



# **Standards for angiography and image-guided endovascular interventions**

**June 2018**

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## Foreword

These standards for angiography and image guided endovascular interventions replace the 2011 publication, *Standards in vascular radiology* and have been updated to take account of numerous developments to improve patient safety that have occurred, leading to changes in individual and organisational responsibilities since the last publication.

24/7 delivery of safe angiography and endovascular interventional services relies on appropriately trained, competent staff, in sufficient number, with access to adequate facilities, equipment and consumables. Pre-procedure patient assessment, consent, safety checklists, provision of sedation and analgesia in a safe and timely fashion, adequate peri- and post-procedural monitoring and care of patients with adequate handover procedures are all essential components. Robust governance procedures are essential, with formal arrangements to secure on-site delivery or patient transfer to a unit where these facilities are available.

Accurate information is available in the United Kingdom on success and complication rates for vascular procedures due to the dedication and hard work of UK vascular radiologists who have contributed so much data to various interventional radiology (IR) databases. This supports demonstration of individual performance for appraisal purposes, research and service delivery, enabling review of complications and individual and service delivery.

The Royal College of Radiologists (RCR) is grateful to members of the British Society of Interventional Radiology's (BSIR) standards committee, with leadership from Dr Raman Uberoi, for updating this guidance.

*Dr Caroline Rubin*

Vice-President, Clinical Radiology

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## Summary of key points

- There is a duty to ensure interventional radiologists have adequate training to perform vascular interventional procedures.<sup>1</sup>
- There is a duty to ensure there are appropriate staff, facilities and consumables available to perform vascular interventions safely.<sup>2-6</sup>
- There is a duty to ensure there are formal arrangements to secure elective and emergency services.<sup>2,5,7</sup>
- There is a duty to ensure adequate peri- and post-procedural monitoring and care of patients undergoing vascular interventions.<sup>6,8</sup>
- There is a duty to ensure adequate handover procedures are in place when patient care is being transferred between practitioners, teams and departments.<sup>9</sup>
- There is a duty to ensure that there is provision to administer sedation and analgesia in a safe and timely fashion.<sup>8</sup>
- Prior to commencing a procedure, the interventional radiology team must perform a surgical safety checklist.<sup>10-12</sup>
- Individual doctors (interventional radiologists) have a responsibility to demonstrate performance based on evidence drawn from their medical practice.<sup>13</sup>
- All procedural outcomes and complications should be logged and categorised according to the procedure, the operator and the clinical indication with review of major complications at morbidity and mortality meetings where necessary.
- Whenever necessary, additional education and training should be undertaken to correct deficiencies in performance.

## 1. Introduction

The aim of standards is to define aspects of practice which promote provision of high-quality services to patients. These encompass not only the individual practitioner, but also the wider team with who they provide services to patients and the facilities in place. Demonstration of a high-quality service requires regular assessment of performance and review of practice, central to which is peer review through participation in collection of data and outcomes, both locally and nationally.

Since the publication of the *Standards in vascular radiology* in 2011, numerous developments to improve patient safety have occurred, leading changes to individual and organisational responsibilities, including:

- Updates to *Good Medical Practice* (2013)<sup>13</sup>
- Introduction of the World Health Organization (WHO)/National Patient Safety Association (NPSA) surgical safety checklist<sup>10-12</sup>
- Introduction of a statutory duty of candour, following on from the Francis report<sup>14</sup>
- Introduction of National safety standards for invasive procedures (NatSSIPs)<sup>1</sup>

The title 'interventional radiologist' used in this document refers to any medical practitioner who undertakes vascular diagnostic and or interventional/endovascular procedures.

Vascular/endovascular interventions are procedures performed through the blood vessels under direct imaging guidance. These include, for example, angioplasty/stenting of arteries and veins, endovascular aneurysm repair (EVAR), percutaneous treatment of vascular malformations, embolisation procedures and trans-jugular intrahepatic portosystemic shunts (TIPSS), however this list is not exhaustive.

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## 2. Good medical practice

The General Medical Council (GMC) has defined the expectations of a registered doctor in *Good Medical Practice*.<sup>13</sup> Interventional radiologists should ensure their practice complies with the standards in the four domains of *Good Medical Practice*. Those areas particularly pertinent to interventional radiology practice are emphasised in this document.

