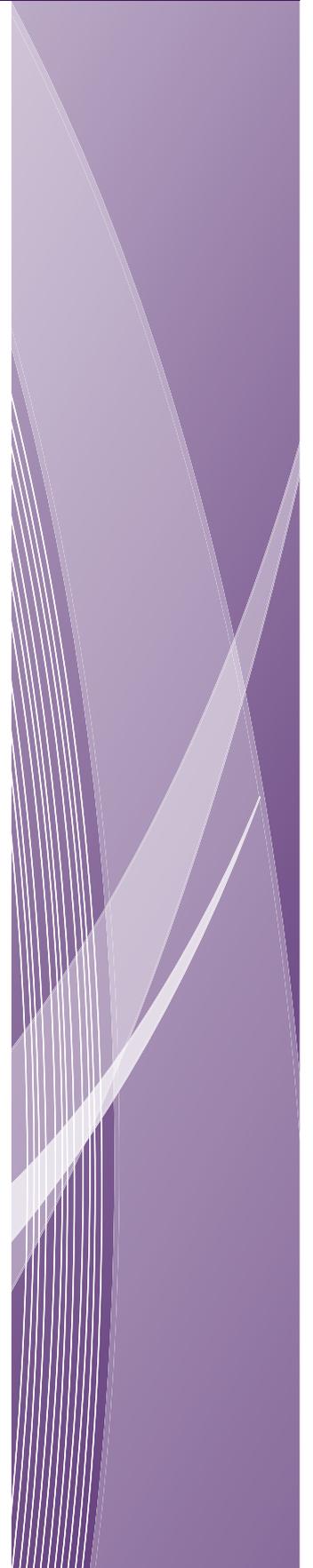


Standards for the introduction of new procedures and new devices

Second edition



RCR Standards

The Royal College of Radiologists (RCR), a registered charity, exists to advance the science and practice of radiology and oncology.

It undertakes to produce standards documents to provide guidance to radiologists and others involved in the delivery of radiological services with the aim of defining good practice, advancing the practice of radiology and improving the service for the benefit of patients.

The standards documents cover a wide range of topics. All have undergone an extensive consultation process to ensure a broad consensus, underpinned by published evidence where applicable. Each is subject to review four years after publication or earlier if appropriate.

The standards are not regulations governing practice but attempt to define the aspects of radiological services and care which promote the provision of a high-quality service to patients.

Current standards documents

Standards for radiofrequency ablation (RFA)

Standards for providing a 24-hour diagnostic radiology service

Standards for patient confidentiality and PACS

Standards for providing a 24-hour interventional radiology service

Standards for the communication of critical, urgent and unexpected significant radiological findings

Standards for Self-assessment of Performance

Standards for Radiology Discrepancy Meetings

Standards in Vascular Radiology

Standards for Ultrasound Equipment

Standards for Iodinated Intravascular Contrast Agent Administration To Adult Patients

Standards for Patient Consent Particular to Radiology

Standards for the Reporting and Interpretation of Imaging Investigations

Cancer Multidisciplinary Team Meetings – Standards for Clinical Radiologists

360° Appraisal – Good Practice for Radiologists

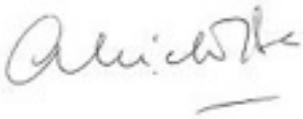
Individual Responsibilities – A Guide to Medical Practice for Radiologists

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Foreword

Medicine is changing rapidly and nowhere is that rapidity seen more clearly than in radiology. New techniques and new devices are most often but not always to the benefit of patients and we should all be enthusiastic but careful when assessing these. The purpose of these standards is to protect the safety of patients and to support radiologists when pushing forward the boundaries of diagnosis and treatment. I also hope it will be useful when advising other clinicians, clinical governance committees and healthcare organisations as a whole in managing clinical innovation responsibly. It will also help all radiologists comply with the Interventional Procedures Programme run by the National Institute for Health and Clinical Excellence (NICE). My thanks go to the authors of this important document (led by Trevor Cleveland) and to the Standards Sub-Committee of the College for commissioning it.



