Joint Working Group to produce guidance on delivering an **Endovascular Aneurysm Repair** (EVAR) Service.

Royal College of Radiologists

British Society of Interventional Radiology

The Vascular Society of Great Britain and Ireland

The Vascular Anaesthesia Society of Great Britain and Ireland

MHRA Committee on the Safety of Devices

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British Society of Interventional Radiology

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Delivering An Endovascular Aneurysm Repair (EVAR) Service

Summary

An Expert Advisory Group representing the Royal College of Radiologists, the British Society of Interventional Radiology, the Vascular Society of Great Britain and Ireland, the Vascular Anaesthesia Society of Great Britain and Ireland and the Committee on the Safety of Devices, in association with the Medicines and Healthcare products Regulatory Agency (MHRA) was set up to provide guidance for those centres that have or are setting up an Endovascular Aneurysm Repair (EVAR) service within their Trusts. These recommendations cover the facilities, staffing and standards of equipment necessary to set up and deliver a safe and effective service for patients and satisfactory user working conditions. This advice is also extended to all independent sector organisations.

The resources detailed in this document are considered essential to provide a safe EVAR service. In the meantime, all Trusts where EVAR is undertaken, should review their existing facilities and take action to ensure that adequate resources as described (in terms of surgical, radiological and anaesthetic staffing, equipment and working environment) are available, to ensure they are providing for optimal patient outcome, staff protection and working environment and especially that adequate backup imaging is available.

Background

The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health, responsible for the regulation of medical devices and pharmaceutical products. As part of this function, it manages a device related adverse incident system for the assessment and investigation of device related adverse events, taking action as appropriate.

A few months ago the Agency became aware that it was receiving a number of adverse reports of interventional procedures in relation to the placement of stent grafts, many of which were associated with inadequate imaging facilities for fluoroscopy. Subsequent investigation of the events indicated that this factor, at least partially, contributed to a number of the adverse events, resulting in a failure to recognise and act appropriately to problems of device positioning or deployment.

MHRA subsequently wrote to Professor Adam, President of the Royal College of Radiologists, and the Presidents of other relevant professional bodies, expressing these concerns. As a result, a small group of experts nominated by these bodies was set up, as below, to produce guidance:

- The Royal College of Radiologists – Dr Mark Downes, Dr Jai Patel;
- The British Society of Interventional Radiology – Dr Trevor Cleveland;
- The Vascular Society of Great Britain and Ireland – Mr John Brennan;
- The Vascular Anaesthesia Society of Great Britain and Ireland – Dr Jonathan Thompson
- The Committee on the Safety of Devices – Dr Richard McWilliams
- MHRA – Dr Susanne Ludgate, Ms Valerie Field

EVAR is a minimally invasive alternative to open surgical repair for a number of thoracic and abdominal aortic pathologies. It requires access to the femoral artery followed by placement of a stent-graft typically beyond the left subclavian/left common carotid artery (in the case of thoracic stent grafts) or renal arteries (in the case of abdominal stent grafts). Should an irrecoverable complication occur, there may be a need to convert the minimally invasive procedure to a fully open procedure, as an emergency.

There are, therefore, two essential elements for a dedicated EVAR facility:

(i) High quality imaging equipment is crucial for the accurate positioning and deployment of the stent graft to avoid covering important branch vessels and compromising blood flow to essential organs such as the brain, the upper limb or the kidneys. Such equipment would also allow the use of alternative contrast agents, (e.g. CO^2) to minimise risk to patients.

(ii) Theatre specification setting to provide a safe, appropriate environment to allow for induction of anaesthesia, surgical cut-down, post-operative recovery and conversion to open repair, should the need arise.

Both elements need to be incorporated into any facility undertaking EVAR. The following are considered essential pre-requisites for an ideal EVAR facility.

Location

EVAR facilities should ideally be sited within or directly adjacent to an existing theatre complex. This would enable utilisation of facilities already in place for the management and recovery of patients undergoing complex interventions under general/regional anaesthesia. Such a location should, however, house high quality fixed imaging equipment and the full range of consumables required to perform the EVAR procedure and manage potential complications by endovascular means.

High quality imaging equipment is expensive and is used for a wide range of image guided interventions. Local considerations may, thus, dictate that such resources are more effectively located close to an imaging department rather than a theatre complex. This, together with other local organisational constraints, may make an alternative location away from an existing theatre complex more appropriate.

In either scenario, the location should have access to the full range of high quality imaging equipment, theatre specification room and full anaesthetic facilities and support. Trusts should assess the most appropriate location in their organisation.

Room Specification

- Design of the facility should be of the same standard and conforming to the same principles of design, sterility, power, piped gas supply and scavenging of piped gas supplies, etc as a standard surgical operating suite.
- Maintenance should be in accord with theatre standards of infection control
- Clinical and overall design specifications should be drawn up with the aid of an appropriate multi-disciplinary team. As a minimum this should include interventional radiologists, an interventional radiographer, anaesthetists and surgeons, as well as a radiation protection advisor/medical physicist. Input from theatre nurse management and operating department practitioner lead is also essential.

- Consideration needs to be given to the size of the EVAR room as this should be of sufficient dimensions to house the extensive ancillary equipment necessary and potential numbers of staff involved. The RCS has recommended a floor space of 58 m^2 and an absolute minimum of 45 m^2 for the size of operating rooms. Ideally an EVAR theatre should be larger in order to house the bulky radiology equipment necessary.
- Adequate storage space and temperature control should be available to accommodate a range of stent grafts and consumables (this is a feature that should not be under-estimated).
- The environment should be allowed optimal temperature and humidity control for the patient during the procedure, including warming facilities.
- Adequate radiation protection (this should be determined on discussion with radiation protection advisor and supervisor for staff, patients and others).
- Full integration of equipment with the hospital PACS system.

