Committee on Medical Aspects of Radiation in the Environment (COMARE)

Nineteenth report

Radiation doses in interventional radiology: issues for patients and staff within the UK.

Chairman: Dr C J Gibson

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Preface

i. The Committee on Medical Aspects of Radiation in the Environment (COMARE) is a Department of Health and Social Care (DHSC) expert committee that provides independent expert advice to the UK Government on the health effects of natural and man-made radiation. In over 30 years the committee has provided advice on a range of issues from childhood cancer clusters in the vicinity of nuclear installations to sunbeds and to radiation doses resulting from the use of computed tomography (CT) in the UK.

ii. The aim of this COMARE report is to provide advice to DHSC on the radiation dose issues associated with the use of interventional radiology (IR), both for staff and patients. A particular concern is the recent reduction in the dose limit to the eye and the potential impact this may have on staffing numbers.

iii. The report provides an introduction to IR and an overview of the benefits, including shorter hospital stays and reduced mortality and morbidity, of these procedures in comparison to other possible treatments. In many cases the use of IR has revolutionised the ease and effectiveness of treatments. However, one of the main associated risks is the exposure to some level of ionising radiation. This report explains the level of risk and provides an overview of the wide range of radiation protection measures to minimise risks to both patient and staff.

iv. Initially to establish whether relevant data were available, letters were written to several bodies including the Health and Safety Executive (HSE), the Institute of Physics and Engineering in Medicine (IPEM), Public Health England (PHE) and the Royal College of Radiologists (RCR). Some radiologist staffing information was kindly supplied by RCR in their annual reports. The British Cardiovascular Intervention Society (BCIS) also permitted access to its audit data relating to percutaneous cardiac intervention (PCI). Aside from these, few data were extant.

v. The Subcommittee therefore had to carry out a sample survey of hospitals across the UK, using the questionnaire shown in Appendix E, to obtain better information on the range and numbers of procedures being undertaken, staff numbers involved and the range of radiation doses to patients and staff. From these and other data, the Subcommittee has attempted to forecast the future requirements for facilities, equipment and staff.

vi. The report has also highlighted a number of issues which are elaborated in the conclusions.

Lay summary

Background

S.1 The use of real-time X-ray imaging to guide a wide range of minimally invasive surgical and therapeutic treatments has developed significantly in recent years. An example would be angioplasty, which is used to dilate narrow segments of blood vessels in many body areas. This field of health care is known as interventional radiology (IR) and it has both replaced many existing surgical procedures and enabled treatments which were not possible before. This report describes common IR procedures and some of their implications.

S.2 Following a request from the Department of Health and Social Care, COMARE's Medical Practices (IR) Subcommittee considered the application of IR in vascular and non-vascular, cardiac, neurosurgical and oncological practice. The most common application of IR in paediatric medicine is cardiology, and this was considered separately.

S.3 An IR service requires specialised equipment housed in operating theatre-standard conditions and is provided by a multi-disciplinary team which mainly includes clinicians, radiographers and nurses.

S.4 The radiation dose received during IR procedures carries with it a small risk of harmful health effects This applies to both patients and staff, and the risks are described in the report, along with the UK regulatory framework governing the use of IR. This requires radiation doses to be kept As Low As Reasonably Practicable (ALARP).

S.5 While patients experience direct health benefits from the IR procedures, this is not the case for staff, who will be exposed (albeit to much lower radiation dose levels per procedure) throughout their careers. Techniques are described to minimise the radiation exposure of both patients and staff, while maintaining the image quality necessary for a successful outcome. There is a balance to be achieved.

S.6 From a national perspective, it is therefore important to understand the extent of IR practice and the relative performance of health care providers from a radiation safety perspective. However, the Subcommittee found there was a lack of good quality data available, and so found it necessary, to conduct an indicative survey of UK IR practice.

S.7 The survey looked at UK Diagnostic Reference Levels (DRLs), which are used in radiology to permit each healthcare provider to carry out audits of their own practice to ensure that the associated radiation doses are reasonable when compared to national values. The only (limited) UK DRLs available for IR procedures are some years old.

S.8 Staff training and governance issues are discussed along with a description of the patients' experience of IR.

S.9 Where available, comparisons with international practice are included. It appears that there are several areas in which the UK performs relatively fewer IR procedures (for example, per million population) than other European countries.

Conclusions

S.10 The benefits of IR procedures to patients are considerable and significantly outweigh any detriment due to the associated radiation exposure.

S.11 While formal training exists for some staff groups, there is a need to extend existing, and to provide new, courses.

S.12 The UK has a relatively low number of IR specialists compared to many other countries and has difficulty in maintaining an adequate out-of-hours service at most sites.

S.13 There is a need for the UK to develop updated DRLs for IR radiation doses to better monitor and audit performance. This is of particular importance for paediatric practice since there is a relatively higher potential risk to children from any given radiation exposure.

S.14 There is also a need to improve the transparency of IR practice. Mandatory annual reporting of the numbers of procedures carried out on each site, the range of associated patient radiation doses and the range of cumulative staff radiation doses (whole body, eye and hand) should be introduced.

S.15 Further research into IR procedures, particularly those utilised in paediatric practice, should also be supported.

S.16 Manufacturers should be encouraged to develop standardised systems to measure patient dose and permit output into the patient record.

Key points of COMARE's recommendations

1. COMARE recommends that formal training which includes radiation protection for staff and patients should be completed by all healthcare staff undertaking image guided procedures in the UK. Existing courses should be updated regularly. New courses may be established through liaison between the Department of Health and Social Care (DHSC), the Health Departments of the devolved administrations and appropriate professional organisations, as required. The radiation dose structured report (RDSR) should be included in all existing and future IR training curricula.

2. COMARE recommends that minimum acceptable out of hours staffing arrangements for service provision are recommended by DHSC, the health departments of the devolved administrations and relevant professional organisations.

3. COMARE recommends that NHS England and the Health Departments of the devolved administrations ensure that the recommendations 1 and 10 of the National Confidential Enquiry into Patient Outcome and Death 2013 report (NCEPOD 2013) are fully implemented across the UK.

4. COMARE recommends that international efforts to harmonise data outputs from current IR equipment is supported by the UK, with manufacturers adopting standard radiation measurement methods and ensuring that these can be downloaded to Radiology Information Systems for inclusion in the patient record.

5. COMARE recommends that the use of real-time electronic personal dosemeters (APDs) should be promoted for all staff.

6. COMARE recommends the rapid establishment and reinforcement of national IR DRLs, particularly for paediatric IR procedures, with the UK collaborating with the International Commission for Radiation Protection (ICRP) and international partners to develop an agreed methodology. Resources should be made available to enable Public Health England and its equivalents in the devolved administrations to include IR procedures in UK dose surveys, supporting regular updating of national DRLs.

7. COMARE recommends that a requirement for health care providers (both NHS and private) to submit IR procedure numbers and summarised patient and staff dose data on an annual basis should be included within regulations by DHSC and the Health Departments of the devolved administrations.

8. COMARE reiterates the recommendation made in the 16th COMARE report (COMARE 2014; Recommendation 1, page 69) that the UK is actively involved in further research of radiosensitivity of high-risk groups as a factor in a range of clinical applications involving ionising radiation. Professional bodies and medical and scientific societies should continue to provide educational opportunities to increase the understanding of clinical staff regarding all the potential risks to patients, and not just the dose received, from radiological procedures. This is particularly relevant for children and other groups with genetic disorders associated with an increased susceptibility to ionising radiation, predominantly autosomal recessive conditions.

9. COMARE recommends that further research into paediatric IR procedures and associated radiation doses is supported by appropriate grant-funding bodies, particularly for those procedures associated with the treatment of congenital heart disease (CHD).

10. COMARE reiterates recommendation 7 from its 16th Report, that optimisation of protocols offers significant potential for dose reduction. COMARE recommends that in conjunction with the production of new regulations for medical exposures, the DHSC provides supporting guidance on optimisation, including a requirement for radiology services to consider formally appointing a team of radiation protection champions, consisting of a radiologist, a radiographer and a medical physicist.

11. COMARE recommends that the overall safety regime for IR when introducing new technology and in training for staff includes a role for equipment manufacturers in all procurement and on-going maintenance contracts, to maximise the benefits of new technology.

Chapter 1: Introduction

Interventional Radiology (IR)

1.1 In the last 4 decades the number and scope of medical procedures guided by interventional radiology (IR) have increased enormously. IR procedures (also referred to as Fluoroscopically Guided Intervention (FGI) procedures) are minimally invasive treatments performed under imaging guidance that play a vital role in both elective and emergency patient care. In many situations they have replaced standard surgical procedures, providing many benefits for patients; the minimally invasive nature of the procedures significantly reduces the risk of post procedure complications and decreases recovery periods, often allowing procedures to be carried out on a day case basis or with significantly shortened stays in hospital. In addition, elderly patients with poor performance status are often eligible for IR interventions whereas major surgery would be untenable.

1.2 This report identifies the importance and benefits of IR in modern medicine. However, since the vast majority of procedures require exposure of the patients to low doses of ionising radiation it is recognised that there is a small risk associated with this exposure. In addition, staff involved in delivering IR procedures on a daily basis will have a cumulative exposure to radiation which poses a potential risk to their health. This report considers these issues and provides guidance on how to ameliorate the radiation risks to both patients and staff while acknowledging the clear benefits of IR in many situations.

1.3 IR encompasses a wide range of procedures. Interventions are principally aimed at treating vascular disease, haemorrhage control, benign and malignant tumours, renal dialysis support and intervention to relieve obstruction of the gastrointestinal (GI), urinary and hepatobiliary systems. A large number of procedures are also carried out on patients with heart problems including a considerable number of infants and young children. Table 2.1 provides a list of examples of current procedures.

1.4 This report considers IR procedures to treat disease in the vascular and non-vascular system and includes cardiac, oncological and paediatric IR and neurointerventional radiology.

1.5 The report has not considered any diagnostic IR procedures such as biopsy and has also excluded consideration of image guided drainage procedures. The reason for exclusion is because many biopsy and drainage procedures do not require the use of ionising radiation. Those which do are usually short duration procedures with an associated limited exposure.

1.6 Common interventional vascular procedures include angioplasty/stent insertion, used to dilate narrow segments of blood vessels in many body areas; stent graft/lined stents used to seal across swelling of blood vessels (aneurysms); and embolisation, used for occlusion of blood vessels to stop haemorrhage or treat tumours.

1.7 Common non-vascular treatments include stent insertion, used to open areas of narrowing of the GI tract and urinary tract, and ablation techniques used to treat solid tumours in a variety of locations.

1.8 IR procedures are often less invasive than traditional surgical procedures, reducing morbidity and mortality and allowing more rapid patient recovery and discharge from hospital. The majority of procedures use skin incisions less than 5 mm performed under local anaesthesia and hospital discharge can often be the same day.

1.9 Technical developments in the range of available medical devices used in IR have been instrumental in extending the range of potentially treatable conditions. Notable developments in the technology of stent - grafts has permitted treatment of common vascular conditions such as aortic aneurysms. In the non-vascular system, the development of techniques to ablate solid tumours has led to safer effective treatment for a wider range of patients.

1.10 Some of the newer devices available have increased the complexity of possible treatments which may be reflected in an increased period of radiation exposure for both staff and patients.

1.11 The minimally invasive nature and low morbidity of IR procedures has been particularly appropriate to deliver treatment for the ageing patient population and this has been an additional factor driving up the number of procedures undertaken.

1.12 There has been a significant increase in the number of procedures undertaken within all areas of IR. A survey by the Royal College of Radiologists showed an increase in IR procedures by 21% in the period between 2010 and 2012 (RCR 2014).

1.13 Both ionising and non-ionising radiation are used for image guidance during IR procedures.

1.14 Conventional X-ray including fluoroscopy and digital subtraction angiography is by far the most commonly used imaging modality for imaging guidance in the vascular system.

1.15 Non-vascular interventions use a wider range of imaging techniques including ultrasound, computed tomography (CT) and less commonly magnetic resonance imaging (MRI). Non-vascular intervention will sometimes use a combination of imaging modalities including fluoroscopy to deliver treatment.

1.16 The treatments are delivered by a diverse group of physicians dependent on the clinical specialty. The main physician groups delivering treatment are Interventional Radiologists (vascular and non-vascular body treatments), Interventional Cardiologists (cardiac treatments) and Interventional Neuroradiologists (treatments for the brain and spinal cord).

1.17 Treatment delivery teams also include several other staff such as radiographers, specialist nurses, clinical physiologists, healthcare assistants and anaesthetic staff (including operating department practitioners (ODP)). The numbers and types of staff required depend on the type of procedure being performed.

1.18 The clinician most closely involved with the patient is invariably the radiologist. Also adjacent to the patient there is frequently a scrub nurse and further away will be the radiographer and other nursing staff who may be managing sedation or supplying equipment.

1.19 Following a description of IR applications, the report covers radiation biology, radiation risks and appropriate elements of the UK radiation protection framework, emphasising the importance of justification and optimisation. Operational factors contributing to patient and staff radiation doses are described, together with techniques to reduce these while maintaining image quality.

1.20 Data on UK practice are presented and compared with those from other countries. Staffing and governance issues are included, with an emphasis on dose reduction and formal training schemes.

1.21 Chapter 12 presents the Committee's conclusions, from which 11 recommendations are derived.

Chapter 2: Applications and benefits of IR

Introduction

2.1 IR has revolutionised the treatment of many medical conditions, reducing very considerably the need for surgery with all its attendant risks. In addition, many more conditions can be treated in a fast, efficient and minimally invasive manner, where previously they were only treatable by surgery or not at all.

Table 2.1: Common IR procedures

IR procedure	Body area[1]	Frequency[2]	Age[3]
Radiology			
a) Vascular			
Peripheral angioplasty/ stent / embolisation	Peripheral	Common	50+
Aortoiliac angioplasty/ stent	Abdomen pelvis	Common	50+
Mesenteric angioplasty/ stent /embolisation	Abdomen pelvis	Moderate	50+
Endovascular stent graft- abdominal aorta	Abdomen pelvis	Moderate	50+
Endovascular stent graft- thoracic aorta	Thorax	Rare	50+
Transjugular intrahepatic portosystemic shunt (TIPS)	Abdomen	Moderate	30+
Central venous catheter or port insertion	Thorax	Common	All
Selective Internal Radiotherapy (SIRT)	Abdomen	Rare	50+
Transcatheter chemoembolisation	Abdomen	Moderate	50+
Uterine Fibroid Embolisation	Pelvis	Moderate	30-50
b) Renal dialysis intervention			
Fistula angioplasty/ stent	Peripheral	Common	50+
Fistula thrombectomy	Peripheral	Moderate	
Dialysis line insertion	Peripheral	Common	
c) Non-vascular			
Nephrostomy Insertion	Torso	Common	All
Ureteric stent insertion	Torso	Moderate	50+
Percutaneous Nephrolithotomy	Torso	Rare	30+
Gastrointestinal stent insertion	Thorax/ Torso	Moderate	30+
Biliary drainage / stenting	Torso	Moderate	30+
Vertebroplasty	Torso	Rare	50+
Interventional Cardiology			
Coronary angioplasty/ stent	Thorax	Common	50+
Pacemaker insertion	Thorax	Common	50+
Device deployment / balloon intervention	Thorax	Moderate	All
Electrophysiological mapping /ablation	Thorax	Rare	All
Percutaneous valve insertion	Thorax	Rare	
Interventional Neuroradiology			
Coil embolisation aneurysm	Cranial	Moderate	30+
Embolisation of AVM	Cranial	Rare	All
Spinal AVM embolisation	Cranial	Rare	All

[1] Body area – area of body exposed to the highest dose of ionising radiation during the IR procedure
[2] Frequency indicates how often the procedure is performed
[3] Age indicates the predominant age group that is likely to require the procedure

2.2 The benefits of IR procedures across many medical disciplines are clearly illustrated in the following sections detailing the range of conditions now amenable to IR procedures. Given the benefits of these techniques it is likely more will become available in the ensuing years.

2.3 The risk / benefit ratio for such diverse indications will vary considerably and while some vascular IR (VIR) procedures treat malignant or immediately life-threatening conditions, it should be noted that a significant proportion treat benign non-life-threatening conditions. It follows therefore that a single value for an acceptable radiation dose is not appropriate. This issue is discussed further in Chapter 5.

2.4 The complexity and technical prerequisites of IR requires the provision of dedicated IR suites in all hospitals where the procedures are performed (see Appendix B for more detail).

Vascular IR (VIR)

2.5 VIR includes a wide variety of minimally invasive image guided procedures. The term endovascular surgery is sometimes used to describe a subset of VIR procedures for the treatment of atherosclerotic and aneurysmal vascular disease. The vast majority of VIR interventions are now with therapeutic intent. Advances in non-invasive cross-sectional vascular imaging techniques utilising MRI and CT provide the vast majority of diagnostic vascular imaging.

2.6 The diversity of possible targets for vascular intervention means that a variety of different specialist groups may undertake these procedures including interventional radiologists, endovascular surgeons, cardiologists and interventional neuroradiologists.

2.7 The initial indication for VIR was in the treatment of atherosclerotic disease, the first peripheral angioplasty being undertaken in 1964. As technology and expertise have developed, the number of potential therapeutic targets has expanded greatly over several decades and more particularly in the last 20 years. The development of new imaging equipment and interventional procedures has revolutionised the way vascular abnormalities are treated. These techniques now provide methods to treat a very wide range of lesions in an efficient and much less invasive manner than was possible previously.

2.8 VIR procedures are now used to treat a wide spectrum of conditions including atherosclerotic disease, aneurysmal disease, control of haemorrhage, some forms of cancer therapy, venous and dialysis access procedures and also in the treatment of a number of benign conditions such as uterine fibroids and prostatic hypertrophy.