Dr Tony Nicholson

Dean of the Faculty of Clinical Radiology
The Royal College of Radiologists

Introduction

Radiologists have a history of embracing new challenges and procedures. As a result, interventional radiology continues to be at the forefront of new procedures and devices which are designed to improve standards of patient care. This has often been in the form of novel approaches to patient care, frequently employing new devices with the intention of improving outcomes and/or to reduce the invasiveness of the procedure. It is an unfortunate fact of life that, however well intentioned, some procedures or devices do not stand the test of time or do not achieve the benefits that were intended. It is, therefore, incumbent upon all radiologists, clinicians and healthcare providers to introduce new approaches and devices responsibly, using evidence-based mechanisms for monitoring their success or otherwise. This has to be balanced against the risk of over-regulation with cumbersome processes that may stifle innovative approaches, with the result that patients may be denied modern treatment techniques. It is the intention of this Standards document to give guidance to members and Fellows of The Royal College of Radiologists (RCR) on the introduction of such new procedures and devices.

Background

Interventional radiology has a long history of involvement in both the development and delivery of new procedures and devices. In the past, a number of devices and procedures have been offered to patients, frequently with little supportive evidence and limited co-ordinated review and audit. The intentions for these interventions have been laudable and in many cases very successful. This, in turn, has not infrequently lead to significant improvements in patient care. Unfortunately, in some cases the results have been less successful, and in some cases have caused more problems than benefits. Inevitably, new procedures and devices are introduced in relatively small numbers, and there needs to be nationally co-ordinated monitoring of these procedures so that benefits and problems can be rapidly identified, alterations made and lessons learned.

In this publication, differentiation will be made between new procedures and new devices. The definition of each of these is difficult. The National Institute for Health and Clinical Excellence (NICE) has defined an interventional procedure as 'a procedure used for diagnosis or treatment that involves:

- Making a cut or a hole to gain access to the inside of a patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel, or
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body – for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth, or
- Using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) – for example, using a laser to treat eye problems.¹

New devices are being developed all the time, usually by, or in conjunction with, commercial device manufacturers. For a device to be put forward for sale, the manufacturer is responsible for obtaining a Conformité Européenne (CE) mark. This is a mandatory conformity mark placed on the single market in the European Economic Area (EEA).² The CE mark indicates conformity with the essential health and safety requirements set out in European Directives. To permit the use of a CE mark on a product, proof that the item meets the relevant requirements must be documented. A notified body in the EU which has assessed the device is designated by a number which goes along with the CE mark. However, CE marking does not certify that a product has met EU consumer safety, health or environmental requirements. Therefore, RCR members and Fellows must be aware of this limitation and that device adverse incidents must be promptly reported to the Medicines and Healthcare products Regulatory Agency (MHRA; www.mhra.gov.uk). If a device manufacturer is aware, or is made aware, of a device-related adverse event, they have a legal responsibility to report this to the MHRA, irrespective of any report made by a healthcare professional. Reports can be lodged either electronically or by completing a hard copy form.

Occasionally, clinicians may wish to use a device that is not CE marked. This may for instance arise when use on clinical grounds outside an existing clinical trial is considered. In this situation, the clinician must seek the advice of the appropriate officer within their employing trust. This is normally the Director of Corporate and Legal Affairs. This action is advised in addition to the actions recommended in connection with using any other new device and/or procedure.

This document is intended to provide standards advice on the introduction of devices that are significantly different from those already in use and is not intended to be applied to minor alterations on equipment already in use. For example, these standards would be expected to apply to a novel inferior vena cava filter, but not to a new shape of diagnostic catheter. However, members and Fellows should remain vigilant when devices are modified (even with seemingly minor changes) to ensure that they are aware of any alterations and that they are used in the intended manner.