In accordance with *Good Medical Practice*, as a doctor you must:

- Make the care of your patient your first concern
- Provide a good standard of practice and care
  - Keep your professional knowledge and skills up to date.
  - Recognise and work within the limits of your competence.
- Treat patients as individuals and respect their dignity
  - Treat patients politely and considerately.
  - Respect patients' right to confidentiality.
- Work in partnership with patients
  - Listen and respond to their concerns and preferences.
  - Give patients the information they want or need in a way they can understand.
  - Respect patients' right to reach decisions with you about their treatment and care.
- Work with colleagues in the ways that best serve patients' interests
- Be honest and open and act with integrity.

You are personally accountable for your professional practice and must always be prepared to justify your decisions and actions.

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## 3. Patient safety in vascular radiology

The safety of patients is of paramount importance. Senior management teams within organisations, particularly medical and clinical directors, as well as interventional radiologists should take steps to ensure they minimise risks to patients having treatment under their care. Safety alerts and guidance issued by national bodies should be reviewed and practice amended appropriately in light of these. The following are critical in ensuring patient safety.

- There is a duty to ensure interventional radiologists have adequate training to perform vascular interventional procedures.<sup>1</sup>
  - There is a duty to ensure there are appropriate staff, facilities and consumables available to perform vascular interventions safely.<sup>2-6</sup>
  - There is a duty to ensure there are formal arrangements to secure elective and emergency services.<sup>2,5,7</sup>
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- There is a duty to ensure adequate peri- and post-procedural monitoring and care of patients undergoing vascular interventions.<sup>6,8</sup>
- There is a duty to ensure adequate handover procedures are in place when patient care is being transferred between practitioners, teams and departments.<sup>9</sup>
- There is a duty to ensure that there is provision to administer sedation and analgesia in a safe and timely fashion.<sup>8</sup>
- Prior to commencing a procedure, the interventional radiology team should perform a surgical safety checklist.<sup>11,15</sup> Policies should be in place to prevent 'never events', specifically 'wrong site surgery', 'wrong implant/prosthesis' and 'retained foreign object post procedure'.<sup>16</sup>
- Radiation doses during interventional radiological procedures must be kept as low as reasonably practicable.<sup>17,18</sup>

#### 4. Standards of practice relating to vascular radiology

Standard setting is a complex process; standards should, as far as possible, be evidence-based and supported by professional consensus relating to national practice. The most reliable standards are contemporary and derived from prospective collection of a large volume of outcome data for defined procedures. For interventional radiology, this is optimally achieved by systematically collecting and submitting performance data to national registries. For vascular radiology in the UK, iliac artery angioplasty and stenting is an established index procedure.

The BSIR performed the British iliac angioplasty and stenting (BIAS) national audit of outcomes in iliac artery intervention.<sup>19</sup> This helped define procedural outcomes and complications for a range of clinical indications. BIAS has now been superseded by the National Vascular Registry (NVR).<sup>20</sup> The latter collects data on a broader range of peripheral vascular and aortic endovascular interventions. This allows a robust analysis of institutional outcomes in comparison with nationally established performance indicators.

Additional standards relating to the practice of vascular radiology have been described and published by the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) and the Society of Interventional Radiology (SIR).<sup>21,22</sup>

It is expected that local practice will also be monitored through local audit of practice and review of cases at regular morbidity and mortality and learning from discrepancies meetings.

Where a new procedure is being introduced into a department or a new device is being used by an individual, local processes should be followed for their introduction, and any special arrangements for consent, audit and governance should be in place to prospectively monitor outcomes and adverse events.<sup>23</sup>

Any device-related adverse events should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) using their 'yellow card' scheme to allow the systematic monitoring of device failures and, where appropriate, enable these to be highlighted at the earliest opportunity.<sup>24</sup>

Where appropriate, imaging should be discussed in multidisciplinary team meetings (MDTMs) before the procedure is performed.

- The process of informed consent of patients must ideally take place in an appropriate setting and well in advance of the procedure, under the supervision of, or with, an individual suitably experienced in the procedure; relevant information leaflets should also be provided.<sup>25</sup>
- Procedure related outcomes should be entered into available national registries or databases.<sup>20</sup>

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## 5. Recommendations for recording data

### Direct clinical care (DCC) time should be set aside in job plans for this important activity.

- Individual doctors (interventional radiologists) have a responsibility to demonstrate performance based on evidence drawn from their medical practice.<sup>13</sup>
- Data should be submitted to national registries. Data from peripheral vascular interventional procedures and aortic procedures should be submitted to the National Vascular Registry.<sup>20</sup> Doctors will be able to extract their individual performance data and relate this to contemporary nationally derived outcomes. Statistical data analysis will take into account caseload. This data will be robust evidence of clinical performance that can be used to inform appraisal and recertification.
- The National Institute for Health and Care Excellence (NICE) periodically issues recommendations on the performance of specific interventional procedures. Data should be submitted to those registries specified by NICE as part of their recommendation.
- Where there is no national database, it is recommended that radiologists undertaking diagnostic and vascular interventional procedures should audit their procedural outcomes and any complications that occur. These records may be required for external review. Periodically, results should be compared with published standards. This is not as effective as comparison with contemporary outcomes derived from many doctors' practice.