EVAR Room Equipment

- Dedicated tilting radiolucent angiography table fitted with purpose designed mattress suitable for imaging, surgery and anaesthesia.
- Piped suction both sides of the room.
- Piped medical air for powering surgical tools.
- Air filtration systems.
- Fixed ceiling mounted lights, providing adequate illumination without interfering with patient and staff flows.
- Radiation protection advisor (RPA) approved radiation protection screens.
- Standard piped gases, scavenging etc. positioned near the head of the operating table, best provided by an overhead gantry for anaesthetic requirements.
- Adequate power outlets.
- Dedicated contrast injector pumps.
- Provision of accessory equipment should be as for surgical theatres including warm air blowers, diathermy equipment, level 2 transfusion equipment, rapid fluid infusion device, fluid and patient warming devices and infusion pumps etc.

Radiology Equipment

EVAR is an image guided intervention and, as such, high quality imaging with the lowest possible radiation dose is of paramount importance.

This requires a dedicated fixed interventional x-ray machine capable of:

- digital subtraction angiography;
- rotational facility in at least two planes;
- pulsed fluoroscopy and other dose reduction features;
- road mapping, fluoroscopy fade or other similar image superimposition;
- large field of view (40cm) image intensifier or flat plate detector;
- facility to use alternative contrast media (eg. CO2);
- monitors for viewing images linked to pre-operative imaging via PACS;
- ultrasound equipment.

- In order to manage procedural complications, a full range of ancillary interventional radiology consumables should be available within the facility, eg. stents, angioplasty balloons, snares, etc.

Anaesthetics (Facilities and Equipment)

- All anaesthetic equipment and facilities should be to recommended standards for conventional operating theatres, including postoperative recovery. These include adequate space, an anaesthetic machine, mechanical ventilator and appropriate monitoring equipment to theatre standards.
- A dedicated facility or area is needed for anaesthesia, with storage space for drugs and equipment. It should be at least 17m^2 floor space and preferably larger. It should be sited within a sterile environment to allow invasive lines, neuraxial blocks to be performed to surgical standard sterility.
- When the EVAR suite is separate from the radiology suite, anaesthesia (local, regional or sedation) should only be administered by an appropriately qualified anaesthetist who is competent in providing anaesthesia in an isolated location.
- The anaesthetist should be assisted by a fully trained anaesthetic assistant who has specific training and experience in vascular anaesthetic practice.
- All areas where patients undergoing EVAR are anaesthetised must be equipped with the facility to perform invasive pressure monitoring. If anaesthesia is induced in an anaesthetic room then the monitoring should be of similar specification and condition to that used in the operating theatre.

- Facilities should be available for the rapid and appropriate provision of blood and blood products. Hospitals should ensure that personnel directly involved in the distribution and administration of blood and blood components are qualified to perform those tasks and are provided with timely, relevant and regularly updated training. Protocols and guidelines should be drawn up locally for the management of major haemorrhage so that necessary blood products and drugs are available without delay. There should also be the facility to establish prophylactic CSF drainage in some patients undergoing thoracic EVAR.
- There should be a named individual responsible for checking and maintaining the anaesthetic and monitoring equipment

Post-Procedural Care

- All patients should be managed after EVAR in a dedicated area (post-anaesthesia care unit). The standards for post-procedural recovery facilities and staffing should be the same as for similar areas in main operating theatre suites.
- Units should possess adequate critical care facilities to provide adequate and appropriate Level 2 or Level 3 care at all times before the start of any major endovascular procedure.
- Facilities to provide renal replacement therapy on-site are highly desirable. Where this is not possible, staffing, relationships and guidelines should be in place to facilitate transfer to a unit where renal support can be provided.

Radiation Protection

The following are recommended and apply both if EVAR is performed in theatre or another dedicated location. Radiation protection should always be discussed with the radiation protection advisor.

- Console room/controlled area for staff protection.
- Fixed screening unit.
- Full range of dose saving technology e.g. last image hold, last image recall, range of fluoroscopy and acquisition parameters.
- radiation protection screens to reduce scatter dose to scrub staff.

Staffing

- Multidisciplinary team of clinical specialists including interventional radiologist, vascular surgeon, anaesthetist and dedicated anaesthetic assistant experienced in vascular and endovascular anaesthetic practice both in the theatre or radiology suite settings.
- Specialist interventional radiographer experienced in working in both theatre and radiology suite settings.
- Specialist nurses trained in the use and support of endovascular procedures.
- Appropriate number of experienced scrub nurses, support nurses and support staff.
- RPA/Medical Physics involvement for quality assurance and radiation protection advice.

Backup

It is crucial to ensure that a strategy is in place in the event of facility or equipment failure. The procedure should not go ahead if there is no backup plan.

Features to be considered include:

- uninterruptable power supply to the theatre to allow continued working in the event of power failure;
- uninterruptible power supply to imaging equipment to prevent image loss in the event of power failure;
- alternative means of fluoroscopy, ie. another static unit (in the close vicinity or suitable for patient transfer) with confirmed satisfactory infection control records, or mobile C-arm (with digital subtraction angiography package) as backup only;
- alternative injector pumps.

It has been recognised that problems with facilities and equipment may have contributed to adverse outcomes from EVAR.
We therefore recommend that Trusts providing EVAR services, follow these recommendations to ensure that adequate facilities are available to perform EVAR safely and successfully.

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