Introduction of new procedures

Recommendations for departments/management teams

- Trusts are encouraged to support and foster innovation, within a safe framework. Trusts were required by Health Service Circular 2003/11³ to establish a process of approval for the introduction of new procedures by clinicians. This will normally be handled by either the trust's clinical governance committee or another specific committee.
- In all instances, the doctor intending to introduce the new procedure is immediately accountable to the patient for the safety and efficacy of the intended new procedure. The doctor will also be accountable to his or her employing body or trust, and the General Medical Council.
- The doctor has a duty to notify the Interventional Procedure Advisory Committee (IPAC) at NICE of any new interventional procedure, unless already notified. The doctor also has a duty under HSC 2003/11³ to notify their trust or employing authority, and failure to do so may risk loss of support or indemnity should a need arise.
- As indicated above, radiology management teams are encouraged to support and encourage innovation. In addition, departmental teams have a responsibility to have in place monitoring and clinical governance processes and procedures to ensure that new procedures are being performed in line with their approval arrangements. Any adverse events should be monitored, and appropriate action taken as is deemed necessary. This may include the identification of an individual who has knowledge of the procedure, but does not have direct involvement in its delivery, who may oversee this procedure. Departmental management teams have a responsibility to ensure that appropriate liaison exists with wider trust clinical governance arrangements.
- Once a procedure is established within a department/directorate, the usual clinical governance and audit procedures should apply.

Recommendations for individual radiologists

Definition of a new procedure

There is no simple definition. The outcome of consultation by NICE is adoption of suggestions to develop a list of criteria, supply examples and to learn from experience.

Some of the suggested definitions were:

- A substantial degree of difference from any procedures currently in use
- A major modification (technical or conceptual) of an existing procedure, likely to result in changed outcomes in term of efficacy or safety
- The application of an established technique to a new clinical purpose
- Limited previous use in the UK
- A potential for significant risk
- Creating a need for clinicians in the relevant specialty to undergo further training
- A lack of existing guidance
- Limited published evidence.

Peer review

- Fellows are advised to seek robust peer review prior to introducing the procedure. Peer review should include a consideration of training and competence, patient consent, evidence of safety and efficacy, a consideration of the alternatives and increasingly evidence of the potential or real cost-effectiveness. Peer review will normally mean the consultation with medical peers within your own department and hospital, but should not be limited to the hospital, and may include colleagues within specialist societies and other national bodies.
- Peer review should be regarded as a test of reasonableness. It would be unlikely that support from the trust would be offered if such advice was uniformly negative.
- The operator should specifically consult with the head of department or clinical director in their role as manager of the service and accountable local lead for clinical governance and patient safety.
- Cost implications for the procedure should be considered and discussed with the departmental/management team.

Training

- The clinician must be able to demonstrate acquisition of competence to perform the procedure.
- The clinician as team leader will also need to take into account the training needs of the team performing the procedure, and any specific training for colleagues providing aftercare for the patients undergoing the new procedure (such as the nurses on the ward). In particular, the staff providing aftercare will need training for early detection of any specific complications that may develop.
- For most procedures, the operator will have already acquired a number of the skills required, but may be required to combine them in a different way or location. Specific training in the new technique is required for nearly all new procedures, followed by a period of proctorship within the doctor's own trust. The operator will be responsible for assessing their skills, and peer advice is an important element of this. A variety of training modalities are often available and they are usually additive rather than sufficient in isolation.
- It is not possible to define the number of procedures required to train safely, but operators should ensure they understand the learning curve likely to apply and that they have taken all steps to modify the risks to the patient which arise.
- The operator will also need to consider the number of procedures per annum required to continue to develop the skills required to perform the procedure safely.

Consent

- The fundamental process involved in each case is covered by the principles associated with consent to treatment.^{4,5}
- A clinician has a duty to inform the patient of the nature of the proposed procedure, including information on the risks, benefits and the competencies and training of the individual(s) who are going to carry out the procedure(s).
- The patient must be informed of the uncertainty around the safety and efficacy of the procedure.
- In the light of recent guidance from the Department of Health,⁶ it is accepted that in any situation where a patient is being offered a new or innovative procedure the details of the approval be recorded in the notes and in the appropriate part on the consent form.
- All clinicians must allow a reasonable period to elapse between the initial recording of consent and the confirmation by the patient.
- The clinician is strongly advised to prepare specific written information about the new procedure for the patient to review during the process of consent.

