic aneurysm - (August 2007) (February 2009)
- IPG388 Carotid artery stent replacement for asymptomatic extracranial carotid stenosis – (April 2011)
- IPG390 Endovascular stent-grafting of popliteal aneurysms – (April 2011)
- IPG389 Carotid artery stent placement for symptomatic extracranial carotid stenosis – (April 2011)

## 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)

## 6. Location of Provider Premises

The Provider's Premises are located at:

*ONLY LIST PROVIDERS IF THERE HAS BEEN A FORMAL DESIGNATION PROCESS.*

## 7. Individual Service User Placement

### Key Quality Standards

#### Abdominal Aortic Aneurysm

Metric	Agency	Definition	Target	Acceptable
Mortality	NVD/NVR	Unit overall elective AA in hospital mortality (by end 2013)	≤3.5%	<6%

Length of stay	<del>NVD</del> /NVR	LOS for elective AA repair	<7d	<10d
Number of AA repairs per arterial centre	<del>NVD</del> /NVR	Number of AAA repairs (total – elective and emergency)	>60	>50
Mortality: elective repair	<del>NVD</del> /NVR	All cause mortality at 1 year (collect from ONS)	≤15%	≤20%
Time to treatment	NAAASP	% of subjects with AAA ≥ 5.5cm deemed fit for intervention operated on by vascular specialist within eight weeks	≥80%	≥60%

#### Carotid Intervention

Metric	Agency	Definition	Target	Acceptable
Stroke rate	<del>NVD</del> /NVR*	Stroke rate 30 days after surgery	<2%	<3%
Mortality	<del>NVD</del> /NVR	Death rate 30 days after surgery	<1%	<2%
Referral	National Stroke Strategy	Delay from symptom to treatment for suitable patients (by 2013)	<7 days	<14 days

\*National Vascular Registry

#### Peripheral Arterial Disease – Lower Limb Bypass (PAD)

Metric	Agency	Definition	Target	Acceptable
Mortality	<del>NVD</del> /NVR	Death 30 days after surgery	<5%	<10%
Amputation free survival	<del>NVD</del> /NVR	Amputation free survival 1 year post surgery	Needs benchmarking in NVR	

#### Lower Limb Amputation

Metric	Agency	Definition	Target	Acceptable
Mortality	<del>NVD</del> /NVR	In hospital mortality	5%	≤15%
Procedure	VSGVI QIF*	Patients should undergo surgery on day time lists (between 0800 and 2000)	90%	75%
Procedure	VSGBI QIF	Ration of below to above knee amputation in unit	>1	1
Outcome	VSGBI QIF	Rate of amputation revision to higher level	<10%	<12%

\*Quality Improvement Framework

## **Appendix A (linked to Appendix B)**

### **The Provision of Vascular Interventional Radiology Services to Patients at Non Arterial Hospitals within a Vascular Network**

#### **What constitutes an MDT?**

Major arterial cases that are being considered for intervention should be discussed at a Vascular MDT. The MDT should be held at least once a week and involve all clinicians concerned with the care of vascular patients. This will include vascular surgeons and interventional radiologists and may include vascular nurses, radiographers, radiology nurses, other medical specialities and anaesthetists.

There should be one MDT meeting for each vascular network, where patients can be considered for all available open and endovascular treatments. Clinicians from non-arterial networked hospitals should be encouraged to attend in person, but arrangements for teleconferencing should also be available. In some centres it may be appropriate to have separate specialised MDTs.

#### **What sorts of patients are suitable for peripheral angioplasty or stenting at non-arterial sites?**

All major arterial interventions should be performed on the designated arterial site with 24/7 cover from vascular surgery, interventional radiology and anaesthesia/ITU. Subject to locally agreed protocols audited for quality of outcomes against agreed standards, some patients may be managed on non-arterial sites, so long as there are robust arrangements for transfer in case of emergency. These will primarily involve patients which can be managed as day cases. Patients requiring an overnight stay for social rather than medical issues must be managed on a ward experienced in the care of vascular patients; this should include 24/7 cover arrangements for the management of complications. Renal patients requiring intervention can be treated within a designated renal access/transplant centre, so long as there are firm 24/7 protocols for vascular referral if required.