2.9 There is no single database that captures the number of VIR procedures performed. Certainly, there is evidence of expansion in the use of these techniques and of conversion of previous conventional surgical procedures to endovascular procedures. For example, trends over the last 10 years indicate a switch to the majority of elective aneurysm repairs undertaken by endovascular techniques rather than operative repair (Waton and others 2019).

2.10 The reduction in the requirement for surgery has had a major benefit. Recovery from VIR procedures is much quicker since it only requires minimally invasive interventions which can mostly be carried out as day procedures. The risks of general anaesthesia and surgery are also avoided, and this allows more frail and elderly patients the possibility of successful treatment that was not available to them previously. However, there is a risk associated with the use of imaging techniques requiring ionising radiation. Although the dose required is moderate to low (see Table 3.2), the actual dose is dependent on a number of factors, in particular the X-ray exposure time required to complete the intervention, which are addressed further in this report.

2.11 Atherosclerosis is the most common form of vascular disease. This involves narrowing (stenosis) or occlusion of blood vessels, which is usually treated with percutaneous angioplasty or stent insertion respectively. These techniques have revolutionised the treatment of atherosclerosis providing a relatively simple, non-invasive method for treating something which was previously life threatening. After a simple day procedure, most patients can return to a relatively normal life with minimal after-effects.

2.12 The radiation dose to patient and operator during interventions for atherosclerosis is dependent upon a number of interlinked factors including the anatomical location of the lesion, the complexity of the required intervention and thus the required beam angulation, staff proximity to the beam and the screening time. Doses are typically highest for procedures within the abdomen and pelvis; for example, renal and iliac intervention.

2.13 The treatment of aneurysms (weakness or bulging of an artery wall) ranges from small intracerebral lesions measuring a few millimetres to much larger aneurysms arising from the thoracic or abdominal aorta. The treatment of aneurysms involves more complex interventions. The radiation dose may vary substantially, primarily dependent on the duration of the procedure and location of the lesion. In elderly patients this is unlikely to have any consequences, but in younger patients there is a potential risk of associated detriment (discussed in detail in Chapter 3).

2.14 Embolisation refers to the deliberate occlusion of blood vessels with a variety of liquid, particulate and mechanical devices depending on the particular indication. Embolisation techniques are used in the treatment of a diverse range of conditions including gastrointestinal haemorrhage, treatment of malignant tumours (for example, transarterial chemoembolisation) and in the treatment of benign conditions such as varicocele, uterine fibroids and prostate embolisation. Typical radiation doses vary depending on the site of intervention, complexity of intervention and individual patient factors. Embolisation can also be used in emergency situations to control haemorrhages which are often life threatening.

2.15 The risk from the radiation incurred is heavily outweighed in emergency cases by the control of haemorrhage by embolisation. Such cases vary enormously in their complexity; however, it should be noted that in a previous study a significant number of GI embolisation procedures accounted for higher doses.

2.16 Embolisation is also used in the treatment of a range of non-life-threatening conditions such as uterine fibroids and more recently prostatic hypertrophy.

2.17 The prevalence of diabetes in the population today is also driving the need for peripheral interventions to combat vascular disease resulting in lower limb ischaemia (Reekers 2016).

2.18 IR has a pivotal role in the maintenance and preservation of the vascular access grafts and fistula used for renal dialysis. The preservation of function of arteriovenous grafts and fistula is a lifeline for patients and is increasing in parallel with the use of dialysis in an increasingly aged population. Dialysis access is particularly prone to the development of venous stenoses due in the main to increased arterial pressure and the need for repeated needle access. The majority of the interventions relate to upper limb access and doses to the patient and operator are relatively low (typically 0.05 mSv) (Huang and others 2019) but will be double for more central lesions. Dialysis access intervention are usually fairly rapid procedures but, while the dose per individual intervention may be modest, the potential is present for a significant cumulative dose.

2.19 Vascular interventions are now very widely used in medicine with great success and the benefits to patients are substantial. However, the use of radiation to guide imaging during the interventions has an associated risk, although this is normally very small. The risk / benefit ratio for such diverse indications varies considerably and while some VIR procedures treat malignant or immediately life-threatening conditions, it should be noted that a significant proportion treat benign non-life-threatening conditions. Age of the patient is also a major determining factor in determining risk. The influence of this and other factors is considered later in this report.

Non-vascular

2.20 The techniques used in IR extend to almost every body system, particularly the biliary, gastrointestinal and genitourinary systems. In the acute setting, IR plays a very significant role in the management of sepsis in these body systems as it offers a minimally invasive technique to drain sources of infection in sites that would often only otherwise be accessible by major abdominal or pelvic surgery. This is particularly important in the severely ill patient with sepsis as IR techniques offer effective treatment with much lower morbidity and mortality than conventional surgical approaches.

2.21 Non-vascular procedures use a variety of imaging modalities to guide the intervention. In solid organ procedures (for example, the urinary system and the biliary system) percutaneous procedures most often use a combination of ultrasound and fluoroscopy. Dose to the operator is potentially higher with these procedures as the access point is directly adjacent to the organ system and the operator is closer to the primary beam. In the vascular system, access is more often remote to the site of intervention and therefore the operator is standing further from the primary beam. These procedures vary in their complexity, but typically highest dose would be incurred in percutaneous transhepatic cholangiography (PTC) as this often requires more prolonged fluoroscopy, sometimes at oblique angulation.

2.22 In the urinary system, IR may be used to treat obstruction by benign or malignant processes. The technique of percutaneous nephrostomy provides lifesaving relief of obstruction by placement of a percutaneous drainage catheter into the collecting system using imaging guidance. The technique of antegrade ureteric stent placement is often performed after percutaneous stent placement and achieves internal drainage by inserting a stent within the ureter (a tube that connects the kidney to the bladder) to bypass the obstruction.

2.23 In the obstructed biliary system, endoscopic retrograde cholangio-pancreatography (ERCP) or PTC may be used to achieve drainage of the biliary system and relieve jaundice. Both of these techniques offer a minimally invasive alternative to major surgery which is now rarely performed because of the effectiveness of these techniques and their significantly lower morbidity and mortality.

2.24 In the gastrointestinal system, IR techniques are used to relieve obstruction and to achieve access for enteral feeding. The insertion of metallic stents is used to relieve the symptoms of obstruction in multiple different areas of the gastrointestinal tract. Percutaneous access can also be used to achieve access to the stomach to permit enteral feeding, a procedure known as a percutaneous gastrostomy which avoids the need for a surgical procedure.

Interventional Cardiology

2.25 Interventional cardiology (IC) is a subspecialty of IR whereby traditional surgical procedures have been replaced, for many indications, by interventions performed using cardiac catheterisation. This has provided very considerable benefit in the treatment of heart disease providing day procedure solutions in place of major heart surgery in many cases. The techniques used, have also considerably widened the scope of treatable cardiac conditions.

2.26 IC includes a range of minimally invasive procedures involving insertion of catheters/other devices through superficial arterial access, facilitated by fluoroscopic imaging to guide practitioners. Diagnostic cardiac catheterisation was first introduced in the 1940s and angiocardiography was well established by the 1950s (Bourassa 2005). The first human percutaneous coronary intervention (PCI) using a balloon angioplasty catheter was performed in 1977 (Grüntzig and others 1977). In recent years there have been very significant advances in technology greatly extending the range and complexity of cardiac defects that can be treated using cardiac catheterisation in both adults and paediatric patients.

2.27 Common IC procedures involve opening or widening narrowed areas with balloons and stents and/or closing unwanted vessels with coils or intravascular devices thus regularising blood flow to the heart. In adults the most common IC procedures performed in the UK and Ireland include coronary angiography (CA), PCI, CA with PCI and permanent pacemaker insertion (PPI) (D'Helft and others 2009), and emergency primary PCI (PPCI) for patients with ST-segment elevation myocardial infarction (STEMI) (Banning and others 2015). Another treatment now seen as a safe, reliable alternative to open heart surgery is trans-catheter valve replacements, resulting in much shorter recovery times and less risk of complications (Shemin 2016).

2.28 Closure of adult secundum atrial septal defects (ASD) by IC procedure has been shown to be very successful and new devices continue to be introduced (for example, de Hemptinne and others (2017)), while the AHA/ACC Guidelines 2019 (Stout and others 2019) set out exclusion guidelines where surgery is still the recommended course.

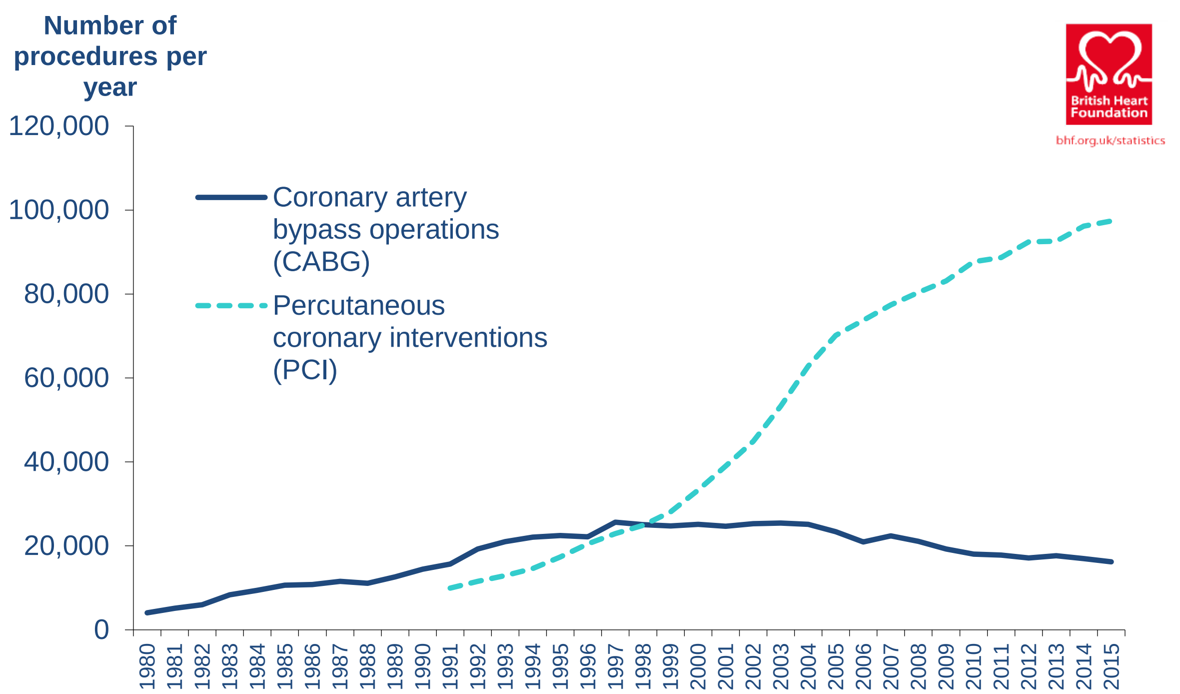
2.29 Soma and others (2019), reported a successful staged closure of combined patent ductus arteriosus and atrial septal defect.

2.30 Noting that the use of transcatheter aortic valve replacement (TAVR) is being extended to younger patients and that there is a paucity of data on the lifespan of transcatheter heart valves, Landes and others (2020) evaluated the success rate of repeat TAVR. It was found that the repeat procedure was relatively safe and effective, with low complication rates and substantial symptomatic improvement.

2.31 PCI is now being delivered to patients with chronic total occlusion (CTO) who would have previously been deemed high risk or inoperable. Complex lesions now account for more than 40% of total PCIs being performed in interventional suites (Fazel and others (2013). Although these treatment methods provide many benefits, it should be noted that the more complex multi-vessel and CTO revascularization procedures can often result in some of the highest radiation exposures in IR.

2.32 The National Cardiac Audit Programme in the UK (NCAP) (NCAP 2018a, b) annually collates the data on both surgical and catheter-guided interventions for all the most common cardiac conditions. In 2016 to 2017 there were over 380,000 treatments performed. The data shows that there is a continuing increase in treatments for cardiac disease over many years; a considerable proportion of the increase is due to the increase in catheter-guided treatments. This increase is illustrated by statistics from the British Heart Foundation (BHF) on the treatment of coronary artery stenosis. The data show a very significant increase in the use of PCI, which has been shown to provide a reliable, non-invasive alternative to open heart surgery with many advantages for patient recovery, with a corresponding decrease in the number of open-heart surgical procedures (Figure 2.1). Similar increases are found for other treatment interventions in cardiology (Kinnaird and others 2018).

Figure 2.1: Number of Coronary artery bypass graft operations (CABG) and Percutaneous coronary interventions (PCI) per year, United Kingdom 1980 to 2015[1]



[1] Data from British Heart Foundation

2.33 With advances in medical technology the use of IC as a diagnostic and therapeutic tool has continued to increase as new and more complex interventions are developed. However, the rise in the use of IC has resulted in reports of deterministic injuries (see Chapter 3) to both adult and paediatric patients due to radiation exposure (Sun and others 2013). Patients who were treated in earlier years may have been exposed to a higher dose of radiation due to the use of older image intensifiers. In more recent years modern flat panel systems have helped to reduce the radiation dose (Livingstone and others 2015), though this reduction is somewhat offset by the development of more sophisticated and prolonged procedures requiring additional imaging time.

Paediatric Interventional Cardiology

2.34 The use of IC in infants and adolescents has improved the life expectancy of individuals born with congenital heart disease (CHD). The most recent annual NCAP audit underlines the continuing increase in CHD treatments. In 2016 to 2017 there were 13,018 procedures performed; 9,011 were paediatric cases and 4,007 were adults with ongoing problems associated with CHD (NCAP 2018a). Only 43% of cases were solely surgical procedures and the remainder were performed wholly or in part in cardiac catheterisation departments. This increased reliance on IC, and the increase in availability of new techniques means that the numbers treated using IC will continue to increase. In addition, the very considerable success of IC procedures in treating infants with CHD, has resulted in an increase in these individuals returning several times over the duration of their lifetime for follow up assessment and, in a proportion of cases, additional treatment (see Appendix C).

2.35 In paediatric IC the most common procedures involve balloon interventions or device deployment. Balloon interventions include diagnostic catheterisation, pulmonary valvuloplasty, pulmonary artery angioplasty, co-arctation of the aorta, aortic valvuloplasty and septostomy. Device deployments include patent ductus arteriosus (PDA), atrial septal defects (ASD), ventricular septal defects, pulmonary artery angioplasty + stenting and occlusion) and collateral vessels (McFadden and others 2013a).

2.36 Some 85% of ASDs are closed by IC, the main contraindication being an insufficient rim of viable tissue around the defect (Fraisse and others 2018). A comparison of transcatheter and surgical closure of ASD in children was carried out by Ooi and others (2016), who found the advantages of the IC procedure to be a shorter length of stay (4 vs 1.5 days), reduced risk of infection (odds ratio 3.73) and reduced risk of procedural complications (odds ratio 6.64). They also calculated a cost advantage of $19K versus $25.5K. There was no mortality in either group.

2.37 Heart defects are diagnosed in at least 1 in 180 births in the UK, that is, 12 babies born daily with further cases being identified in the early years after birth[2]. The aim of cardiac services for infants is to diagnose heart disease as early as possible and preferably in utero. The use of routine ultrasound imaging during pregnancy has greatly improved diagnosis and currently almost 50% of CHD is diagnosed antenatally (NCAP 2018a). In the early 1960's the majority of these babies would not have survived to their first birthday; currently 8 out of 10 survive to adulthood

[2] British Heart Foundation heart statistics

as a result of the use of IC and ongoing technological advancements. The prognosis for patients undergoing IC for CHD is excellent and their quality of life as adults with simple grown-up congenital heart (GUCH) disease, is similar to the quality of life of adults in the general population; the only difference found was that physical activity and health perception was lower (Petersen, 2003)

2.38 The application of IC procedures for the diagnosis and treatment of heart disease in infants and children has provided a major improvement in treatment methods and survival and with reduced post treatment morbidity. Although it is well recognised that children are at a higher risk from exposure to ionising radiation than adults (Rassow and others 2000, Koenig and others 2001), the risks at all ages are generally small and will be substantially outweighed by the benefits of the use of IC. Furthermore, the risks of more invasive surgery are almost always higher than any potential risk of radiation detriment (discussed further in Chapter 3).

2.39 In summary, overall the development of cardiac catheterisation techniques has saved many lives. It has made successful treatment possible in both paediatric and adult practices for many conditions that were previously inoperable or for which their treatment was associated with much more severe risk. For most IC procedures the benefits very much outweigh the risks associated with older surgical techniques.

Interventional Neuroradiology (INR)

2.40 Interventional Neuroradiology (INR) encompasses a variety of minimally invasive image guided procedures (most with level 1A evidence) that have become established practice in the treatment of a range of cerebral and spinal vascular conditions including hyperacute ischaemic stroke, cerebral aneurysms (ruptured and unruptured), arteriovenous malformations (AVM), arteriovenous fistulae of the brain and spine, angioplasty and stenting (intra and extra cranial) and also adjunctive tumour therapy. As in VIR, non-invasive cross-sectional vascular imaging techniques provide the vast majority of initial diagnostic vascular imaging in the clinical Neurosciences.

2.41 There is no single database that captures the number of INR procedures performed but the Sentinel Stroke National Audit Project (SSNAP) captures the great majority of stroke thrombectomy procedures performed in the UK excluding Scotland (where thrombectomy numbers are currently low). Ultimately, stroke thrombectomy will be the highest volume procedure performed in the INR setting with an estimated 10,000 per annum eligible for it in the UK annually (McMeekin and others 2017).