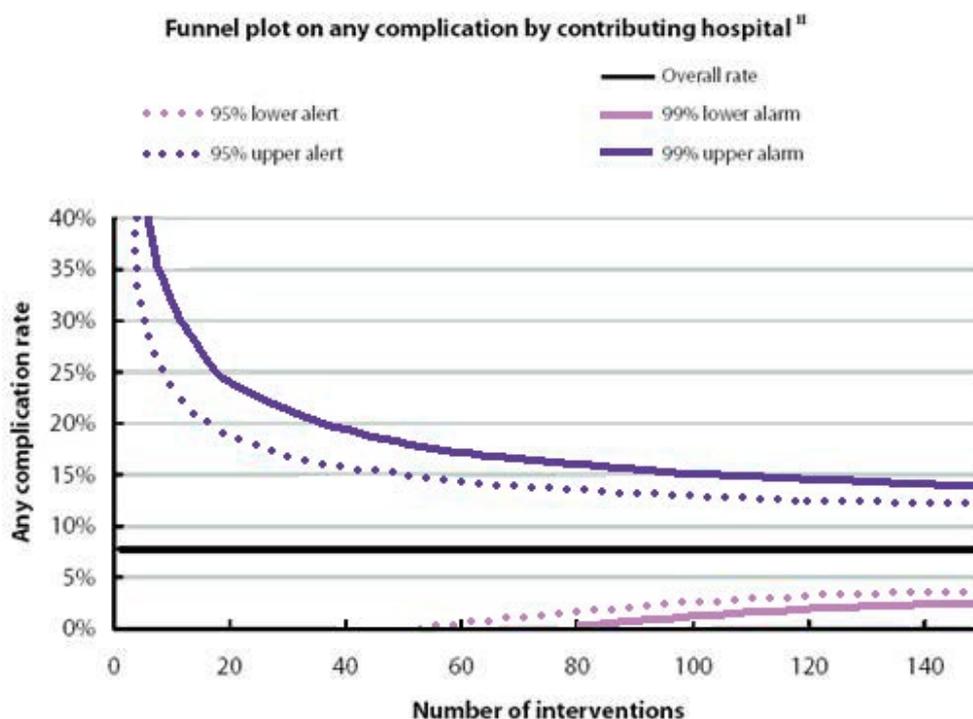
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## 6. Recommendations for monitoring practice

- All procedural outcomes and complications should be logged and categorised according to the procedure, the operator and the clinical indication.
  - As with any medical team involved in a patient's peri-operative care, interventional radiologists should also be involved in any morbidity/mortality review of the case and receive a copy of the discharge summary and, where appropriate, the autopsy report. Clinical outcomes and complications should be reviewed at formal meetings at least four times a year.<sup>9,26</sup>
  - Documented action should be taken to prevent recurrence of avoidable complications.
  - When complication rates for an individual or department exceed an agreed threshold, cases should be reviewed with attention to appropriateness of indication and experience of the operator. The results of this review should be recorded and reported to the head of department/medical director as appropriate.
  - Example suggested thresholds for triggering review are set out in Figure 1 based on data from the BIAS 3 report.<sup>19</sup>
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- For iliac intervention, the threshold has been set at the upper 95% confidence interval. This does not indicate unsatisfactory practice, merely that there should be review. Many factors could underlie the result, for example a high proportion of patients with rest pain and tissue loss or with significant co-morbidity.<sup>19</sup>
- Complication rates 3–4 standard deviations (sd) from the mean should raise significant questions concerning operator performance and patient selection. It should be noted that the Society of Cardiothoracic Surgeons use 99.99% (3 sd) as their defined standard for operative mortality from primary coronary artery bypass surgery.<sup>27</sup>
- Confidence intervals are much wider in a low-volume practice (Figure 1). In these circumstances, a single event can cause a complication rate to exceed threshold limits; for example if a patient experienced a stroke during an operator's second carotid stent this would suggest a 50% stroke rate. This does not make the data less reliable but means that the data analysis should be viewed critically and in context. This is a clear indication that the case should be reviewed and if the complication was unavoidable this should be recorded.