#### **What sorts of workloads are appropriate to maintain skills?**

All patients undergoing vascular interventional procedures should be recorded on locally or nationally held databases. Those hospitals with insufficient workload to maintain competency, should discuss transferring their caseload to a designated arterial centre.

#### **How do we measure competency?**

All patients undergoing peripheral vascular intervention should be audited through the national databases (e.g. NVR/British Society of Interventional Radiologists Iliac Angioplasty and Stenting database (BIAS)) and complications discussed at a regular mortality & morbidity meeting. This should be convened centrally and outcome measures should include death or major complication (i.e. bleeding, occlusion, amputation). In

addition, details of urgent transfer or request for assistance should be monitored and audited annually.

**Should a surgeon be present on site if intervention is being carried out?** (please also see Appendix B)

All vascular surgeons involved in a vascular network should perform their major arterial cases at a designated arterial hospital, but must provide a daily service to non-arterial sites. This will involve attendance at OPD clinics, ward rounds to review patients, either prior to or after their intervention at the major arterial centre, and to support colleagues from other specialties requiring vascular assistance. There will not necessarily be a vascular surgeon present at all times, but there should be formal on-call rotas to allow for 24/7 cover for all patients in an emergency.

**What should the transfer arrangements be if patients require emergency surgical intervention?**

These should be decided by agreed protocols and will vary depending on the local arrangements for provision of specialty services and geography. Where 24/7 cover is not possible, this must be provided by the designated arterial centre with robust arrangements in place for review/transfer. This should apply to all clinicians performing arterial or venous catheterisation.

## **Appendix B**

### **Definition of Service Provision Requirements for Non-Arterial centres within a Vascular Network**

#### **Introduction**

This aims to define the requirements for a non-arterial centre where the preferred model of care is delivered by centralising inpatient arterial care to a Arterial Centre with key aspects of the vascular service being maintained at Non-Arterial Centres across a Vascular Network. This serves the dual aims of generating the best outcomes for patients requiring inpatient care whilst delivering as much of the service as possible closer to the patient.

There is no single model that describes how vascular services should be provided at Non-Arterial Centres, this will be subject to local factors such as geography and pre-existing service configuration, but there are number of key factors to consider which will be common to all. These include provision of outpatient clinics, timely review of inpatient referrals, day-case lists and supporting allied specialities such as Diabetic Foot Services.

In many areas an Arterial and Non-Arterial or hub and spoke type arrangement already exists and in such cases the model of service provision should be reviewed in light of the recommendations in this document.

Speed of access to urgent vascular assessment and investigation should not be dependent on whether a patient enters at the Arterial Centre (hub) or Non- Arterial Centre

(spoke). Minimising inequalities should be a quality indicator of any reconfiguration, with patients prioritised according to need, not geographical location. It is imperative that proposed changes to service provision are communicated effectively to relevant parties throughout the reconfiguration process, with service reorganisation resulting in improved access to specialist vascular care at Non-Arterial Centres sites, for both elective and emergency cases.

### **Vascular consultant presence at Non Arterial Centres sites**

Vascular presence at Non –Arterial centres is primarily required to provide outpatient clinics, perform day case lists, manage ward referrals on inpatients admitted under the care of other specialties, support medical specialties and deal with patient related administration.

Other activities which can be utilised to extend the vascular presence include medical student teaching. The number of sessions required to fulfil these duties is dependent on the size of the hospital should be spread through the week and should not be regarded as a pre-requisite that a vascular presence is provided Monday to Friday from 9 to 5. The aim should be to ensure a presence on part, or all, of 3 to 5 days a week, which will enable inpatient referrals to be seen within 24hrs wherever possible. Surgeons are not required to be present at Non-Arterial centres outside of specific sessions to cover an on-site vascular emergency, It is recommended that each Non-Arterial centre is allocated a minimum of 2 surgeons, with the number of delegated surgeons and sessions increased depending on the size of the Non-Arterial centre to enable the development of professional and referral relationships with other specialties and GPs and facilitate cross-cover. It is estimated that 40% of an individual consultants' job plan will be devoted to the Non–Arterial centre, with the remainder at the Arterial Centre for consultants with a split site contract. It is essential that in the event of gaps in on-site presence, there are clear pathways in place describing the management of urgent referrals and vascular emergencies.