2.42 A meta-analysis by Goyal and others (2016) documented a 20% absolute increase in patients assessed as ‘alive + functional independence’ at 90 days after stroke for thrombectomy performed by an expert neurointerventionist together with best medical therapy compared with best medical therapy alone. The number needed to treat with thrombectomy to achieve one person with less disability was 3. From around 300 mechanical thrombectomies per annum just prior to the publication of this level 1A trial evidence, thrombectomy numbers have risen steeply in the UK to almost 1600 per annum at the end of 2019.

2.43 However, the UK should as a nation be performing many more thrombectomy procedures and that will be the clear direction of travel over the next 3 to 5 years towards a 10,000 annual target. Mechanical thrombectomy for stroke is a time critical procedure with better outcomes the quicker thrombectomy is achieved and in most cases the time window to achieve this is within 7 hours of stroke onset. As a result, it is a very disruptive innovation to established care paradigms and pathways requiring a step change in stroke imaging as well as delivery of the intervention where appropriate.

2.44 The endovascular treatment of cerebral aneurysms, developed in the early 1990s, has become established since 2002 (Molyneux and others 2002) as the treatment of choice for most cerebral aneurysms in most UK units. An absolute benefit of more than 7% in the 'alive + independent' category was demonstrated for endovascular coiling over neurosurgical clipping, with the number needed to treat to prevent one death or disabled outcome being 13. A follow-up paper (Molyneux and others 2015) demonstrated that this advantage for endovascular coiling was sustained at 10+ years

2.45 A report by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) in November 2013 reviewed the care received by patients with aneurysmal subarachnoid haemorrhage (NCEPOD 2013). They reported the overall coiling rate for ruptured aneurysms coming to treatment in UK Neuroscience units as 85% endovascular to 15% neurosurgical clipping. That equates to about 4,000 INR ruptured aneurysm embolisation procedures per annum in the UK. There has been a steady slow downwards trend in the population rate for subarachnoid haemorrhage (SAH) but as techniques have improved since the 1990s, an ever-greater proportion of ruptured aneurysms has been treated endovascularly, such that nationally the numbers treated by INR remain fairly stable. The national guidance is to aim to secure ruptured aneurysms (in good grade patients) within 48h of aneurysmal SAH being confirmed (RCP 2016), which requires weekend service provision of INR.

2.46 Johnston and others (2000) highlighted that the recovery period for elective aneurysm treatment (50% return to normal) was 25 days for INR versus 1 year for surgery. Endovascular treatment of unruptured intracranial aneurysms (UIA) now account for 30 to 40% of total aneurysm procedure activity in most UK units, approximately 2,000 procedures per annum, although there is more variation in practice between individual units than for ruptured aneurysms. This UIA caseload is rather lower than most international comparators as there is a stronger practice towards conservative management of small incidental UIAs in the UK than many countries operating under different healthcare economies and different reimbursement systems. As a result, the unruptured aneurysms treated in the UK are often larger, more complex lesions than a typical ruptured aneurysm and the radiation doses are correspondingly rather higher on average.

2.47 The radiation dose to patient and operator during interventions in INR is dependent upon a number of interlinked factors including the pathology (AVMs often requiring considerably longer procedures with more fluorography and screening), anatomical location of the lesion (brain or spine), the complexity of the required intervention, the need for biplane screening/fluorography, staff proximity to the beam and the screening time.

2.48 Other INR procedures are much lower in volume and tend to use a range of techniques including liquid and/or particle embolisation, vessel occlusion with coils or other plug devices, angioplasty, stenting.

2.49 Non-vascular neurointerventional procedures are also performed though usually at appreciably lower volumes – including spinal vertebral procedures (vertebroplasty, kyphoplasty, sacroplasty), blood patches for cerebrospinal fluid (CSF) leaks, therapeutic nerve root and facet joint injections, percutaneous injection of facial malformations. These are more varied around the UK, both in terms of volumes and the clinical speciality of those who perform them than the endovascular INR procedures, which remain overwhelmingly delivered by Neuroradiologists.

2.50 Most INR procedures, particularly the endovascular ones, treat immediately life-threatening conditions in adults (often late middle aged or more elderly) – major ischaemic stroke, ruptured brain aneurysms and vascular malformations. As such, the associated risk of radiation is exposure is usually a fairly minor consideration in assessing the overall risks and benefits of INR procedures.

2.51 Paediatric INR procedures are rare, some of them being very complex, and as a result tend to be concentrated in just 2 or 3 units in the UK, primarily the Great Ormond Street Hospital London which operates the National Vein of Galen service.

Oncology

2.52 There are currently many established specialties providing ‘interventions’ for the treatment of cancer (for example, surgery, radiotherapy and systemic drug therapy). More recently ‘interventional oncology’ involving specific IR procedures has become available for selected cancer patients, in some cases replacing existing therapeutic procedures and also providing options for previously untreatable conditions.

2.53 The rationale for many oncological treatments/procedures is prolongation of life and/or quality of life, without necessarily eradicating the cancer. IR interventions are frequently aimed at achieving equivalent benefits to surgery but with lower morbidity. Palliative interventions are aimed at reduction in the severity of symptoms without necessarily prolonging survival, in which case minimising or avoidance of toxicity is important. Consequently, the measured outcomes for oncological interventions are normally evidence of extension of life and/or improved quality of life.

2.54 Over the last decade IR has continued to evolve with a burgeoning role in the management of cancer patients. The skills and competencies of an interventional radiologist required to provide IR procedures in the context of cancer management are an important component of the cancer multi-disciplinary team (MDT).

2.55 However, because of the relatively recent introduction of many techniques and the dependency on availability of local skills, the application of IR is not entirely uniform across the UK throughout different cancer services, although the Royal College of Radiologists (RCR) has defined professional and service standards for the incorporation of IR procedures into the management of patients with cancer (RCR 2017b).

Interventional oncology procedure categorisation

2.56 Interventional oncological procedures can be considered under 2 main headings with respect to their primary intent. The following provides an indication of the types of procedures which may be undertaken.

Supportive or symptomatic procedures

2.57 Supportive procedures refer to those which support the provision of definitive treatment but are not in themselves directed at treating the tumour or its effects; in other words, adjuncts to enable systemic anti-cancer therapy (SACT), radiotherapy or surgery. An example of this is Portal Vein Embolization (PVE) which is a preoperative IR procedure to initiate hypertrophy of the anticipated future liver remnant several weeks prior to a liver resection. This involves injecting the right or left portal vein with embolic material to occlude portal blood flow. As a result, blood is diverted to healthy parts of the liver and induces hyperplasia. This may allow for a more extensive resection which would otherwise be contraindicated, resulting in better surgical oncological outcomes.

2.58 Furthermore, the IR procedures themselves may minimise the need for these interventions to be performed. For example, Selective Internal Radiation Therapy (SIRT) can be a substitute for systemic anti-cancer chemotherapy.

2.59 Symptomatic procedures provide relief from tumour-related symptoms but do not necessarily modify the underlying malignant disease process. The main supportive/ symptom-relieving techniques are summarised in Table 2.2. The availability of these procedures has added extra options to facilitate cancer treatments and alleviate symptoms.

Table 2.2 IR procedures used for managing and treating cancer patients

Procedures	Examples	Benefits
Central venous access	Insertion of central venous lines for chemotherapy administration	Safer administration of chemotherapy
Enteral tube placement	Radiologically inserted gastrostomy (RIG)	Support of nutrition
Stenting	Including: vena cava, gastro-intestinal nephrostomy and ureteric stenting	Relief of obstruction due to malignancy
Image-guided insertion of fiducials	Used as markers for stereotactic ablative radiotherapy (SABR) or other forms of image-guided radiotherapy	Improved accuracy of radiotherapy
Image-guided aspiration/drainage	Pleural and ascetic aspiration	Symptom relief
Vena cava filtration	Inferior vena cava filter insertion	Prevention of pulmonary embolus
Biliary drainage and stenting	Endoscopic biliary drainage	Relief of obstructive jaundice
Neo-adjuvant embolisation	Portal vein embolisation	Improves outcome of hepatic resection for malignant disease
Ascitic diversion	Peritoneo-venous or peritoneo-cystic shunt/pump	Relief of symptoms
Image-guided ablation	Radiofrequency ablation (RFA) and Cryoablation for tumours	Used for patients not suitable for surgery.

Disease-modifying procedures

2.60 Disease-modifying procedures are those where the intent is to modify malignant progression and/or to modify the prognosis. Patients may potentially be suitable for a range of therapeutic options, for example stereotactic ablative radiotherapy (SABR), radiofrequency ablation (RFA), microwave ablation (MWA), irreversible electroporation (IRE), cryotherapy (CRYO) or selective internal radiotherapy (SIRT) for liver metastases. Radiofrequency ablation (RFA) and cryoablation are the 2 most commonly used ablation modalities. RFA destroys tumours by coagulation necrosis from temperatures above 60°C. Cryoablation causes tumour necrosis by intracellular dehydration and disruption of cell membranes from temperatures below -20°C.

2.61 Examples of disease modifying procedures are summarised in Table 2.2. In many cases these options provide an alternative or additional approach to targeting therapy directly to the tumour site.

2.62 Trans-arterial chemo-embolisation (TACE) is a good example of the use of IR in oncology to treat patients with primary liver tumours and/or liver metastases. TACE is the current standard of care for patients with intermediate-stage hepatocellular carcinoma (HCC) and relatively well-preserved liver function. In a meta-analysis of randomised controlled trials TACE has been demonstrated to improve median survival from 16 to 20 months. A development from TACE, embolic drug-eluting bead (DEB) has been shown to substantially improve the pharmacokinetic profile of TACE. In randomised trials, DEB-TACE significantly reduced liver toxicity and drug-related adverse events compared with conventional TACE.

2.63 SIRT is also referred to as transarterial radio-embolisation or radio-embolisation. It is a form of arterially delivered brachytherapy and involves delivering microspheres containing yttrium 90 (Y-90), a beta-emitting radionuclide, directly into the tumour via the hepatic artery using a percutaneous transarterial approach. In the UK colorectal cancer (CRC) is the fourth most frequent cancer. Liver metastases are common among patients with CRC and a frequent cause of death. In selected patients, resection of the metastatic disease, if feasible, is the recommended approach. However, for the majority of patients this approach is not possible. SACT (systemic anti-cancer chemotherapy) is the standard treatment for unresectable metastatic disease, which may be combined with other biological agents. Patients failing first and second line SACT have few treatment options and have a median overall survival from 2.4 months to 6.6 months. Loco-regional therapies, such as SIRT or DEB-TACE are currently under evaluation as potential new techniques to prolong survival. A systematic review of the evidence (NICE 2017) from studies of unresectable, chemotherapy-refractory patients with CRC liver metastases treated with SIRT has identified 23 studies involving 2,517 patients for which the overall median survival was 9.6 months. A critical factor in deciding how SIRT should be used is appropriate patient selection in order to identify those likely to benefit.

2.64 In summary, IR now has a significant role to play in the treatment of cancer patients. Considerable benefits accrue from its use, and for many patients there is a measurable increase in their survival time. The advantage of using IR techniques in these patients is that they are minimally invasive and generally less toxic. In general, toxicities associated with IR for oncology patients are negligible compared to the many toxicities these patients have to incur due to the nature of most of the alternative available treatments such as major surgery, external beam radiotherapy, the use of systemically administered cancer chemotherapy drugs and often a combination of some or all these.

Conclusions

2.65 IR has revolutionised many medical procedures providing for an extensive range of treatments that were previously impossible or only achieved using conventional surgical techniques. This had led to many benefits.

2.66 The availability of alternative IR procedures has reduced the number of (often) long and expensive surgical procedures that require opening of body cavities with consequent prolonged recovery and convalescence of the patients.

2.67 Elderly and frail patients are more likely to be deemed fit for IR procedures which require limited anaesthetic intervention.

2.68 The cost of the procedures is much reduced compared to conventional surgery (see, for example, paragraph 2.36) though this is offset by the burgeoning increase in the number of IR procedures that are performed or by the need for repeat procedures (see, for example, paragraph 11.13).

2.69 Many of the IR procedures can be carried out within the working day or with a minimal length of stay in hospital, much reducing the demand on hospital beds.

2.70 Patient recovery rates are much quicker and more successful than conventional surgical procedures.

2.71 IR has provided a huge benefit to the treatment of many conditions. It is likely that this will increase as the technology evolves and more interventional techniques are developed.

Chapter 3: Effects associated with radiation exposure from IR

Introduction

3.1 The use of IR has had a major beneficial effect on advancing therapeutic approaches in clinical medicine for many conditions. Indeed, IR has revolutionised the treatment of many conditions as discussed in Chapter 2. However, there are small potential detriments associated with its use. In the context of this report there is a need to balance the major benefits to be gained from an IR-guided procedure against the potential harm that might be caused by the radiation exposure.

3.2 It should be noted that there are other risks, independent of radiation exposure, which also result from IR procedures and must be explained to patients (see paragraph 8.2). These include complications of the vascular access site (Gewalt and others 2018), non-radiation related dermatological complications (Ramirez and others 2019), bacterial infection (Sutcliffe and others 2015) and allergic reaction to contrast agents although this has a very low incidence (Hunt and others 2009). In this report, however, the focus is on the level of risk associated with exposure to ionising radiation both to the patient and the staff involved in the interventional procedures.

Describing radiation dose exposure levels in medicine

3.3 The fundamental physical quantity for assessing radiation dose is termed absorbed dose and is a measure of the energy deposited in any material as a result of its exposure to radiation. Absorbed dose is measured in gray (Gy) and has units of Jkg^{-1}. At diagnostic and interventional X-ray energies the absorbed dose to air is numerically equivalent to a quantity called air kerma, which can be readily measured and is also recorded in Gy (see also paragraph 5.49).

3.4 The harm caused to body tissues resulting from ionising radiation can be divided into 2 main types, stochastic and deterministic (ICRP 2007) (see paragraph 3.15 et seq.) Tissue reactions, or deterministic effects, occur above specific absorbed dose thresholds for specific organs and their severity increases as the radiation dose increases. They can manifest shortly after an exposure or after a delay of many months or years. The organ of most concern, with regard to tissue reactions in IR, is the skin. Threshold values for a range of skin effects are shown in Table 3.3. Stochastic effects, mainly cancer, occur by chance, without a dose threshold level; the probability of a transformation occurring is proportional to the dose, but the severity is independent of the dose. As explained in paragraphs 3.9 to 3.11 the detriment associated with stochastic events can be related to a quantity called effective dose.

3.5 The absorbed and effective radiation doses received by patients undergoing interventional procedures can be calculated from the directly measurable quantity incident air kerma (IAK) and its derivatives. The word ‘incident’ is used to reflect the fact that it is the amount of radiation that is incident on the patient. The most commonly recorded quantities derived from IAK are kerma-area product (KAP), which is a measure of all the radiation entering the patient at any projection and cumulative air kerma (CAK), which is the total IAK that builds up during a procedure and so provides a measure of the total amount of radiation incident on the patient. A further metric, entrance surface air kerma (ESAK), which provides a measure related to the absorbed dose to the skin surface, can be derived from IAK or measured using dosemeters placed on the skin.

3.6 The absorbed dose to different organs in the body cannot be measured directly. However, the mean absorbed dose to an organ can be estimated from IAK, KAP or ESAK using data that are readily available.

3.7 Radiation detriment is a concept used by the International Commission on Radiological Protection (ICRP) to quantify the overall potential harm to health from low-level radiation exposure, based on the possible risk from stochastic effects occurring in different parts of the body (ICRP 2007). The main stochastic effect of concern is cancer, but detriment also includes a small precautionary contribution from heritable effects (see paragraph 3.26). The primary source of information on cancer caused by radiation is the life span studies (LSS) of the Japanese survivors of the atomic bombings at Hiroshima and Nagasaki in 1945. Estimates of lifetime risks of cancer incidence derived from studies of these populations, supplemented by other epidemiological data, are transferred and averaged across Asian and Western populations, adjusted for severity and years of life lost, and summed with a component of estimated risk of heritable effects to provide overall stochastic detriment values. A linear non-threshold (LNT) dose response relationship is assumed to apply to stochastic effects at low doses, consistent with the cancer data from the LSS.

3.8 Effective dose (*E*) is a measure of radiation dose related to the detriment, which has the unit sievert (Sv) (ICRP 2007). *E* takes into account that body tissues have different radiosensitivities and that different types of radiation can produce more or less damage per Gy. The effective dose is the weighted sum of the mean absorbed dose to each radiosensitive organ, thus:

$$E = \sum_T w_T \sum_R w_R D_{T,R}$$

where E is the effective dose in Sv, w_T are the tissue weighting factors, w_R are the radiation weighting factors and $D_{T,R}$ is the mean absorbed dose in Gy for organ or tissue, T, and radiation, R. For the X-rays used in diagnostic radiology and IR, the radiation weighting factor is 1 (ICRP 2007).

3.9 Effective doses are calculated for so-called Reference Persons of specified ages (ICRP 2009a). For this, male and female digital phantoms have been developed by ICRP, based on tomographic images of real individuals, adjusted to body and organ masses of the reference male and female adult (ICRP 2002). ICRP has also developed reference phantoms for children of different ages (ICRP 2020). Simulations of radiation exposures are used to calculate equivalent doses to all organs and tissues within pairs of male and female phantoms. The results for every organ are then averaged to give the sex-averaged equivalent doses, and from these the effective dose to the Reference Person is calculated using the equation above. This methodology fulfils the primary purpose of providing a quantity for use in the control of radiation exposures of members of the public and workers, including medical personnel. Effective dose was not designed to provide a measure of dose relating to risk to individuals and so the assessment of possible risk to specific patients requires care (see below).