Figure 1. Funnel plot on any complication by contributing hospital<sup>ref</sup>



- In low-volume practice, it may be necessary to group complications together and review the overall major complication rate rather than the incidence of specific complications. This can be calculated as follows:

$$\text{Overall major complication rate} = \frac{\text{The number of procedures with major complication} \times 100\%}{\text{Total number of procedures}}$$

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## 7. Implications for practice

- Demonstration of satisfactory performance forms a key element of individual consultant appraisal and revalidation and also departmental certification. It can only reliably be demonstrated by submitting data to national registries.
- Trusts must ensure that there are formal arrangements for cover for out-of-hours emergencies and periods of leave.
- The time required to collect and record data should be reflected in the consultant job plan.
- Departmental accreditation is likely to depend on satisfactory demonstration of individual, departmental and trust compliance with the recommendations for practice outlined in this document.
- Whenever necessary, additional education and training should be undertaken to correct deficiencies in performance.

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## 8. Duty of candour

The principles of a professional duty of candour are set out by the GMC in *Good Medical Practice*:<sup>13</sup>

- ‘You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should put matters right (if that is possible), offer an apology, and explain fully and promptly what has happened and the likely short-term and long-term effects.’<sup>13</sup>
- More information about how to follow the principles set out in *Good Medical Practice* is found in the joint GMC and Nursing and Midwifery Council (NMC) guidance: *Openness and honesty when things go wrong: the professional duty of candour*.<sup>28</sup>
- In addition, new legislation in 2014 introduced a statutory duty of candour for healthcare providers (Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014).<sup>29</sup> As senior members of the clinical team providing care to patients, interventional radiologists will be required to assist their organisation in discharging their duty under this legislation. There are similar equivalent legislations in the devolved nations.

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## 9. Recommended standards for diagnostic and interventional vascular radiology

It should be noted that the current rates of complication for iliac intervention established by BIAS 3 are considerably lower than the complication rates quoted for diagnostic studies in the previous 2011 standards (see Table 1 overleaf).

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**Table 1. Procedure related complications for iliac artery angioplasty +-stenting<sup>19</sup>**

Interventional vascular procedures iliac artery angioplasty ± stenting‡	Rate	Confidence intervals	
		95% <sup>a</sup> Upper alert	99% <sup>b</sup> Upper alarm
<b>Outcome</b>			
>50% residual stenosis	3.70%	3.20–4.30%	3.00–4.60%
<b>Unplanned intervention</b>			
Delayed discharge	1.30%	1.00–1.80%	0.90–2.00%
Unplanned endovascular procedure	0.90%	0.60–1.30%	0.60–1.50%
Unplanned surgery	0.90%	0.60–1.30%	0.60–1.50%
Amputation	0.20%	0.10–0.50%	0.10–0.60%
<b>Puncture site</b>			
Haematoma (requiring transfusion, surgery or delayed discharge)	1.50%	1.20–2.00%	1.10–2.10%
Occlusion‡	0.50%	–	–
Pseudoaneurysm	0.20%	0.07–0.36%	0.06–0.45%
<b>Non-puncture site</b>			
Distal embolisation	0.80%	0.54–1.10%	0.48–1.22%
Unintended occlusion of selected vessel/flow-limiting dissection	0.50%	0.34–0.81%	0.30–0.90%
Vessel rupture/perforation requiring intervention or surgery	0.50%	0.28–0.73%	0.25–0.83%
Emergency/unplanned surgery	0.90%	0.60–1.30%	0.60–1.50%

Thresholds: <sup>a</sup>95% alert – trigger for informal review of practice; does not necessarily reflect unsatisfactory practice in itself.

<sup>b</sup>99% alarm – trigger for formal review of practice; should raise questions concerning operator performance/case selection.

Source

‡ Reprinted by permission from Springer: Uberoi R, Milburn S, Moss J, Gaines P, BIAS Registry Contributors. British Society of Interventional Radiology Iliac Artery Angioplasty-Stent Registry III. *Cardiovasc Intervent Radiol* 2009; **32**(5): 887–895.<sup>19</sup>

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**10.**  
**Audits**

**Audit 1:**

Completed radiology WHO or modified equivalent safety checklist – standard 100% compliance.<sup>1</sup>

**Audit 2:**

Percentage of vascular procedures submitted to NVR – 100% compliance:<sup>20</sup>

Aortic aneurysm stent grafting

Peripheral angioplasty.

**Audit 3:**

Compliance standards as per BIAS:<sup>19</sup>

Iliac artery angioplasty

Technical success

Major complications.

Approved by the Clinical Radiology Professional Support and Standards Board 26 January 2018.

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Ref No. BFCR(18)3

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