In most cases of reorganisation, consultants at Non-Arterial Centres are unlikely to have regular junior medical support, with the service predominantly consultant delivered. If there are pre-existing arrangements with middle-grade support then these may be retained as part of delivering the agenda of teaching and training, although in practice, this type of support is likely to be unpredictable, due to commitments to general surgery rotas, and should be regarded as supernumerary.

### **Vascular Specialist Nurses (VSN)**

It is envisaged that the role of VSNs will become increasingly important in the delivery of vascular services generally, especially at Non-Arterial Centres. It is recommended that, during any reconfiguration, their role is reviewed and developed as required in order to support consultant colleagues in out-patient clinics, facilitate management of inpatient referrals and act as a link for patients being worked up for inpatient treatment at the Arterial Centre. It is anticipated that VSNs will need to adopt a much more proactive role, acting as the patients advocate and the principle point of liaison between the Arterial and Non-Arterial centres.

In most cases it is likely that the existing VSN complement will need to be increased, with at least one VSN, working to the model described, allocated per site. One option

would be to introduce a degree of rotation so that VSNs have Arterial Centre commitments in addition to their Non Arterial Centre duties enabling professional development, team working and a degree of cross-cover.

### **Emergency cover**

All Trusts will have systems in place for vascular cover and it will need to ensure that the initial call regarding a vascular emergency will need to be directed to the on call vascular surgeon at the Arterial Centre. Emergencies deemed to require admission or urgent assessment will need to be transferred to the Arterial Centre. There will, however, be rare occasions in which it may be necessary for a vascular surgeon to travel to the patient. In all circumstances the call for assistance will be directed to the Arterial Centre and the on call vascular surgeon will determine the most appropriate way to manage the case.

Ambulance services will need to be informed of the changes to vascular services and, where possible, steps should be taken to revise existing operating policies to enable direct transfer of vascular emergencies to the arterial centre, bypassing non-arterial sites. In the event that a vascular emergency presents at a Non-Arterial Centre clear guidelines must be developed to facilitate prompt ambulance transfer, especially in the case of suspected/confirmed ruptured aortic aneurysm. These arrangements are similar to those used to manage major trauma cases.

If an unforeseen emergency occurs in a non-vascular theatre at a Non-Arterial centre the initial call for help should be directed to the on call vascular surgeon at the Arterial centre to determine the best course of action. Where a vascular surgeon is available locally they can be detailed to attend the case. If there is no vascular surgeon available locally it will be necessary to dispatch a surgeon from the Arterial centre to deal with the emergency if transfer is impossible. It is therefore essential that adequate vascular instruments and operating trays are kept and maintained at Non-Arterial Centres for such emergencies

### **Outpatient Clinics**

Outpatient Clinics form one of the main components of the service at the Non-Arterial centres, enabling patients to be seen closer to home. Clinic templates will need to be reviewed as part of any reorganisation in order to ensure there is sufficient capacity for the predicted demand. Booking systems should be able to flex the initially agreed template according to demand in order to ensure that clinics are used as effectively as possible. Templates should be flexible enough to enable urgent referrals to be seen within a week. There should also be a facility for very urgent cases to be seen at the Arterial centre within a shorter timeframe if clinically necessary. The system should also enable cases presenting urgently to A&E, or from GPs, to be seen in the next available clinic at the Non-Arterial Centre, rather than being admitted as an emergency to the Arterial Centre.

It is recommended that, where appropriate, new patients should be offered a 'one-stop' service, with consultation and Duplex scanning taking place at their initial visit. This is convenient for patients and reduces the demand for follow-up appointments.

### **Vascular Lab support**

An appropriately resourced Vascular Lab, in terms of both personnel and equipment, is essential to enable the service to run as efficiently as possible, especially in enabling the provision of one-stop clinics and urgent investigation of inpatients referred from other departments such as Stroke and Diabetes. The Vascular Lab should have systems in place to provide follow-up of patients after arterial intervention, avoiding the need for further follow-up appointments after the first post-procedure visit.

The Vascular Lab is also the ideal place to base an aortic surveillance programme for patients with an aneurysm identified outside of the National AAA Screening Programme.