3.10 One use of effective dose in medicine is to compare relative doses received by patients from examinations involving different parts of the body or of the same part of the body using different techniques. It is useful for taking the possible risk of radiation exposure into account for purposes of justification and optimisation of a proposed procedure, bearing in mind that the dose and associated risk apply to a sex-averaged Reference Person. Investigations can also be grouped into broad categories according to levels of effective dose and possible associated risks to facilitate risk communication to both patients and clinicians.

3.11 The tissue weighting factors, as defined by ICRP (2007), are given in Table 3.1. These values are simplified and rounded from relative detriment values representing the contribution of individual organs and tissues to overall detriment of 7.3×10^{-2} Sv^{-1} applying to a population of all ages and both sexes. As shown in Table 3.1, contributions from just 5 organs (bone marrow, breast, colon, lung and stomach) make up 60% of the total risk in this simplified scheme. However, it should be recognised that the epidemiological evidence shows that lifetime risks of cancer, and hence detriment, are generally greater in females than males and greater at younger ages of exposure (see paragraph 3.45). The various cancer types show differing patterns of dependence on sex and age at exposure; for example, thyroid cancer is much greater in young children, particularly females, than in adults, while risks of lung cancer appear less dependent on these factors. When using effective dose to gain an approximate idea of possible stochastic risks at low doses, it is helpful to be aware that the risks per Sv are likely to be higher in children than adults, generally by a factor of 2 to 3, as well as lower for older patients (see paragraph 3.45).

Table 3.1: Recommended tissue weighting factors*

Tissue	w_T	$\sum_T w_T$
Bone-marrow (red), Colon, Lung, Stomach, Breast	0.12	0.60
Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.04	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04
Remainder tissues: Adrenals, Extrathoracic region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate (♂), Small intestine, Spleen, Thymus, Uterus/cervix (♀)	0.12/13	0.12
Total		1.00

* Tissue weighting factors as described in the ICRP report 103 (ICRP 2007).

3.12 IR is used in a wide range of procedures (see Table 2.1). Most IR procedures result in absorbed doses to patients that are below the threshold for the induction of deterministic skin effects. Some do not, and deterministic skin effects are observed. Any patient irradiation, either diagnostic or therapeutic, will result in potential risk from stochastic effects. Effective and absorbed doses in IR can vary considerably; they depend on the part of the body being investigated, the length of time required to complete the procedure, the techniques used and the way the equipment is operated. Because of the risk of both deterministic and stochastic events occurring, all procedures involving the irradiation of patients must by law be justified – that is, the benefit to the patient must be evaluated as being greater than the risk - prior to their taking place (see Chapter 4). The regulations also require that exposures to patients are kept as low as possible without compromising the intended outcome – this is termed optimisation (see Chapter 4).

Table 3.2: Some effective doses for radiological procedures

Examination	Typical effective dose (mSv)	Equivalent period of natural background radiation [1]	Term used to describe risk
Chest X-ray (single posteroanterior projection)	0.015	2.5 days	Negligible
Abdomen X-ray	0.4	2 months	Minimal
CT - head	1.8	10 months	Very low
CT - chest	6.6	3 years	Very low
PET-CT body	18	8.1 years	Low
Short IR procedure, for example, Hickman line insertion	0.1[2]	16 days	Negligible
Cardiac diagnostic coronary angiography	3.9[3]	18 months	Very low
PTCA (1 stent / 2 stents)	6.8 / 10.4[2]	32 / 48 months	Very low
Prolonged procedure, for example, endovascular aneurysm repair (EVAR)	35	16 years	Low

[1] UK average natural background radiation dose = 2.2 mSv per year
[2] Derived from Hart and others 2012
[3] Wall and others 2011

3.13 Representative effective dose from some widely used IR procedures and a range of diagnostic procedures are shown in Table 3.2; these are contextualised by comparison with the exposure experienced by the general population from natural background radiation. Standard terminology for the risks associated with each procedure is included in Table 3.2 (ICRP In press).

3.14 Although effective dose is calculated as a sex-averaged dose using male and female reference phantoms using a single set of simplified tissue weighting factors, it can provide an approximate indication of possible risk. The doses under consideration are in many cases below the levels at which direct epidemiological observations of excess cases of cancer are available and risk estimates are uncertain. However, the most straightforward interpretation of the available scientific evidence for the purposes of radiological protection is that a nominal lifetime fatal cancer risk of about 5×10^{-2} per Sv applies at low doses or low dose-rates; that is $< 10^{-4}$ per mSv. The evidence also shows differences in risk between males and females and particularly with age at irradiation. Such differences should be taken into account when estimating individual risk. The use of effective dose to provide an approximate indication of possible risk of low dose procedures is not a substitute for the use of best scientific data in more rigorous assessments of doses and risks. Such analyses would consider organ / tissue absorbed doses derived for a phantom approximating the build of the patient, together with age, sex- and population-specific risk estimates for individual cancer types, addressing uncertainties in the dose and risk estimates.

Biological effects associated with radiation exposure

3.15 The harm within body tissues resulting from ionising radiation can be divided into 2 main classes, stochastic and deterministic, alternatively called 'tissue reactions (ICRP 2007).

3.16 Stochastic effects occur by chance and the general assumption for radiological protection purposes is that the LNT model applies, that is, that the risk at low doses is proportional to dose with no threshold level below which there is no risk (see paragraph 3.7). Thus, the probability of a deleterious effect is proportional to dose, but the severity is independent of the dose. The primary cause of stochastic effects is the acquisition of a radiation-induced mutation by induction of double strand breaks (DSBs) in the deoxyribonucleic acid (DNA) of individual cells. If radiation induces a mutation in the DNA of somatic cells, this may lead to cancer formation. If a germ cell is affected this may lead to a heritable effect.

3.17 Tissue reactions result from radiation-induced cell killing in tissues. They occur above specific dose thresholds for individual organs and their severity increases as the radiation dose increases. They can manifest shortly after an exposure when the radiation dose is above the threshold. This threshold varies for different tissues and is also determined by the sensitivity of individual people to ionising radiation damage. This variation is not fully understood but is thought to be related to genetic predisposition. For some individuals, who have a genetically inherited disease these effects are much greater (see paragraphs 3.54 et seq). When no initial deterministic effect is observed this does not mean that no damage has been done; under certain circumstances tissue reactions will occur after a delay of many months or years (see paragraph 3.27 et seq).

3.18 When cells are exposed to ionising radiation a wide range of damaging lesions are caused, including base damage, single strand breaks (SSBs), double strand breaks (DSBs) of varying complexity and DNA cross links. If this results in cell death, the frequency of this, at the radiation doses experienced during IR procedures, is normally of minimal consequence. Cells also have very effective repair pathways, which in many cases can result in an efficient repair of a range of different DNA damaging events. However, misrepair can occur, especially since ionising radiation often causes complex cluster damage. This results in a loss of, or insertion of, abnormal information within the DNA (Jeggo and Löbrich 2006, Mavragani and others 2017). The DNA-damaging events can also result in a range of different types of chromosomal aberrations such as terminal deletions, translocations and dicentric chromosomes (Manning and Rothkamm 2013). Misrepair can also result in genetic instability predisposing cells to further mutational events (Mavragani and others 2017). All of these changes can be crucial for the initiation of a cell's predisposition to tumour formation.

3.19 Radiation hormesis (or adaptive response) is the suggestion that very low doses of radiation may prevent rather than cause disease. Although there is evidence of effects at a cellular level, there has been no linking evidence to disease outcomes (Shibamoto and Nakamura 2018).

Biological consequences of stochastic effects in somatic cells

Cancer risk

3.20 When stochastic damage occurs in somatic cells, this has the potential to result in the development of a cancer a number of years later. The probability of a deleterious stochastic change occurring as a consequence of exposure to the ionising radiation dose normally used in IR procedures is very small (Suzuki and Yamashita 2012).

3.21 The primary source of information on cancer caused by radiation is the life span studies (LSS) of the Japanese survivors of the atomic bombings at Hiroshima and Nagasaki in 1945. The LSS cohort is a very large group of individuals (>93,000) who were exposed to ionising radiation during the bombing and controls who were not in the cities at the time (>26,000). This cohort has been extensively studied for over 60 years to analyse the detriments associated with whole body radiation, including estimation of the likelihood of cancer development (Ozasa and others 2019). Evidence from this cohort, for whom there were dose estimates shows that for leukaemias the highest excess risk appears after approximately 5 years (Hsu and others 2013); though the risk falls off with time it remains for over 55 years especially for acute myeloid leukaemia. The potential for development of solid tumours is not normally evident for over 10 years after an initial radiation exposure; however, the risk is apparent for over 60 years (Grant and others 2017). One exception is thyroid cancer, which has about a 5 to 10 year latency period and is particularly a risk for individuals exposed as children; the risk diminishes significantly in older age groups (Iglesias and others 2017). It should be noted that, while studies of the LSS cohort have provided important information on cancer incidence at low dose exposures, these individuals were exposed to whole body irradiation. Patients exposed during a medical procedure, including IR, have a much more limited area of body exposure, this considerably reduces their risk compared to the LSS cohort. The importance of age of exposure to cancer risk is discussed more fully below.

3.22 In general, the epidemiological evidence from the LSS and other studies confirms a linear dose-response relationship between cancer rates and absorbed dose from gamma rays from around 100 mGy to a few Gy (ICRP 2007, UNSCEAR 2008, NCRP 2018) . Attempts are being made to extend observations to lower doses/dose-rates, notably studies on large worker cohorts (Richardson and others 2015, Sokolnikov and others 2015, Haylock and others 2018, Richardson and others 2018) and studies of children receiving CT scans (Pearce and others 2012, Mathews and others 2013, Berrington de Gonzalez and others 2016, Meulepas and others 2019). The CT studies reported some statistically significant elevation of cancer rates at doses of a few 10s of mSv. However, caution has been advised in the interpretation of these studies (Walsh and others 2013, 2014, Boice 2015). A number of problems were identified including lack of information on the reasons for the scans and lack of individual dose reconstruction. It is considered that the patients may well have had undetected cancers that prompted their CT examinations, an example of reverse causation, or that factors that predispose to cancer also lead to medical conditions that require CT scans, an example of confounding by indication (UNSCEAR 2013, Walsh and others 2013, 2014, Boice 2015).

3.23 A number of assumptions and judgements are made in quantifying low dose/dose-rate cancer risks (ICRP 2007). Based on epidemiological analyses from the 1990s, a Dose and Dose Rate Effectiveness Factor (DDREF) of 2 was applied to the solid cancer risks derived from the LSS studies. Currently, epidemiology provides limited evidence of a DDREF >1 for solid cancer in humans, although analyses continue (Rühm and others 2016, Shore and others 2017), but animal and in vitro data indicate curvilinear dose response relationships that provide some support for the use of a DDREF >1. For leukaemia, the LSS study data are consistent with the use of a linear-quadratic dose response relationship, with the dose-response being linear at doses less than 0.1 Gy. Having obtained cancer risk estimates for exposures at low doses of a few 10s of mGy, an LNT dose-response relationship is assumed. This LNT dose-response assumption is considered to represent a prudent interpretation of current evidence including mechanistic understanding of radiation-induced cancer at low doses or low dose-rates (Preston and others 2003, ICRP 2007, Preston and others 2007, UNSCEAR 2012). In a review of all relevant epidemiological studies, NCRP (2018) concluded that current data support the continued use of the LNT dose-response relationship for radiological protection purposes, with no other model representing a more pragmatic or prudent interpretation.

3.24 During IR procedures, patients inevitably receive a concomitant skin exposure. Some studies have shown an increase in non-melanoma skin cancer (NMSC) caused by occupational exposure to IR (Wang and others 2002) and during radiation treatment (1 to 8 Gy) for a range of benign indications. Other reports have failed to confirm this finding, including a study of tuberculosis patients exposed to multiple fluoroscopies (average 77) during treatment (Davis and others 1989, McKeown and others 2015). The most common NMSC is basal cell carcinoma (BCC). The lifetime risk of development of a radiation-induced BCC was estimated to be approximately 0.006% based on 100 cm^2 skin treated to a mean dose of 3 Gy; although it should be recognised that this figure is very much smaller than the spontaneous lifetime risk of BCC which is >20% (Trott and Kamprad 2006). The ICRP (2007) has assumed a population-averaged risk of skin cancer incidence of 10^{-1} per Gy. Previously this risk was thought to be increased in a sun-exposed field by an order of magnitude compared to skin not exposed to the sun (ICRP 1991b). However, more recent studies have resulted in conflicting conclusions and the issue of interaction of effects is considered to be unresolved (ICRP 2015). It should be noted these BCCs can usually be treated successfully, although some studies suggest that BCCs resulting from ionising radiation exposure are more aggressive than those arising spontaneously and should ideally be excised with wider margins (Hassanpour and others 2006). There is evidence from studies of the LSS and of radiotherapy patients that risks are substantially higher for exposure at younger ages (ICRP 2015). Consequently, long-term surveillance and reporting of suspicious changes in irradiated skin is advised, especially in individuals exposed to ionising radiation as children and those who have had prolonged IR procedures, especially when young.

Biological consequences of stochastic effects in germ cells

3.25 Stochastic effects can also occur in cells of the reproductive system, resulting in the potential to cause genetic changes that can be passed on to future generations. In animal models transgenerational effects have been shown to affect offspring of exposed males (Dubrova 2003, Niwa 2003, Barber and others 2006). It has also been shown that radiation exposure can cause both overt DNA damage and also epigenetic effects in germ cells leading to genomic instability (Morgan 2003b, a, Merrifield and Kovalchuk 2013).

3.26 LSS studies of genetic diseases in offspring of A-bomb survivors showed no evidence that paternal or maternal radiation dose was associated with an increased risk of any multifactorial diseases in either male or female offspring (Tatsukawa and others 2013), although it was noted that the study population (11,951 individuals) was in mid-life and will experience much of the studied disease incidence in the future decades. ICRP (2007) concluded that, while there is no reliable direct evidence from human epidemiological studies of deleterious heritable effects of radiation, the inclusion of a heritable risk in overall stochastic risks is a prudent interpretation of the evidence of heritable effects observed in experimental animals and understanding of mutation rates in humans. Estimates of heritable risk over 2 generations were applied in calculations of radiation detriment, referring to detailed analyses by UNSCEAR (2001). Several other publications have reported there is no conclusive evidence to suggest that human health has been significantly affected by transgenerational changes induced by radiation (Little and others 2013, UNSCEAR 2013, Kamiya and others 2015). For practical radiation protection purposes, recent advice (BIR 2020) has confirmed that gonadal protection is unnecessary, although good technique is encouraged and there may be some exceptions, that is, where the patient care pathway requires a number of repeat examinations, particularly in the case of paediatric patients.

Tissue reactions caused by ionising radiation in tissues

3.27 Tissue reactions (previously called deterministic effects) involve impairment of tissue and organ function due to gross cell killing, which become evident above dose thresholds with the severity increasing with increasing dose (Little 2003, ICRP 2007). Originally tissue reactions were described as overt reactions observed during and/or shortly after exposure to ionising radiation which result from cell killing and inflammatory reactions within tissues, for example skin inflammation / desquamation / epilation (ICRP 1991a). It is now recognised that other tissue effects occur that are not manifest at the time of irradiation, but can become evident sometime later (ICRP 2007).

3.28 The tissue reaction most likely to occur following IR procedures is damage to the skin at the site of the highest dose exposure (Ramirez and others 2019). Other effects of potential importance which have been classified as deterministic are cardiovascular damage and cataractogenesis. Whereas skin effects normally occur above 2 to 3 Gy and within about 90 days of exposure. the latter effects are harder to quantify since they occur at some considerable time after exposure. It should be noted that a lower threshold for tissue reactions of around 0.5 Gy may apply for damage to the eye and circulatory system. Indeed, the evidence suggests that these events are not classically deterministic as they do not depend upon cell killing alone, but also on cell transformation. As discussed below, thresholds may not apply.

3.29 The staff team who experience regular radiation exposure during their working life in the interventional suite may be at risk of subsequently developing tissue reactions. The interventionalist who operates closest to the radiation beam is most at risk, as are staff who spend considerable lengths of time in the working week within the radiation suite supporting more than one physician (for example, radiographers and nurses). The operator may also receive a relatively high cumulative dose to the extremities, which needs careful monitoring. Tissue reactions most important to staff are discussed in paragraphs 3.35 et seq) and radioprotection measures to reduce the staff risks are discussed in detail in Chapter 6.

Tissue reactions in skin

3.30 The probability and severity of skin damage can be estimated from the local or peak skin dose. ICRP (ICRP 1991b, 2007) recommends assessment of dose to the most exposed 1 cm^2 of skin at a nominal depth of 70 µm corresponding to the basal layer of the epidermis. This is a separate consideration from that of cancer risk, for which the average dose to the skin of the whole body is assessed. In a review of skin reactions following IR procedures, the response was found to be related to the peak skin dose and time after irradiation.

3.31 Many IR procedures are short and involve very low doses of ionising radiation and skin reactions are not normally expected. However, acute skin reactions can be observed following more complicated/longer procedures; these occur within about 90 days of exposure when the dose exceeds about 2 to 3 Gy, with patients exhibiting a dose-dependent erythematous reaction (Wagner 2007, Balter and Miller 2014, Ramirez and others 2019). Previous radiation exposure may also influence responses. Even when the skin looks normal following an initial exposure, it may be more sensitive to subsequent exposure(s) (Balter and others 2010).