Evidence of safety and efficacy

- The procedure, if not accepted by IPAC as an established and effective treatment, will need to be performed as part of a registry or trial, so that data is collected and analysed. The operator is strongly advised to identify data collection and analysis method before implementing a new procedure.
- Fellows may find that registries or trials do not exist, particularly if the procedure is new to the UK (or internationally). In which case consideration should be paid to developing such a structure in conjunction with peers, such as the British Society of Interventional Radiology (BSIR; www.bsir.org).
- This data should regularly be submitted for peer review within the trust's clinical governance structure.
- If the operator does not normally follow up these patients in outpatients, then robust arrangements to ensure that whoever does so understands what complications and adverse events might arise. The patient should be equally well informed. Primary care trusts (PCTs) may wish to restrict the number of outpatient visits for patients. Where this occurs, providers should ensure that PCTs understand the need to follow up patients who have undergone novel interventions.

The alternatives

- Competent consent will in all instances require a review of the alternatives to treatment, including doing nothing.

Introduction of new devices

New devices may herald, or be an integral part of, a completely new procedure. In such circumstances, the standards indicated for new procedures should be followed. However, there are situations where a new device is developed and becomes commercially available, as a part of established clinical practice. These new devices should be introduced responsibly, with the processes put into place to follow them up to ensure long-term safety and efficacy. If a doctor has any financial interest in the device, or its manufacturer, this must be declared to both the hospital trust and the patient. New devices should always be purchased via the local trust procedures and policies for procurement of medical devices.

Directions for use (DFU)

- All medical devices are accompanied by a written DFU.
- Before using a device which is new to the operator, all physicians should have read and understood the DFU. This should be done in time to allow for alternative/additional information to be sought as necessary.
- If there is any doubt as to the mechanism of delivery of the device, all manufacturers have product specialists who are trained in their use. This expertise should be used if needed (either before or during use of the device).
- The advice and opinion of a colleague who has experience in the use of the device should be sought, and consideration made about whether referral to that colleague would be in the patient's best interest. Alternatively, the direct help/support of that colleague, in the form of proctorship (direct individual help in the form of on-site verbal or hands-on assistance), may be appropriate.

Adverse events

- All medical devices, both new and established, are subject to adverse events.
- Such events will be minimised by strict use as indicated in the DFU and use for the indication designed.
- On occasion, devices may need to be used 'off label' in the interests of patients. Before considering such actions, clinicians should consider the clinical problem carefully. If 'off label' device use is not established (for instance, as in superior vena cava stenting) and is for an elective procedure, radiologists should seek advice of colleagues and inform the appropriate risk management team in their trust. The 'off label' use of any device should be recorded in the patient's record, including the reasons for using it. The patient should be fully informed before any elective procedure and after an emergency procedure.⁷
- Should an adverse event occur, this must be reported to the MHRA at the earliest opportunity (www.mhra.gov.uk).

Sterilisation and infection control

- A new device may carry new requirements for sterilisation, and the advice of the trust infection control team is advised both for the use of the new device, and for any infection control impact that may arise from the new procedure.

Audit

- Use of all new devices should be audited after use.
- Audit should include follow-up data to ensure safety and efficacy.
- Adverse events must be reported to the MHRA to allow for a wider/national perspective. Manufacturers must also be made aware of such adverse events, so that they can liaise effectively with the MHRA (and also to consult their own records on events occurring internationally).
- It may be appropriate to contribute data to, or initiate, a national registry of groups of devices.

An audit template is in preparation and will be available on AuditLive on www.rcr.ac.uk

Standards summary

- New procedures and devices are integral to the development and advancement of healthcare and radiology practice.
- Trust and departments are encouraged to support innovation.
- All new procedures must be registered with NICE.
- Trusts must be made aware of any new procedures being introduced by its employees, prior to the procedure being performed.
- Trusts must have a process for monitoring new procedures and have an action plan to manage adverse outcomes.
- Individual radiologists must ensure:
 - Appropriate peer review
 - Training
 - Consent
 - Appropriate documentation of evidence of safety and efficacy
 - That alternative treatments are considered.
- New devices should be used as directed by their directions for use (DFU).
- Adverse events from devices must be reported to the MHRA.
- The outcomes from new procedures and devices must be carefully audited.

Approved by the Board of the Faculty of Clinical Radiology: 19 June 2009

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