Thought should be given to the possibility of developing a degree of cross-site cover by vascular technologists within the network in order to cover significant gaps in service at Non-Arterial centres sites.

### **Other Diagnostic services**

The relevant diagnostic services should continue to be provided at Non-Arterial Centres within the network.

In addition to Duplex ultrasonography patients should have ready access to CT and MR angiography. Image transfer is increasingly being facilitated by new PACS systems but where these are not yet in place there should be systems in place to ensure rapid transfer of relevant imaging.

For the most part it should be possible for most preoperative workup to be carried out at the Non-Arterial Centre, although more complex cardiorespiratory assessment such as cardiopulmonary exercise testing and stress echocardiography may need to be provided at the hub.

### **Inpatient referrals**

There should be a well described system for making referrals, either electronically, or via a vascular secretary/PA at the Non-Arterial centre with the stated aim that patients are seen within 24hrs whenever possible. If consultant or VSN review cannot take place within a reasonable timeframe, or a more urgent opinion is required, the referrer will need to be directed to the Arterial Centre on-call consultant to discuss the best course of management.

### **Day-case lists**

These serve the dual purpose of maintaining a vascular presence as well as treating patients locally and will form the bulk, if not all, of the operating at Non-Arterial sites. The overwhelming majority of day-case work will involve treatment of varicose veins and vascular access work.

For varicose veins treatment should follow the recently published NICE guidance (<http://publications.nice.org.uk/varicose-veins-in-the-legs-cg168>). Day case general anaesthesia lists may also be performed with provision made for on-site cover, rather than transfer, of the rare patient who may subsequently require an overnight stay.

Vascular access work might be restricted to local and regional anaesthetic cases, which constitute the majority. This type of work may also involve placement of Hickman lines and implantable ports. More complex cases, such as those requiring general anaesthetic or an overnight stay in hospital, will be the subject of local discussion.

### **Diabetic Foot Services**

Any reconfiguration must take full account of Diabetic Foot Services at Non-Arterial Centres, ensuring that they are fully supported by the vascular team. The frequency of sessional commitments will need to be negotiated locally according to local requirements and built into local commissioning contracts and job plans for vascular consultants at Non-Arterial Centres.

These services should be headed by diabetologists, with vascular involvement for MDT meetings and combined clinics. Inpatients with diabetic foot disease should remain under the care of diabetologists, with vascular review provided as required.

Depending on local arrangements minor foot surgery, including toe amputation, on daycase lists or orthopaedic lists, may be performed without the need for transfer. Inpatients requiring more urgent or extensive treatment, however, require rapid transfer to the Arterial centre according to clear pathways. Communication should be maintained pre- and post-operatively with the Non-Arterial centre MDT when a patient is an inpatient at the Arterial centre, with full information on discharge made available to the Non-Arterial centre MDT, as well as to the patient's GP. Clear pathways should be agreed for repatriation of patients to Non-Arterial Centres following vascular intervention at the Arterial centre.

### **Major Amputations**

Patients requiring lower limb amputation represent the highest risk group in terms of morbidity and mortality. The Vascular Society's QIF for major amputation surgery aims to reduce peri-operative mortality rate after major amputation surgery to less than 5% by 2015. In addition, NCEPOD are currently undertaking a Lower limb amputation study commissioned by the Health Quality Improvement Partnership as part of a Clinical Review Programme, with the aim of exploring remediable factors in the process of care of patients who undergo lower limb amputation.

Patients requiring major amputation require appropriate early input to determine the best course of action. Wherever possible these procedures should take place in the Arterial centre on planned lists with consultant surgeon and vascular anaesthetist input. The advantages this offers in terms of improved outcomes and clinical governance outweigh the disadvantages of transferring high-risk patients. Following amputation they require a well co-ordinated approach to facilitate recovery and rehabilitation.

### **Interventional Radiology (IR) (Please also refer to Appendix A)**

There are a number of reasons for vascular IR work to continue in Non-arterial centres. These include capacity issues in the Arterial Centre, the commitment to treating patients closer to home and maintenance of non-vascular IR services. It is important that there

are agreed guidelines in place regarding this activity. Good MDT working will be pivotal in ensuring appropriate case selection and quality control. The complexity of cases manageable within this framework is for each network to determine and will be dependent on local expertise. Complex elective cases, hybrid cases and the majority of emergency cases will need to be performed at the arterial centre.