3.32 The likelihood of skin reactions is often linked to the fluoroscopy time of the procedure. However, in a study of radiation dose exposure during IR procedures, the variation in the relationship between peak skin dose and fluoroscopy time was found to vary over 2 orders of magnitude (Miller and others 2003). The severity of reactions can be influenced by factors including the area of the body exposed, and fluoroscopic dose rates (Balter and others 2010). Thus, fluoroscopy time should not be relied on as the sole metric for predicting deterministic skin reactions following complex interventional procedures

3.33 The time of onset following medical exposure to ionising radiation and the type of deterministic effect is shown in Table 3.3. Erythema and epilation occurring at doses of a few Gy are reversible but are likely to become permanent as doses increase towards 10 Gy. Late effects culminating in necrosis are seen after doses above about 25 Gy (Wojcik and Martin 2015), although it should be noted that radiation doses above 5 Gy are rare during IR.

Table 3.3: Radiation dose* to the skin and time to onset of skin injuries (Wojcik and Martin 2015)

Skin dose (Gy)	Under 2 weeks	Time of onset 2 to 8 weeks	Later
0 to 2	No effect		
2 to 5	Transient erythema	Epilation	Recovery from hair loss within 1 year
5 to 10	Transient erythema	Erythema, epilation	Recovery; prolonged erythema and permanent partial epilation at higher doses
Greater than 10	Transient erythema	Erythema, epilation, possible dry or moist desquamation	Prolonged or permanent epilation; dermal atrophy / induration and skin likely to be weak in long term

* Radiation Dose: measured as Entrance Surface Air Kerma (ESAK)

3.34 Hair loss can also be a problem for patients undergoing neurological IR procedures. In an 8-year follow-up study of patients, hair thinning and hair loss was found to occur primarily in patients receiving a cumulative surface air kerma dose to the scalp of above 4.5 Gy (Corrigall and others 2020).

Tissue reactions in the eye

3.35 For many years it has been known that the lens of the eye is sensitive to cataract induction by radiation. A comprehensive review (ICRP 2012) of all the epidemiological and experimental data on cataract formation following radiation exposure, included data from the LSS, studies of Chernobyl accident liquidators, astronauts, medical patients and radiation workers. The data suggested that acute and protracted exposures were similarly deleterious and were consistent with the assumption either of a low threshold of around 0.5 Gy or of a non-threshold relationship. This threshold of 0.5 Gy is significantly lower than the previous values of 2 Gy for acute exposures and 4 to 5 Gy for fractionated and protracted exposures. The ICRP therefore recommended an annual occupational limit of eye lens exposure of 20 mSv (equivalent dose); more precisely, 20 mSv/year averaged over defined periods of 5 years, with no single year exceeding 50 mSv (ICRP 2012). This change in the limit was supported by further review of the evidence by the Health Protection Agency (HPA) in the UK (Bouffler and others 2012).

3.36 A recent extensive review (Ainsbury and others 2016) has evaluated the importance of a wide range of factors that are implicated in cataractogenesis resulting from exposure to low dose ionising radiation, but acknowledges that there is a need for further studies to reveal any true effect at low doses. Human studies show that radiation-induced changes in the eye lens result, primarily, in posterior subcapsular cataracts. A range of intracellular processes have been implicated, including oxidative damage, DNA damage/response pathways, telomeric effects, genetic background and intracellular communication. Latency periods are known to range from just over one year in a patient who has received high-dose radiotherapy (40 to 60 Gy), to many years at lower levels of exposure (Chodick and others 2008, Ainsbury and others 2009, ICRP 2012, Neriishi and others 2012). When exposure occurs in childhood, an increased risk of approximately 50 % for 1 Gy exposure to the lens has been reported (Hall and others 1999). When exposed at age 10 years, children had an odds ratio of 1.44 at 1 Sv, which decreased significantly with increasing age of IR exposure (P=0.022) (Nakashima and others 2006).

3.37 Radiation-induced cataracts are unlikely to occur in patients as they will normally only experience ionising radiation exposure on a few occasions during their lifetime, and with limited exceptions, primarily to areas moderately distant from the eyes. However, eye protection is advised if a patient is likely to receive a significant dose to the eye as in some INR procedures. Their exposures may increase if they are exposed to additional diagnostic ionising radiation imaging techniques (for example, CT scanning to the upper body area) and also if they receive radiotherapy in the region of the eye.

3.38 Of particular concern, in relation to radiation-induced cataractogenesis, is the exposure of the staff team to this risk, since of necessity they are exposed to ionising radiation every time they work in the IR suite, and often regularly over months or years of a career in radiology.

Tissue reactions in the cardiovascular system

3.39 The radiation doses pertinent to IR and IC are unlikely to be sufficiently high to cause cardiovascular changes that result in overt symptoms in patients. However, it may be possible that unidentified changes could lead to a sensitivity of the cardiovascular system to other treatments (particularly repeated ionising radiation exposures and some forms of chemotherapy used in cancer treatments (Lenneman and Sawyer 2016, Zamorano and others 2016)).

3.40 It is now clear that radiation exposure involves a dose-dependent risk of changes to the heart and vasculature (cardiovascular disease; CVD) that are apparent at both high (radiotherapy) and high (radiology) doses; these changes are normally manifested several years after treatment (ICRP 2012, Stewart and others 2013, Little 2016). At higher radiotherapy doses the risk of cardiac damage, though small, has clearly been shown (Jaworski and others 2013, Armanious and others 2018). Above 30 Gy the risk of CVD can manifest within one year of exposure (Darby and others 2010). Recent studies have also suggested that damage may result from lower doses relevant to IR procedures. Such effects have a longer latency period, normally over 10 years (Little 2016).

3.41 The ICRP (2012) have concluded that a threshold dose as low as 0.5 Gy may apply to cardiovascular and cerebrovascular diseases which are caused by ionising radiation doses delivered to the vicinity of the heart and brain. ICRP indicated the need for medical practitioners to be aware that doses to patients of this magnitude can be reached during complex interventional procedures. In a meta-analysis of individuals exposed to whole-body low-dose radiation (< 0.5 Sv; or at a low dose rate < 10 mSv/day), it was shown that if the data are interpreted in terms of a LNT dose-response relationship, the resulting risks are of a similar magnitude to those inferred for cancer detriment at these doses/dose-rates (Little and others 2012, Little 2016). However, a recent review of clinical studies by the National Council on Radiation Protection and Measurements (NCRP) concluded that there is insufficient evidence that absorbed doses to the heart ≤0.5 Gy cause cardiovascular diseases (NCRP 2018).

3.42 An analysis of the risk of death from circulatory disease in the LSS cohort (>86,000 individuals) 50 years after exposure to estimated radiation doses of 0 to >3 Gy

(86% received <0.2 Gy), showed an elevated risk of both stroke and heart disease at doses above 0.5 Gy. The excess relative risk (ERR)/Gy for stroke was 9% (95% confidence interval 1% to 17%, P=0.02) and for heart disease was 14% (6% to 23%, P<0.001). The dose-response effect in individuals exposed to <0.5 Gy was not significant (Shimizu and others 2010). A recent evaluation of the LSS cohort has also suggested an association between renal failure and radiation dose mortality; the renal dysfunction caused may, in part, also result in an increased risk of CVD (Adams and others 2012).

3.43 The increase in heart disease associated with high (radiology) doses <5 Gy is markedly different from that associated with high (radiotherapy) doses (>20 Gy). In the latter group it is well recognised that raised levels of CVD are linked with atherosclerosis, primarily causing an increase in ischaemic heart disease and myocardial infarction. In the lower dose range associated with IR an increase is found in rheumatic heart disease, hypertensive and congestive heart failure. These latter pathologies can be attributed to defects in vascular perfusion, inflammatory and fibrotic tissue reactions; analyses of biological markers show evidence of persistent DNA damage, inflammatory markers and vascular damage consistent with the observed pathologies. Systemic effects causing raised cholesterol, blood pressure and inflammatory proteins may also contribute to increased risk of CVD (ICRP 2012, Stewart and others 2013, Baselet and others 2016). However, the evidence of an effect below 0.5 Gy is lacking, although this could be due to the difficulties of identifying a slightly elevated risk against an extensive background of heart disease attributable to other causes (Baselet and others 2016).

3.44 In summary, although there is a marginal risk of CVD following radiation exposure during IR, the benefits of these procedures over alternative options indicates that this is not a reason for curtailment. However, awareness of these risks is important and should be factored into the patient pathway especially for younger age groups (see Chapter 8).

Radiation exposure and age

3.45 It is recognised that the lifetime risks of cancer (per Gy) following exposure to ionising radiation are higher in children than adults, although different cancer types show different age-at-exposure dependence (UNSCEAR 2013, Kutanzi and others 2016). This greater sensitivity of children is mainly due to their significantly longer life expectancy and the fact that many of their tissues contain more rapidly dividing cells and may consequently be more sensitive to induction of stable mutations. In addition, children may receive doses to more organs and tissues, from the radiation beam and associated scatter (ICRP 2013b).

3.46 Wall and others (2011) examined the variation of lifetime excess cancer risk with cancer type, sex and age at exposure. The cumulative risk of cancer incidence per unit organ/tissue absorbed dose (Gy) up to an attained age of 100 years was calculated separately for males and females and by category of age at exposure (10 age categories of 10 years, from 0 to 9 years to 90 to 99 years), for 11 different cancer types (female breast, lung, stomach, colon, bladder, liver, thyroid, oesophagus, ovary, leukaemia, and other solid cancer sites). Risk models were derived from the LSS cohort (Preston and others 2007), using ICRP (2007) methodology. To define baseline incidence rates, Wall and others (2011) used ICRP (2007) values for a Euro-American composite population. The results show that overall risks from radiation exposure when compared to those in the 30 to 39 years age group, were about double in the youngest group (0 to 9 years) and about half by age 60 to 69 years. However, the data also show substantial differences between cancer types and the contribution of the different cancer types to overall lifetime risk varies substantially with sex and age at exposure. The variations with age at exposure reflect cumulative lifetime risk of cancer incidence, so that reduction of risk with increasing age at exposure reflects mainly the reduction in remaining lifetime after exposure rather than a variation of sensitivity with age at exposure. Estimates of age and sex differences in cancer risks in a Japanese population, calculated using ICRP methodology, resulted in similar conclusions (Ogino and others 2016).

3.47 A considerable body of data on radiation exposures in IR procedures in children comes from paediatric IC since these techniques have provided such major benefits to the treatment of patients with congenital heart defects. Studies have reported the average entrance surface dose to paediatric patients in IC to be 1 to 2 orders of magnitude higher than common standard X-ray examinations (Li and others 2001, Kawasaki and others 2015, Kawasaki and others 2019). A study of the estimated effective radiation dose in >2,000 infants and children undergoing paediatric IC predicted that children may have a 4 to 8 times higher risk of radiation-induced cancer as compared to adults, with infants having the greatest risk. It should be noted that the level of increased risk is still very small and greatly outweighed by the benefits of the procedure (Rassow and others 2000).

3.48 A review of available evidence of the risks of cancer following radiation exposure found no increase in children undergoing paediatric IC procedures although at the time of publication only 2 studies were available for consideration (Kleinerman (2006). More recently, no appreciable increased risk of cancer was found in children and young adults undergoing paediatric IC when all confounding factors were considered, although the follow-up period was relatively short (mean 8.4 years) (Harbron and others 2018). In another recent retrospective analysis, an increased incidence of cancer was found within the first 15 years of life in children who underwent paediatric IC below the age of one year (Stern and others 2020). However, the study did not show a radiation dose-response relationship, and there was no link to any specific cancer types. In addition, no mention was made in the latter study of the incidence of transplantation, a factor known to strongly influence subsequent cancer risk (Harbron and others 2018).

3.49 Several recent large studies have shown that adults with CHD have a small, but slightly increased risk of cancer that only becomes apparent after many years (Lee and others 2015, Gurvitz and others 2016, Cohen and others 2018b). What has been more difficult to identify in these studies are the main causative factors for this increase. Although it is possible that radiation exposure during treatment (often on multiple occasions over a lifetime and involving other imaging modalities) may be involved, this is currently not proven, and several other factors are known to make a contribution (Cohen and others 2018a, Danieli and others 2019).

3.50 The HARMONIC project (Health Effects of Cardiac Fluoroscopy and Modern Radiotherapy in Paediatrics) is an ongoing large-scale pan-European retrospective study of long-term health effects of medical exposure to ionising radiation in children treated for cancer or cardiac defects. That part of the study dealing with cardiac exposures is designed to evaluate any dose response relationship between radiation exposure and health effects, and to investigate modifying factors (Harbron and others 2020).

3.51 One of the most important concerns in young females relates to the risk of developing breast cancer as a result of irradiation of the chest area.

3.52 The evidence for an association of breast cancer with low dose irradiation comes from a variety of different sources. Girls treated for cancer in childhood with chest irradiation (median dose 14 Gy; range, 2 to 20 Gy) have a higher risk of subsequently developing breast cancer (Moskowitz and others 2014). This was supported by a later analysis, which also showed a higher incidence of death from other causes than in the matched control group (Moskowitz and others 2019). It should be noted that the radiation exposure to the breast in this group is likely to be much higher than children receiving interventional procedures, but these data indicate that cognisance should be made of the possibility of an increased risk of breast cancer in individuals exposed to interventional procedures to the chest during childhood.

3.53 A dose response relationship was also found in female infants whose chest area was exposed to low dose radiotherapy for haemangioma with a mean absorbed dose to the breast anlage of 0.39 Gy (range <0.01 to 35.8 Gy). A significant dose-response relationship was found for subsequent breast cancer, with an excess relative risk (ERR) of 0.38 at 1 Gy 95% CI 0.09 to 0.85). The ERR increased significantly with time after exposure and for ≥50 years, emphasising that this effect is present for many years and probably for life (Lundell and others 1996).

3.54 Previously it was not uncommon for adolescents and young women to be monitored regularly for spinal disorders (Ronckers and others 2010) and for tuberculosis (Boice and others 1991) using low dose fluoroscopic imaging. The ERR per Gy for breast cancer incidence was 2.86 (P=0.058) in those monitored for scoliosis (mean dose to the breast was 120 mGy); this risk remained elevated for at least 5 decades following exposure. Risks of lung cancer and leukaemia, however, were not elevated in either of these 2 groups of patients (Davis and others 1989, Ronckers and others 2010).

3.55 Patients with CHD may undergo interventional procedures which require significant imaging times and in a proportion of cases there is a requirement for further interventions during the patient’s life, often during their childhood and adolescence (Beauséjour Ladouceur and others 2016). In addition, it should be noted that, in recent years, patients with CHD are being exposed to increasing numbers of procedures involving radiation exposure and at a progressively younger median age, reducing from about 5 years to 9.6 months (Beauséjour Ladouceur and others 2016). The cumulative exposure to radiation during these procedures will increase the risk of a radiation-induced cancer, particularly of the breast.

3.56 Clearly the risks of open-heart surgery are considerably larger than those of PIC, even when this requires more than one catheterisation procedure. However, the available data underlines the necessity to keep the chest wall/breast dose as low as is possible, especially for young girls. One positive factor is a report showing a reduction in radiation doses during cardiac catheterisations in children primarily as a result of technological improvements (Harbron and others 2015). However, since exposure in childhood to even low doses of radiation may increase their life-time chance of developing cancer, every effort should be made to keep the radiation dose as low as possible commensurate with best clinical practice (Christopoulos and others 2016).

Foetal exposure

3.57 The foetal central nervous system is particularly sensitive to ionising radiation. A foetal dose in excess of 100 mGy may result in a verifiable decrease in IQ, while a dose above 1 Gy will result in a high probability of severe mental retardation. The sensitivity is highest in weeks 8 to 15 post-conception.

3.58 The excess cancer risk (up to age 15) for in utero irradiation from 3 to 4 weeks post conception is approximately 1 in 13,000 for a 1 mGy dose. This compares to a natural cumulative risk of childhood cancer over the same period of some 1 in 500 (HPA 2009).

3.59 Potential foetal dose must be considered for both staff (see paragraph 6.37) and patients (see paragraph 8.7).

Radiation exposure and genetic susceptibility

3.60 In the general population there is considerable variation in response to ionising radiation exposure for both stochastic effects and deterministic/tissue reactions. It is thought likely that one of the most important underlying factors affecting the inter-individual radiosensitivity is the presence of a variety of genes which influence the response to differing degrees. However, in healthy individuals, determination of the importance of genetic inheritance on an abnormally responsive phenotype is considered to be multi-factorial and difficult to elucidate (Applegate and others 2020).

3.61 In the last 4 decades a range of rare genetically-inherited conditions have been identified that are known to display a markedly increased sensitivity to radiation (Gatti 2001). The majority of the autosomal recessive conditions are very rare and only occur when an individual inherits a faulty gene from both parents. Diseases in this category include ataxia telangiectasia, Fanconi's anaemia, Bloom's syndrome, Werner syndrome, Nijmegen breakage syndrome and xeroderma pigmentosum (see Table 3.4). In most of these syndromes clinical radiosensitivity is clearly evident and is problematic for the use of diagnostic and therapeutic radiation in these individuals (Turnbull and others 2006, Demuth and Digweed 2007).

Table 3.4 Examples of some genetic disorders characterised by genomic instability and predisposition to cancer (reproduced from COMARE's 16th Report (COMARE 2014))

Clinical disorder	Gene	Function	Major cellular abnormalities	Cancer types
Ataxia telangiectasia	*ATM*	DNA damage sensor	Chromosomal instability, radiosensitivity, cell cycle abnormalities	Primarily leukaemia and lymphoma and some solid tumours
Bloom's syndrome	*BS*	Helicase (DNA replication)	Chromosomal instability, elevated sister chromatid exchanges	Multiple cancers of all types – in vitro studies show impaired accuracy of repair of double strand breaks in breast cancer cells in this syndrome‡

Clinical disorder	Gene	Function	Major cellular abnormalities	Cancer types
Fanconi's anaemia	*FA**	DNA damage sensing and repair	Chromosomal instability, sensitivity to DNA cross-linking agents	Leukaemia and solid tumours
Familial breast cancer	*BRCA1, BRCA2*	Recombinational DNA repair	Chromosomal instability, radiosensitivity	Breast and ovarian cancer
Hereditary non-polyposis colon cancer	MMR†	Mismatch DNA repair	Microsatellite instability, mutational instability	Colon and certain other solid tumours
Li-Fraumeni syndrome (1)	*TP53*	Control of cell division	Cell cycle abnormalities	Breast cancer, sarcoma, adrenocortical carcinoma, astrocytoma and glioblastoma
Nevoid basal cell carcinoma syndrome (Gorlin syndrome)	*PTCH1*	Tumour suppressor	Production of an abnormal version of receptor (patched-1 protein), uncontrolled proliferation	Basal cell carcinoma and medulloblastoma
Nijmegen breakage syndrome	*NBS1*	Recombinational DNA repair	Chromosomal instability, radiosensitivity, cell cycle abnormalities	Lymphoma and leukaemia
Schwachman-Diamond syndrome	*SBDS*	Ribosome biogenesis and RNA processing/ RNA metabolism	Increase apoptosis	Myeloid hematological malignancy (leukaemia, myelodysplastic syndrome)
Werner syndrome	*WRN*	Critical for DNA replication and maintaining DNA at the end of chromosomes (telomere)	Disruption in DNA replication, repair and transcription	Sarcoma, melanoma and thyroid cancer
Xeroderma pigmentosum (A)	*XPA*	Nucleotide-excision repair	Mismatch repair activity, cell cycle abnormalities	Basal cell carcinoma, squamous cell carcinoma and melanoma
Xeroderma pigmentosum (C)	*XPC*	DNA repair/nucleotide excision repair pathway	Recognition of bulky DNA adducts in nucleotide excision repair	Basal cell carcinoma, squamous cell carcinoma and melanoma

* There are 7 interacting FA genes.

† Mismatch repair. There are several different MMR genes, inactivation of any one of which will give rise to the disorder.

‡ Tachibana (2004).

3.62 The issue of radio-sensitivity in heterozygous individuals is much less clear, that is, they have one copy of the faulty gene associated with these autosomal recessive conditions. For example, ataxia telangiectasia is characterised by a marked radiosensitivity and an increased risk of lymphoid malignancies, but it is uncertain whether heterozygotes have increased radiosensitivity (Leong and others 2000, Taylor and others 2004). However, there is accumulating evidence that some heterozygotes may have an increased risk of breast cancer (Ahmed and Rahman 2006, Renwick and others 2006). Despite considerable efforts to identity a bioassay to quantify the radiosensitivity of normal tissues for apparently normal individuals, so far none has been verified (Rajaraman and others 2018).

3.63 There are also some dominantly-inherited autosomal conditions which predispose strongly to certain cancers. Gorlin syndrome is one example, which is characterised by development of basal cell carcinomas (BCCs) of the skin from a young age (Bresler and others 2016). Some reports suggest an increase in BCC within the radiation field following radiotherapy although since this is a rare syndrome the evidence is equivocal, except in the case of young children (Baker and others 2016). Adult patients with Gorlin syndrome appear to tolerate low dose radiation exposure for the treatment of BCC, although high dose radiotherapy is not normally advised (Baker and others 2016, Bresler and others 2016).

3.64 Individuals with genetically-inherited syndromes that exhibit increased radiosensitivity also display a wide range of other symptoms, many of considerable severity. Moreover, many also manifest an increased susceptibility to cancer (see Table 3.4), which unfortunately may indicate the use of radiation requiring procedures/therapies. Most of these syndromes are rare. However, if a patient presents with one of these syndromes, caution should be exercised in the use of radiation-related procedures. Unless essential, procedures involving ionising radiation exposure, including IR procedures, should be avoided. Prior to the use of any procedure using radiation, it may be advisable to consult a clinical geneticist or expert in radiosensitivity disorders.

Conclusions

3.65 Ionising radiation is known to cause stochastic changes in DNA resulting in the possibility of a slightly increased risk of cancer development in the medium to long term following exposure at the doses used in IR. When germs cells are affected the genetic change induced will have a chance of being inherited in subsequent generations; however, the current evidence for this is limited to animal studies.

3.66 For most interventional procedures the dose of radiation received by patients is very low and, with adequate safeguards, the benefits will be readily judged to outweigh the stochastic risks. However, there are some factors which need to be considered carefully. These are:

a. The total dose – the higher the dose the greater the risk of a detrimental effect, though even at the higher doses associated with prolonged IR procedures the chances of a stochastic event causing cancer are still small.

b. Age of the patient – older patients have a more limited risk for most detriments; however, younger patients have an increased lifetime risk of cancer because of their longer life expectancy and greater tissue radiosensitivity.

c. The organs or tissues exposed during the IR procedure. This especially applies to infants and children since, due to their small size, a wider range of tissues will be included within the radiation field.

3.67 Radiation exposure also causes tissue reactions, normally observable only above a threshold of above 0.5 Gy (the exact threshold depends on the individual patient's radiation sensitivity). This may be an issue for some patients and is more likely shortly after a prolonged IR procedure.

3.68 Tissues that may be particularly affected by tissue reactions in IR procedures are the skin, the lens of the eye and the cardiovascular system, although cataract and CVD may not conform to the classical definition of effects occurring above a dose threshold. Any risks at lower doses will be very small.

3.69 The treatment of paediatric patients for a range of conditions (especially CHD), has been revolutionised by the development of IR protocols. These patients are often treated very successfully using IR early in their life. Currently there is no specific evidence that this may increase their lifetime risk of a subsequent malignancy. Further research and awareness training are required to ensure that the radiation dose used during IR on paediatric patients is kept to a minimum. Clinical protocols need to be closely evaluated to ensure that best practice is being implemented (discussed further in Chapter 5).

3.70 There is also a concern over the cumulative dose received by staff during IR procedures since they are exposed on many occasions over a working life. Awareness training is crucial in the education of all the staff involved, especially as there is an increasing range of specialists using IR techniques.

3.71 Genetic susceptibility syndromes are rare. However, practitioners should be aware of the full range of these disorders and seek advice should they need to treat an affected patient.

Chapter 4: The UK Radiation Protection Framework

Radiation protection of staff and patients

4.1 Protection of the patient in radiology is regulated in the UK by the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R 2017) and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) (IR(ME)R(NI) 2018), while protection of staff and members of the public is regulated by the Ionising Radiations Regulations 2017 (IRR 2017).

4.2 Under these pieces of legislation, the over-riding requirement is that any human radiation exposure, irrespective of level, should be As Low As Reasonably Practicable (ALARP). This leads to the principle of optimisation. In the international literature, the term As Low As Reasonably Achievable (ALARA) is used but this carries the qualifier 'economic and social factors being taken into consideration'. UK legislation and regulation use ALARP.

4.3 A second common principle is that of justification, which states that no practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes.

4.4 Many IR procedures are life-saving and are performed in patients who are not suitable or fit enough to undergo surgery. The benefit greatly outweighs the risks of exposure to the dose of radiation involved.

4.5 Many procedures are carried out on older patients in whom exposure to the radiation dose involved carries a very small risk of consequent complications, whereas the benefits to this group can be very significant. In some cases, procedures are performed in patients with limited life expectancy when radiation risk is even less of a consideration.

4.6 Of more concern is the use of IR in paediatric and adolescent patients, although for many reasons the benefits greatly outweigh the risks (discussed in more detail in Chapter 2).

4.7 Overall, there is a need to protect the patient from unnecessary exposure to radiation with the acknowledgement that the clinical benefits normally outweigh the risks, and radiation exposures are likely to occur on a very few occasions during the life of most patients. Staff on the other hand, spend several days a week in the operating theatre and hence there is a different set of priorities when evaluating the best way to protect them from the long-term risks of radiation exposure.

4.8 Many of the techniques that can be used to reduce patient exposure will also result in the reduction of radiation dose to staff.

The Ionising Radiations Regulations 2017 (IRR17)

4.9 These Regulations are made under the Health and Safety at Work Act 1974 and are enforced by the Health and Safety Executive (HSE).

4.10 Staff receive no direct benefit from the radiation to which they are exposed and should be provided with suitable systems of work, protective equipment and a working environment that ensures that their radiation doses are kept as a low as practicable. Staff must receive training in radiation protection and in techniques to reduce their exposure to radiation. All potential exposures to radiation should be risk assessed.

4.11 Staff are subject to dose limits that are the legal upper limit on exposures (that is, breaching the dose limit is an offence) and which, in the normal course of events, should not be approached during their employment. If there is a likelihood of exceeding three-tenths of a dose limit (or the 15 mSv constraint for the eye), the individual should be designated as a classified radiation worker. The radiation doses of classified staff carrying out IR procedures should be monitored by methods and systems approved by HSE (an approved dosimetry service) and it is usual for these same methods to be used for non-classified staff. If the employer instructs employees to wear personal dosimetry or protective equipment, its use is mandatory.

4.12 The main issues for staff to consider when performing an IR procedure are

(i) protection of themselves and other employees from radiation to a degree that is As Low As Reasonably Practicable (ALARP)

(ii) limiting exposure of the patient to radiation, also to a level that is ALARP

(iii) limiting exposure of members of the public, who are not patients, to a level which is ALARP

(iv) performing a successful procedure in a safe manner.

There is frequently a degree of overlap between the above and consideration of one issue will invariably affect another.

4.13 The Ionising Radiations Regulations 2017 (IRR 2017) explicitly require that every employer engaged in work with ionising radiation such as IR must make appointments as follows.

Radiation protection adviser (RPA)

4.14 The employer must appoint one or more suitable radiation protection advisers (RPAs), who must be consulted on the observance of IRR17. The RPA must have a detailed understanding of radiation protection in the context of IR and the requirements of the regulations, and must have appropriate certification to confirm their competence to act as an RPA. The employer must provide their RPAs with adequate information and facilities for the performance of the functions. The role of the RPA is to provide advice on the requirement of the regulations and the duty of compliance remains with the employer.

Radiation protection supervisor (RPS)

4.15 The IRR17 (2017) explicitly require that all employers who work with radiation in a controlled or supervised area (as defined in these regulations) must draw up local rules that identify the main working instructions necessary to restrict exposure in that area. The employer must then appoint one or more suitable radiation protection supervisors to secure compliance with the local rules when work involving radiation is performed. The particular role of the radiation protection supervisor (RPS) is to supervise the arrangements set out in the local rules, which themselves should identify the RPS. The RPS must consequently have an understanding of IRR17 and the local rules and should also command sufficient authority to enable them to perform their task effectively. However, overall responsibility for compliance with IRR17 always remains with the employer, who has a duty to provide the RPS with the appropriate resources required to perform their role.

4.16 Frequently the RPS is tasked with more than overseeing the work performed to ensure that it is carried out in accordance with the local rules. However, many of these tasks more properly rest with local management unless the RPS is part of that management and the appointment of RPSs does not relieve local management of their role in radiation protection. Typical tasks involve organisation and distribution of personal dosemeters, review of personal dosemeter results, periodical assessment of safety and warning systems, participation in the arrangements for prevention, preparedness and response for emergency exposure situations, investigation of incidents involving unforeseen exposure to radiation, ensuring safe storage of PPE, keeping records of inspection of PPE and commenting on proposals for changes in work practices. The RPS and local management should also work closely with the RPA and should contribute to the radiation risk assessments required by IRR17.

The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R 2017) and The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 (IR(ME)R(NI) 2018)

4.17 In England, Scotland and Wales, the IR(ME)R (2017) apply to exposures carried out using medical radiological equipment. In Northern Ireland the same function is performed by the IR(ME)R(NI) (2018). Both regulations place significant onus on employers to ensure that there is compliance in the workplace.

4.18 Patients are not subject to dose limits under IRR17 because they are expected to receive a benefit from a radiological procedure. Before an imaging procedure can be carried out it must be shown that the benefit to the patient outweighs any radiation risk. This first step is termed justification. As will be described in more detail in Chapter 7, once an examination has been justified the imperative is to produce images that are of sufficient quality for the clinical task or question at hand whilst delivering the minimum radiation dose to the patient. This second step is termed optimisation. The justification and optimisation of all patient imaging procedures are legal requirements. Both are critical elements in the protection of the patient.

4.19 The IR(ME)R do not require employers to formally notify any authority of their activities in interventional radiology; this is a requirement of IRR17.

4.20 The regulations put the onus on the employer to identify and entitle the duty holders listed below and to determine their scope of practice.

a. A Practitioner is a registered health care professional who is entitled by their employer to justify and authorise individual medical exposures.

b. A Referrer is a registered health care professional (medical or dental practitioner or other health care professional) who is entitled by their employer to refer individuals to a Practitioner for a medical exposure. The employer must establish referral guidelines.

c. An Operator is any person who is entitled by their employer to carry out practical aspects of a medical exposure which may affect the patient's radiation dose.

4.21 The regulations also identify a list of binding matters that must, as a minimum, be identified in the employer's IR(ME)R procedures. Examples are the provision of arrangements for: entitling duty holders, correctly identifying patients, providing adequate information to patients, obtaining expert advice, recording patient dose, recording and reporting unintended or accidental exposures, justification of exposures and optimisation of exposures.

4.22 The regulations require that all exposures should be justified by a practitioner prior to any exposure taking place (see paragraph 4.3). In IR, the decision on any individual patient will be influenced by the patient's clinical history and the appropriateness of the request, the question of whether the examination will contribute to or change the individual's healthcare management and consideration of whether there are alternative techniques that would achieve the same result without involving ionising radiation. Optimisation (see paragraph 4.2) of patient exposures means ensuring that patient doses are kept as low as reasonably practicable without compromising the intended outcome, which in the case of interventional radiology is the therapeutic outcome. Any initiative to reduce patient dose will generally result in a reduction of radiation dose to staff.

Medical Physics Expert (MPE)

4.23 The IR(ME)R explicitly require that every employer engage in work with ionising radiation such as IR appoints one or more suitable MPEs with expertise in diagnostic radiology. In terms of the regulations, MPEs are classed as operators. MPEs are required to give advice on:

- dosimetry and quality assurance matters relating to radiation protection concerning patient exposures;
- physical measurements for the evaluation of dose delivered to patients;
- operating characteristics and requirements of medical radiological equipment.

4.24 IR(ME)R17 and IR(ME)R(NI)18 require the MPE to contribute to the following:

- optimisation of the radiation protection of patients and other individuals subject to exposures, including the application and use of diagnostic reference levels;
- the definition and performance of quality assurance of radiology equipment;
- acceptance testing of radiology equipment;
- the preparation of technical specifications for radiology equipment and installation design;
- the surveillance of the medical radiological installations;
- the analysis of events involving, or potentially involving, accidental or

unintended exposures;

- the selection of equipment required to perform radiation protection measurements;
- the training of practitioners and other staff in relevant aspects of radiation protection;
- provision of advice to an employer relating to compliance with IRMER 2017.

Conclusions

4.25 As set out in IR(ME)R 2017, IR(ME)R(NI) 2018 and IRR 2017, the over-riding requirement is that any human radiation exposure should be As Low As Reasonably Practicable. All procedures must be optimised to ensure that the radiation dose to patients and staff is kept to a minimum consistent with a successful clinical outcome.

4.26 Prior to execution, all procedures must be justified, demonstrating that benefits to the patient outweigh any detriment.

4.27 Staff must be provided with suitable systems of work, protective equipment and adequate training. Classified workers must be must monitored by a dosimetry service approved by HSE to ensure that their radiation doses remain within statutory limits; it is usual to utilise such services for non-classified workers also.

4.28 Employers engaged in IR are required to appoint one or more of each of the following duty holders – radiation protection adviser, radiation protection supervisor and medical physics expert.

Chapter 5: Radiation protection of the patient

Patient protection

Types of procedure

5.1 The majority of IR procedures currently performed are listed in Table 2.1. These involve a wide range of radiation exposures, although all are very much lower when compared with therapeutic doses used for cancer therapy. Typical high patient dose IR procedures include: TIPS (transjugular intrahepatic porto-systemic shunt creation), embolisation (neuro and non-neuro) and stent procedures (visceral, renal). More recently established techniques which result in relatively high patient doses include aortic stent insertion (EVAR, thoracic endovascular aortic repair (TEVAR), fenestrated endograft (FEVAR)), trans-arterial chemoembolisation and SIRT. In contrast, many procedures only expose patients to a very low radiation dose, for example, inferior vena cava (IVC) filter insertion, pulmonary angiography or nephrostomy insertion for renal obstruction. The total dose received by the patient is often dependent on the time it takes to carry out the procedure.

Measures to reduce patient exposure

5.2 As outlined in Chapter 3, IR procedures carry a risk of inducing both deterministic and stochastic effects so vigilance in all aspects of patient protection is required.

5.3 IR procedures vary considerably in the time they take to perform. Where possible the radiation source is turned off to reduce exposure since any prolongation of exposure, beyond that which is absolutely necessary, results in an increase in risk to the patient and also to the operator and support staff.

5.4 Examples of the variable time to perform IR procedures include: (i) lower limb angioplasty, central venous catheter insertion or fistuloplasty - these may take less than 30 mins to perform and will probably only involve 2 to 10 mins screening time; and (ii) a GI bleed embolisation procedure - this may take 1 to 2 hrs with 30 to 60 mins screening time.

5.5 The experience and skill of the interventionalist performing a procedure is also an important factor in determining its duration. Less experienced consultants and trainees may take longer to identify an abnormality and manipulate a catheter into position. They may also incur greater personal exposure while performing a procedure due to focusing on technical aspects and anatomy.