It is clearly important that vascular cover for this work is agreed, with protocols in place to deal with complications but the responsibility for the care episode i.e. admission and discharge, should lie with IR.

Inpatient work should preferably be restricted to patients under other specialties e.g. Renal and Diabetes, whose treatment is discussed with the vascular team, but who remain under their admitting team for overall care. In addition there is the potential to transfer some elective IR day-cases from the Arterial centre to non-arterial centres sites in order to facilitate throughput and mitigate potential capacity issues in the Arterial centres.

### **MDT working**

This is recognised as a key factor in driving quality of care provision. In order to be manageable within job planning constraints, however, the number of MDT meetings (MDTs) within a network should be rationalised.

Models exist in which units combine all aspects of their work (carotid, peripheral, aortic, vascular access) into a large, single, weekly MDT or, alternatively, have separate MDTs for each aspect, with input from relevant specialties.

Wherever possible efforts should be made to avoid duplication of MDTs in a network, as these become difficult to cover and the opportunities to share best practice are lost. Technology should be used to enable multiple site participation at these meetings, avoiding the need to travel, with scheduling of MDTs to enable maximal participation..

The long-term aim should be that all specialists involved in the vascular service should participate in MDT working, with mandatory attendance to at least 50% of relevant meetings. A well-structured, well-organised MDT encourages participation and should act as a trigger to revise job plans in order to enable attendance. This information is also crucial to commissioners planning the delivery of specialised services based on the process of MDT working and should ensure that the Non –Arterial centres have full participation in MDTs as a quality indicator.

### **Repatriation**

The majority of patients will be fit to be discharged home relatively soon after treatment and for these repatriation is not a major issue. An outpatient appointment at their local hospital with their vascular specialist should enable a satisfactory episode of care.

A significant proportion, however, will require prolonged rehabilitation and/or attention to

social issues e.g. following amputation. The preferred solution, wherever possible, would be for these cases to be repatriated directly to either intermediate or community care without the need for repatriation to a Non- arterial centre. If repatriation is deemed the most appropriate course of action then care should be transferred to an appropriate non-vascular specialist e.g. Stroke, Diabetes, Care of Elderly, General Surgery, Orthopaedic Surgery. Earlier repatriation to Non-Arterial Centres would make it easier for Arterial centres to accept transfers and improve continuity for outpatient follow-up but Non-Arterial centres need to ensure that clinical staff have the necessary competencies to manage post-op vascular patients. VSN support in the Non-Arterial Centre should be considered vital to ongoing care, along with supervision from the visiting vascular consultant. It is hoped that one of the key roles undertaken by the VSN would be the link up with community care.

It is strongly recommended that there are no named vascular beds in Non-Arterial centres as this has potentially serious implications for continuity of care and cover, both in and out of hours. Vascular review by visiting surgeons and locally based VSNs will continue to be a feature of care but vascular input will be minimal once deemed fit for transfer.

Close working between the various relevant agencies is important to ensure that following acute vascular treatment, patients who are no longer deemed to require an acute vascular bed at the Arterial centre should be transferred promptly along the most appropriate pathway.

It is recognised that in some networks there will continue to be named vascular beds at Non-Arterial centres, at least during transition periods. It is important that there are clear guidelines regarding suitability for transfer into these beds and, how cover is to be provided, especially out of hours. In the longer term it is recommended that networks come to arrangements that result in there being no vascular beds at Non-Arterial centres.

### **Secretarial & administration support**

Administrative support is vital in order to support smooth running of the service at Non-Arterial centres sites and to act as an interface with the Arterial centre and it is recommended that there should be one secretary/PA for 2 consultants.

At the Arterial centre, particularly in networks with more than one Non Arterial centre, the role of network co-ordinator would be key to ensure smooth transfer of patient information, and investigations. Close working between secretarial teams is crucial in order to co-ordinate booking of theatres lists to maximise utilisation and to avoid theatre cancellations for trivial reasons such as lack of notes and investigations.

Vascular surgeons with commitments to Non-Arterial centres should have ready access to a desk and PC and should be able to access relevant IT systems remotely i.e. Arterial centre from Non-Arterial centre and vice versa.