5.6 The factors affecting patient dose are listed in Table 5.1 and their impact on patient dose is discussed below.

5.7 All X-ray equipment is required to incorporate a minimum of 2.5 mm aluminium filtration to remove the low energy component of the X-ray spectrum that does not contribute to the image. Additional filtration of between 0.1- and 0.5-mm copper can be introduced in modern IR systems to reduce the entrance surface dose to the patient and thus reduce the risk of inducing tissue reactions. The disadvantage is that there may be some loss in image contrast. However, experienced practitioners will be able to balance the need for an adequate image to perform the procedure successfully with the need to minimise the radiation dose delivered. When contrast agents, such as barium or iodine, are employed in angiographic procedures, judicious use of such filters will result in enhanced contrast of the vessels being studied.

5.8 The use of short pulses of radiation results in sharper images and when combined with reduced frame rates can also result in lower patient doses for the same perceived image quality.

5.9 Use of last image hold freezes the last frame viewed on the display and thus allows detail to be viewed without exposing the patient. It is also possible to use video loop technology, in which a number of frames are stored automatically to permit a video version of last image hold.

5.10 Carbon fibre couch tops are generally available on all IR equipment and result in reduced patient exposure because they have reduced X-ray attenuation compared to conventional couches.

5.11 Modern flat panel detectors have the advantage of generally better dose efficiency when compared to older TV based image intensifier equipment; this results in lower radiation doses to patients. Their use requires much less of an increase in dose when used in magnification mode and they have better spatial resolution, with consequent better visualisation of detail.

5.12 Reduction of the area of tissue exposure using beam collimation can help reduce the extent of tissue reactions in prolonged procedures. It will also improve image quality by reducing the amount of scattered radiation and reduce the effective dose to the patient. Staff need to be constantly made aware during training of the importance of this issue and its importance for the safety of the patient and themselves, so that it becomes an automatic component of their practice.

5.13 Virtual collimation, which allows the X-ray collimators to be moved using last image hold images for guidance, results in reduced patient exposure.

5.14 Anti-scatter grids placed between the patient and the detector result in improved image quality by removing X-rays obliquely scattered from within the patient before they interact with the detector. However, their use results in increased patient dose. The grid or Bucky factor is the dose increase factor associated with the use of the grid and is typically in the range 2 to 6 (Poletti 2014). Anti-scatter grids should be removed when imaging small/paediatric patients or thin body parts (McFadden and others 2013b, Jones 2014). Grid removal should also be considered when the detector cannot be placed close to the patient (Partridge and others 2006, Gould and others 2017, Roy and others 2017).

5.15 The use of image magnification will increase patient dose (Nickoloff 2011). In traditional image intensifier TV systems, the relationship obeyed a square law, that is, a factor of 2 magnification will result in an increase in tube output by a factor of 4. In modern flat panel systems, the increase should be much less pronounced – it is imperative that this is confirmed to be the case by the MPE when IR equipment is first accepted and commissioned.

5.16 The image receptor should be placed as close to the patient as possible and the X-ray tube kept as far as possible from the patient. Air gap techniques should not be employed. In lateral and oblique projections, the X-ray tube can be closer to the patient than for a posteroanterior view. Spacers are supplied with IR equipment and should be used since their removal can lead to an increase in patient entrance dose by 100% (Jones 2014).

5.17 Patient size affects both patient dose and image quality and this should be remembered when undertaking IR procedures. As patient size increases, patient dose (and therefore staff dose) inevitably increase and image quality decreases because of the additional amount of scatter generated in the patient volume. As patient size increases, X-ray generator considerations mean that it might not be possible to introduce additional copper filtration, resulting in an increased risk of inducing tissue reactions.

5.18 Radiation dose can also be reduced by modifying tube angulation (see paragraph 6.14), especially useful when fluoroscopy times are prolonged. Staff awareness of this adaption is important and will require discussion between the technician or radiographer and the interventionalist performing the procedure, who will normally be focused on more clinical patient-related aspects. The variation of tube angulation during the procedure will change the beam entrance area and therefore will reduce potential skin radiation damage (see paragraph 5.36).

5.19 The number of ‘cine’ runs (for example to follow contrast) should be kept to the minimum required for the procedure since these employ a much higher tube current than fluoroscopy.

5.20 In persons of childbearing age, potential pregnancy must also be considered. Some procedures may be performed with no exposure of the foetus. However, where the foetus may be exposed, techniques should be used to keep the foetal dose as low as reasonably practicable, but patient contact shielding is not generally recommended (BIR 2020).

5.21 Repeat procedures are occasionally required, that is, an initially successful embolisation may require further treatment or an aortic stent may not have successfully sealed an aneurysm. Paediatric patients may also need repeat IR examinations / therapeutic interventions. Where possible, sufficient time should be allowed before the next procedure is performed to reduce the risk of tissue reactions, although this is not always possible. Again, risk versus benefit needs to be considered by the clinical team. Some procedures are deliberately staged for this very reason.

5.22 Pre-treatment planning as part of a multidisciplinary team approach can reduce patient exposure. Interventional Radiologists now have extensive prior 3D patient imaging data available, which allows them to plan procedures much more precisely. This results in more efficient use of their time in the IR theatre and in many instances can help to reduce overall procedure time and hence radiation exposure. However, pre-procedure imaging can involve the use of multiple CT scans. Although the amount of radiation exposure can be reduced by using, where applicable, ultrasound and MRI, CT remains the most frequently used assessment tool depending on the anatomical site thus adding, to some extent, to the overall radiation exposure of the patient.

Considerations for paediatric patients

5.23 The use of IR for paediatric patients is increasing in frequency, and also in the complexity and length of the procedures (McLaren 2014, Kim 2017). ICRP and others recommend that major paediatric interventional procedures, particularly in small infants, should be performed by experienced paediatric interventional operators for both clinical and radiological protection reasons (RCR 2010, ICRP 2013b, Donaldson 2017).

5.24 In neonates, infants, and small children, the detector may well cover the patient completely and therefore has the potential to increase radiation exposure if collimation is not used appropriately (EC 2000, ICRP 2013b).

5.25 Techniques used for paediatric IC may require significant modification from those used for adult patients (Connolly and othersl 2006, Kim 2017). Most of published data on the modifications of technique required for paediatric patients concentrate on paediatric IC (Anderson and others 2009), but similar modification principles will also apply to all paediatric interventions (Willihnganz-Lawson and others 2014).

5.26 The variation in protocols and radiation dose for performing PIC can be attributed to a variety of parameters that may need modification to adapt to the different size of paediatric patients; many of the required changes can increase radiation exposure significantly (Hellinger and Pezeshkmehr 2015, Harbron and others 2016, Osei and others 2016). For example, it may be necessary for the physician to stand closer to the paediatric patient due to the small size of patient. It is also quite possible that the detector will be bigger than the child and completely cover the patient’s body, requiring the physician to work close to the child to get access to the body.

5.27 Increased use of magnification is required when imaging paediatric patients to enable visualization of the small area of interest. This is of potential great significance especially in older image intensifier TV systems (see paragraph 5.15).

5.28 In PIC the higher heart rate of the patient often requires higher frame rates for digital acquisition. All of these factors will significantly increase the radiation dose to the child and the scatter radiation to staff (Harbron and others 2016).

5.29 Work by the DIMOND group set ‘image quality’ criteria for cardiac images as a guide to how angiograms should appear using good techniques. DIMOND III (Bernardi and others 2008) provided a review of these criteria and incorporated ‘aspects of an optimised angiogram’ into the revised guidelines. Further methods applicable to PIC have been recommended by Pirault and others (2014). This aspect of optimised technique takes into consideration the use of wedge filters on bright overexposed areas, frame rates, the number of sequences and images per sequence.

5.30 The DIMOND group guidelines address the more common projections for imaging of the coronary arteries in IC, and the most pertinent recommendations for paediatric patients are:

- A frame rate of 25 to 30 frames per second is recommended if the heartbeat is faster than 90 to 100 beats per minute or for paediatric patients.
- Increased numbers of imaging sequences can be used when the patient has anatomical anomalies which lead to difficulty (as in congenital anomalies).

5.31 A prospective study on paediatric IC has identified wide inter and intra hospital variation for similar examinations (McFadden and others 2013c). Technical and procedural variations between clinical centres have been identified as one of the main contributors to dose variations during IC procedures. Some clinical centres were reported to routinely remove the anti-scatter grid for patients under 10 kg, whilst others do not. This single change of removing the anti-scatter grid can result in a significant dose reduction with no compromise to image or procedural quality (Ubeda and others 2013). However, at present there are no national guidelines detailing standard protocols for paediatric IC; their provision could implement this important modification.

Considerations in Interventional Cardiology

5.32 The doses received by patients during fluoroscopically guided cardiology procedures can be high, and some patients may have several procedures performed in a relatively short period of time (ICRP 2013a).

5.33 Tissue reactions can occur if the dose thresholds for tissue reactions are exceeded (see Chapter 3). For IR procedures, the main tissue reaction of concern is skin injury, so a major thrust of patient protection is the avoidance of these injuries. Trigger levels and follow up should be established in individual centres (see Chapter 7).

5.34 The mean age of patients undergoing PCI is relatively high. The risk of stochastic effects is not a great concern for older patients because of the latency period (10 years or more) for the development of most cancers, and these patients' shorter life expectancies (ICRP 2013a).

5.35 Patients who undergo electrophysiology (EP) procedures tend to be younger, so the risk of stochastic effects in this cohort is of greater potential concern.

5.36 As with all IR, attention should be paid to the dose reduction methods listed in paragraphs 5.2 to 5.22. Operators should avoid steeply angulated projections (especially left anterior oblique cranial) as much as possible and vary the C-arm angulation slightly to avoid irradiating a single site on the patient's skin.

Patient radiation dose measurements

5.37 The measurement of radiation dose received by a patient is very difficult process. Image clarity is normally improved with increasing dose but at the cost of increasing patient dose exposure.

5.38 There is a wide range of doses associated with IR procedures with many having cumulative air kerma (CAK) values less than 1 Gy with no risk of skin reactions and very low effective doses. On the other hand, complex procedures such as endovascular repair of abdominal aortic aneurysms (EVAR), which will commonly have prolonged procedural times, can deliver CAKs of 5 to 10 Gy and effective doses of 20 to 70 mSv. Moreover, some protocols will mandate abdominal and pelvic CT scan follow-up at 1, 3 and 12 months that will contribute a significant additional radiation dose to the patient (Kirkwood and others 2018).

5.39 Patient dose in IR depends on many factors such as the radiation field size, patient position, beam on time and radiation detector (see Table 5.1).

Table 5.1: Factors affecting patient dose in IR.

Factors affecting patient dose in IR
Automatic dose rate control
Beam filtration
Beam on time or pulse repetition frequency
Couch material (X-ray attenuation)
Detector sensitivity
Examination area
Field size / Beam collimation
Grid ratio (scatter reduction device)
Image magnification
Patient orientation
Patient size
Patient to detector distance
Patient to X-ray tube distance
Time of exposure (sec or min)
Tube angulation
X-ray tube voltage (kV)
X-ray tube current (mA)

5.40 Dose meters such as ionisation chambers measure the amount of energy released by incoming X-ray photons rather than the amount of energy actually deposited. Because these can be different, the quantity used to calibrate the ionisation chambers is called kerma (kinetic energy released per unit mass), which approximates to absorbed dose but is not the same. Air kerma is measured with a dose meter that has a calibration traceable to a primary standard. The KAP (sometimes referred to as dose area product, DAP), is the integral of the air kerma over the area of the X-ray beam perpendicular to the central X-ray beam axis (ICRU 2005). X-ray tube output is given as the air kerma, measured in Gy, on the central beam axis at a certain distance, typically 1 m from the focal spot, and normalised to the product of tube current and exposure time with units of Gy/mAs (ICRU 2005).

5.41 The incident air kerma (IAK) is the air kerma on the central axis from the incident X-ray beam at the focal spot-to-surface distance, where the patient or phantom would intersect the beam. The IAK is measured free-in-air without the presence of the patient or phantom. The IAK can also be estimated from the X-ray tube output using the inverse squared law with the distance.

5.42 The entrance surface air kerma (ESAK) is a measure of the dose to the patient's skin at the centre of the X-ray beam. It is recorded in terms of air kerma and the value is similar to that in tissue. ESAK can be calculated by measuring IAK with a dosemeter at the distance where the beam would enter the patient, and then multiplying by a backscatter factor to account for radiation scattered from within the patient. The backscatter factor depends on the X-ray spectrum, patient, field size and other parameters (Grosswendt 1990, Petoussi-Henss and others 1998, Martin and Sutton 2015). A small dosemeter placed directly on the skin can also provide a direct measurement of this quantity; this is not done in routine clinical practice for simple, practical reasons.

5.43 Reference or cumulative air kerma (CAK) at the patient entrance reference point is a term reserved for fluoroscopic procedures. It is intended to represent the total IAK delivered to a reference point approximating to the patient's entrance surface during a procedure. It is used as an indicator of skin dose and as an aid to the avoidance of causing tissue reactions during an intervention. As it is specified for a fixed position it does not take movement of the X-ray tube into account.

5.44 The radiation protection quantities effective dose and organ dose (see Chapter 3) cannot be measured directly. Instead they must be derived using data obtained from computational models applied to mathematical phantoms. To do this the radiation field must first be described using physical parameters of the type outlined above and then converted to the radiation protection quantities. Conversion coefficients can then be derived that connect the physical and radiation protection radiation field parameters.

5.45 The conversion coefficients are derived using reference computational phantoms, for an adult male and adult female defined by ICRP (ICRP 2009a). These are voxel phantoms, derived from real persons, with the average organ masses as defined in ICRP Publication 89 (ICRP 2002). Exposure scenarios are simulated with the voxel phantoms and Monte Carlo radiation transport codes used to compute organ doses and thence derive conversion coefficients. Organ doses derived using these phantoms, $D_{T,R}$, are generally presented as the average of the adult male and female organ doses, and these are used to calculate effective dose. Simpler geometric anatomical phantoms have been used for this type of calculation in the past, and some of the data that are still used at this time were derived using these phantoms. Voxel based paediatric phantoms are also available from ICRP (2020) and can be used to derive appropriate conversion factors.

Peak Skin Dose

5.46 Peak skin dose is the maximum skin dose experienced by any section of the skin surface during an interventional examination and is the most useful quantity for estimating the risk of a deterministic skin injury. In practice, skin dose is complex and time consuming to measure (Balter 2006, Krajinović and others 2020) and the decision to do so must be made before a procedure actually starts (Jones and Pasciak 2011). It is therefore commonly calculated indirectly, either by vendor specific real time solutions (Bednarek and others 2011, Bordier and others 2015, Rana and others 2016) or using offline calculation. Indirectly calculated 2 and 3 dimensional maps of skin dose can be overlaid on the patient image to show the areas where doses are highest. The maps can be colour coded and although there is currently no agreed standard, work is being done towards the development of an international standard.

5.47 Real time systems use proprietary information derived from the equipment itself coupled with ray tracing algorithms (Bednarek and others 2011, Rana and others 2016), and are manufacturer specific. Data for offline calculation should ideally come from the Radiation Dose Structured Report (RDSR). However, such calculations are theoretically possible using image DICOM headers provided that information can be obtained from manufacturers about their use of vendor specific attributes in the headers (Krajinović and others 2020). The uncertainty in calculated peak skin dose can be up to +/- 50% (Balter 2006, Jones 2014, Dabin 2020).

5.48 Indirect calculation of skin dose is not trivial since it involves analysis of every irradiation event in a procedure, modelling of the patient in some way and ray tracing. In addition, whilst the position of the imaging table can be precisely defined, the precise location of the patient on the table is unknown. All of these details contribute to the significant uncertainty already mentioned. Many of the approaches used for calculating peak skin dose use a method comparable to that proposed by Jones and Pasciak (2011) for systems that are compliant with IEC standards (Malchair 2018).

5.49 The methodology involves implementation of an equation of the form

$$S_D = K_{a,r} \times M_a \times BSF \times \left(\frac{SPD}{SID}\right)^2 \times f_{skin}$$

where S_D is the skin dose, $K_{a,r}$ is the air kerma at the IEC reference point, M_a is the attenuation introduced by the table top and mattress, BSF is the back scatter factor, $(SPD/SID)^2$ is a distance correction and f_{skin} is the ratio of mass-energy-absorption coefficients from skin-to-air. SID is the source IEC reference point distance and SPD is the source peak skin distance. Further uncertainty is added because of errors in the determination of BSF, M_a and f_{skin}.

Radiation Dose Structured Report

5.50 The RDSR is a DICOM information object that records data from interventional (and other) procedures. An RDSR object is like an image, with the major difference that it does not contain pixel data; instead it contains structured information organised in a hierarchical tree structure (Omar and others 2016, AAPM 2019). A vast amount of information is stored in the RDSR structure, including data that is general for all irradiation events, such as device serial number and performing physician, and also data that is specific for each irradiation event, such as tube voltage and beam angle (Sechopoulos and others 2015, Hellström 2018). RDSR support on equipment used for interventional radiology was mandated by IEC in 2010 (IEC 2010) and should be available on all equipment subsequently manufactured. An entire interventional fluoroscopic sequence involving one pedal press will be included in the RDSR as a single irradiation event (Sechopoulos and others 2015). For example, if a particular interventional examination requires the exposure pedal to be pressed 15 times, 15 individual irradiation events are captured. However, there are many attribute fields in the RDSR that are optional rather than mandatory (NEMA 2021) and each manufacturer has also taken advantage of the possibility to adapt the standard with so-called ‘private fields’ (Malchair 2018). There are consequently many differences between the structured reports provided by different vendors, which makes the task of interrogating them even more complex.

5.51 An RDSR reader is necessary to covert the DICOM object data into a form that is generally accessible. Radiation dose management systems typically enable RDSR data to be viewed, manipulated and exported. It should also be noted that current PACS (picture archiving and communication system) solutions rarely have an RDSR reader, and some legacy PACS cannot even store the RDSR (AAPM 2019). There are open source solutions, for example OpenRem[3], which also has a simple skin dose assessment package.

5.52 AAPM (2019) recommend that a physicist needs to verify that radiation generating equipment has the capability of generating a correct RDSR as part of the acceptance test, or as part of a software upgrade for RDSR functionality. In the UK context, if hospitals intend to use these reports as a record of aspects of individual patient exposure, then all data therein must be validated, and that validation should be verified by the MPE carrying out the acceptance check.

5.53 Understanding of DICOM and RDSR should be a requirement for medical physicists involved in optimization of all radiology equipment.

Conclusions

5.54 Modern IR systems utilise a pulsed X-ray beam, flat panel detectors and a carbon fibre couch, which permit lower patient doses than older equipment.

5.55 Differences in techniques and procedures between clinical centres are a major contributor to dose variations during IC procedures. A range of techniques, including tube angulation, beam collimation and last image hold, can be manipulated to reduce patient dose. Particular effort should be made in the case of paediatric procedures, as at present there are no national guidelines detailing standard protocols for paediatric IC.

5.56 Attendance at MDTs and utilisation of prior 3D diagnostic imaging will permit the operator to plan procedures more precisely.

5.57 Patient radiation dose depends on a large number of factors (see Table 5.1) and is a complex process, which starts with the measurement of air kerma. The radiation protection quantities effective dose and organ dose are then derived using computational models.

5.58 RDSR capability, first mandated by IEC in 2010, should be included in all systems, ensuring the capability to download to local PACS. Attempts should be made to achieve international standardisation.

5.59 The adoption of technology enabling the production of patient skin dose maps which can be downloaded into patient record systems is strongly encouraged.

[3] OpenREM

Chapter 6: Radiation protection for staff

Factors affecting staff exposure to radiation during IR procedures

Effects of occupational radiation exposure

6.1 A consequence of the burgeoning use of IR procedures is the increase in the numbers of individuals involved in delivery of procedures using IR. Moreover, with increased workloads, the radiation exposure of staff also has the potential to increase (ICRP 2018). This is somewhat offset by improvements in the technology which are acting to reduce doses (Panick and others 2018).

6.2 Current evidence indicates that there is a small dose-dependent risk associated with occupational exposure to radiation for staff working in IR especially for those receiving the highest doses (Smilowitz and others 2013, Klein and others 2018, Tsapaki and others 2018). It has been possible to detect small changes in blood markers of interventional staff, although any associated impact on long-term health remains uncertain (Borghini and others 2017, El-Sayed and others 2017).

6.3 In the mid-1980s, a large U.S. study of radiologic technologists was initiated for individuals who worked for at least 2 years between 1926 and 1982; this included >146,000 individuals , >106,000 were women (Doody and others 2006). Subsequently the cohort has been surveyed 3 times and an increased risk of breast cancer has been shown (Doody and others 2006, Preston and others 2016).

6.4 Further analysis within the same cohort of the incidence of self-reported cancers and additional evidence of cancer mortality showed an approximately 2-fold increased risk of brain cancer mortality and modest elevations in the incidence but not mortality of melanoma and breast cancer. No other outcome evaluated showed significant excess incidence or mortality (Rajaraman and others 2016b). The authors noted that the results could be due to chance or confounded due to unmeasured non-radiation risk factors (Rajaraman and others 2016a, b).

6.5 Lee and others (2018) reported an increased risk of breast cancer in a study of a large cohort of medical workers in South Korea (>94,000), although the radiation-related risks identified were small and varied widely by sex and occupational group. The authors cautioned that careful monitoring and radioprotection is necessary particularly for female radiologic technologists.

6.6 Radiation exposure to the lens of the eye is of particular concern in assessing occupational risks for the development of cataracts in interventional staff as discussed in paragraphs 3.35 to 3.38. It has been noted that standard IR workloads have the potential to deliver lens doses which exceed the ICRP occupational dose limit unless radiation protection tools are used properly (Seals and others 2016, Bera and others 2018).

6.7 In a systematic review of 8 studies of staff working in IC (1,124 subjects; 1,335 controls) posterior eye lens opacity was significantly elevated in the IC staff ($P < 0.00001$); no significant differences were found in cortical or nuclear lens opacity

(Elmaraezy and others 2017). Reports have also shown an increased risk in the incidence of self-reported cataracts /cataract surgery in the large cohort of U.S. radiation technologists described in paragraph 6.3 (Little and others 2018, Velazquez-Kronen and others 2019). These studies confirm that IR staff should minimise radiation exposure to their eyes taking all the advised precautions as described in this report.

6.8 The above demonstrate the need to ensure that care is taken to reduce radiation exposure in line with the ALARP principle.

Radiation exposure to staff

6.9 The risk to staff from ionising radiation depends on proximity to the primary beam and scatter radiation. The person most at risk is the interventionalist performing the procedure as he/she is invariably working adjacent to the patient on the IR table. Consequently, this interventionalist will be exposed to the highest staff dose resulting from the procedure. The risk to other staff within the team depends on their role and their position within the operating theatre relative to the radiation beam.

6.10 The position and design of the IR equipment can influence the level of radiation exposure of staff. In particular, floor mounted X-ray tubes are much less manoeuvrable than those mounted in the ceiling. Similarly, ceiling-mounted shielding is more readily usable.

6.11 The highest dose rates around a fluoroscopic unit are from radiation scattered back from the surface of the patient. Consequently, in IR, doses to the head and hands of the operator are substantially lower when the tube is positioned under the couch.

6.12 Equipment design can influence the position of the operator in relation to the radiation beam which can also influence staff exposure.

6.13 The basic principles of time, distance and shielding apply in IR as in all areas of radiation protection. This means that personnel should minimise the time for which they are exposed to radiation, keep as far from the source of radiation as they can whilst still performing their task appropriately and use shielding and/or wear protective equipment when necessary.

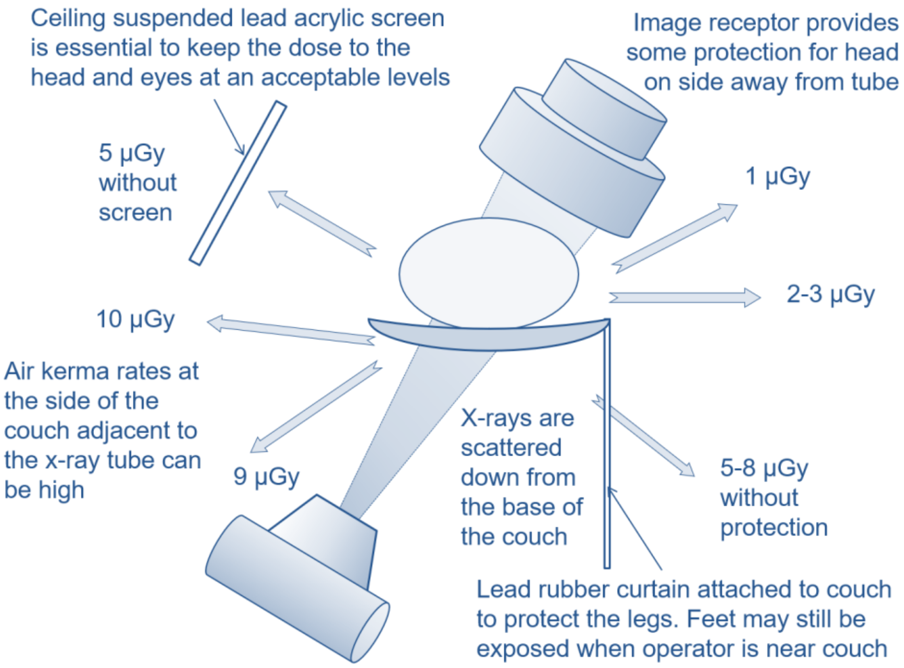
6.14 Any increase in patient dose will increase the amount (fluence) of radiation in the interventional room because, provided that staff do not expose themselves to the radiation beam itself, the scatter from the patient makes up most of the radiation in the room. Thus, any measure designed to reduce patient dose will also reduce potential staff dose. For example:

- as the tube angle is increased, the longer path length of the X-ray beam through the body will raise the X-ray intensity required to form an adequate image, and so will increase the dose to both patient and consequently to staff.
- reducing the number of frames per second will reduce the scattered radiation. The logical extension of this is that use of last image hold will effectively pause the radiation dose being delivered to the patient and consequently any staff involved.

- the smaller the field size employed the smaller the volume of the patient that will be irradiated. The amount of scattered radiation produced depends on the volume irradiated so there will be less scatter and accordingly a reduced dose to staff.
- positioning the patient as close to the detector as possible will reduce the patient dose, with consequent reduction in the amount of scattered radiation.

6.15 It should be noted that many IR procedures, especially in Clinical Radiology, do not take long and result in low patient radiation doses. One example of such a procedure is a peripherally inserted central catheter (PICC line), which is normally a short procedure resulting in a low patient dose. However, staff may well be involved in a large number of such procedures and so the cumulative staff dose should be controlled.

Figure 6.1: Doses to the operator at different positions around the patient per Gy cm^2 KAP for an undercouch X-ray tube angled at 30° to the vertical

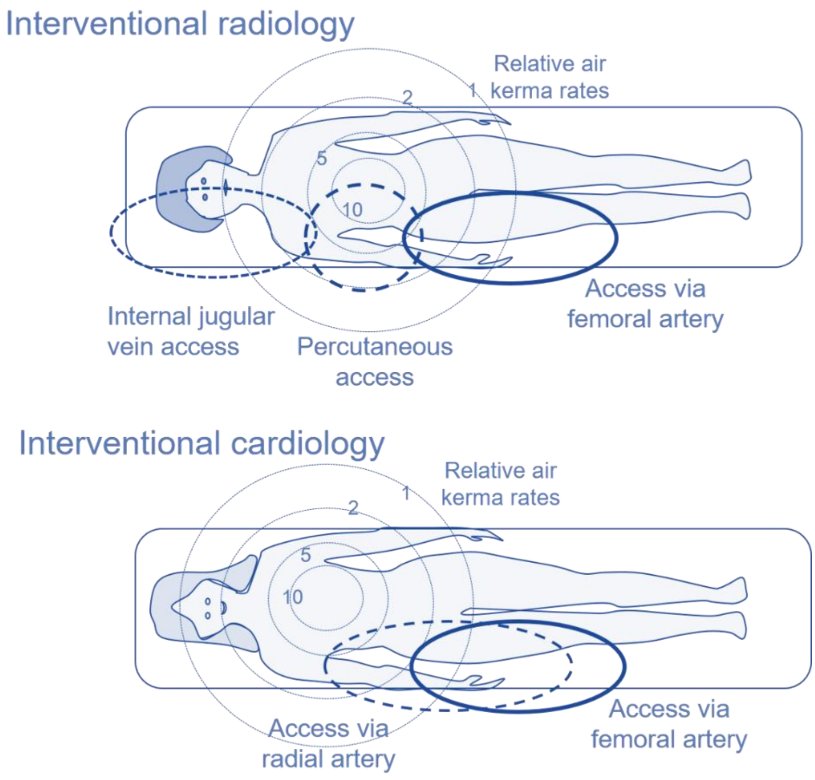


Dose values assume that no protection devices or personal protective equipment (PPE) are being used.

6.16 Radiologists and others performing IR procedures stand more frequently on the right side of the patient, with the X-ray tube and gantry on their left. Both the position of the person performing the procedure and their proximity to the X-ray tube have a significant influence on the amount of scatter to which they are exposed and therefore the doses they receive (Martin and others 2018). For example, the ratio of dose rates on the 2 sides of the couch changes as the angulation of the tube is increased. When the X-ray beam is directed at 10° to the vertical, the dose rate on the side adjacent to the tube will be double that on the side adjacent to the detector. When the angle is increased to 30°, the dose rate may be 5 times that on the far side. Staff who need to stand near to the couch should avoid the region adjacent to the X-ray tube for oblique and lateral projections. When the X-ray tube is positioned below the couch, the primary beam is scattered downwards from the base of the couch, so the legs of the operator can receive a significant dose. Where no shield is available, the doses to the legs can be greater than those to the hands (see Figure 6.1).

6.17 The mode of access used for interventional procedures has significant implications for the radiation dose to the person performing the procedure. Procedures involving radial access routes require the operator to stand closer to the X-ray tube leading to higher doses, especially to the operator's hands and eyes, than those using femoral access. Radial access, however, often has advantages relating to treatment of the patient. For example, transradial artery access for PCI is associated with lower bleeding and vascular complications than transfemoral artery access, especially in patients with acute coronary syndromes (Mason and others 2018) and can result in earlier discharge post procedure. Femoral access still remains necessary for numerous coronary procedures, many requiring large-bore access, including complex high-risk coronary interventions, structural procedures, and procedures involving mechanical circulatory support (Sandoval and others 2017).

Figure 6.2: How the radiation dose to the hands of the operator varies with access point for interventional radiology and cardiology



6.18 Interventional radiologists are required to stand close to the point at which access is gained to the body as they manipulate guidewires through catheters. Interventional radiologists frequently use the femoral artery for access, but increasingly transradial access is being trialled (and adopted) for a range of procedures (Posham and others 2016, Kok and others 2018). As outlined above, whilst being of benefit to the patient, this exposes the operator to higher levels of scatter, especially when manipulations are required, for example in stenting or drainage procedures (see Figure 6.2).

6.19 The variation in operating position also determines the level of radiation exposure to the operator's hands (see Figure 6.2). Manipulation of the equipment close to the area of interest will increase the risk of the operator's hands or fingers being exposed directly (Whitby and Martin 2005).

6.20 Exposure can be reduced for the person administering sedation by using an extended cannula. However, monitoring equipment occasionally needs adjustment which will involve a member of staff moving closer to the area of exposure, albeit for a short period of time. Similarly, the anaesthetist or ODP may need to position themselves close to the patient's head to make adjustments to ventilation equipment or to administer IV drugs.

6.21 Some interventions can be performed using very short intermittent exposures to radiation or no exposure at all, that is, a percutaneous nephrostomy is performed using ultrasound to guide initial access but can sometimes be performed entirely with ultrasound guidance.

6.22 CT-guided procedures, such as tumour ablation, can be performed with no exposure to ionising radiation for the operator but are more time consuming. Use of CT fluoroscopy to guide ablation will increase the risk of exposure to the operator depending on where they stand in relation to the tube and what protection, if any, is provided between them and the tube. There is also a risk of direct exposure of hands whilst positioning the ablation probes with the patient positioned in the scanner.

6.23 Where possible staff should stay as far away as practical from the radiation beam. However, patients may require re-assurance from a member of the team whilst the procedure is taking place and a nurse standing next to the patient's head or holding their hand will be exposed to more scatter than when standing several metres away.

Mitigation of staff doses using protective equipment

6.24 ICRP (ICRP 2018) recommend that staff in the interventional room should wear protective aprons; the interventionalist should be protected by ceiling-suspended screens, table-suspended curtains, and shielding drapes when feasible. If shown to be necessary by risk assessment or other means, interventionalists should wear protective eyewear; however, the ceiling suspended screen provides by far the best protection of the head and eyes if used correctly. Other staff, such as nurses and anaesthesia personnel, who need to remain near the patient, can benefit from protection by movable screens; other personnel can also benefit from protection afforded by distance. Staff should leave the area during digital acquisitions unless necessary for that aspect of the procedure. A Radiation Protection Advisor (RPA) can be consulted to advise on suitable shielding and personal protection.

6.25 The employer's radiation risk assessment will identify what personal dosimetry and personal protective equipment (PPE) is required for particular work with radiation and employees must be trained and instructed on their use. Where local rules are provided for an area as per Regulation 18(2) of the Ionising Radiations Regulations

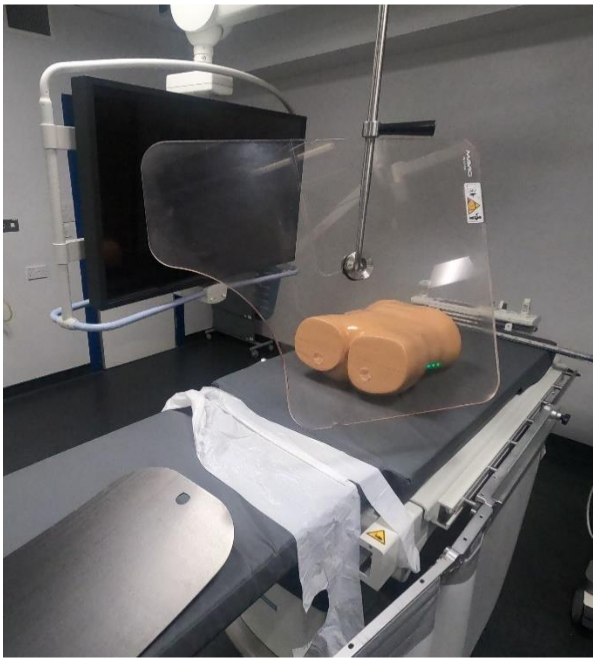
2017 (IRR17) (IRR 2017), details concerning the use of PPE and personal dosimetry should be included as part of the main working instructions intended to restrict any exposures in controlled or supervised areas. The wearing of the identified personal dosimetry and PPE is not optional and employees who fail to adhere to those instructions are likely to be committing an offence under Reg 35 (2) of the IRR17 (IRR 2017) and/or Section 7 of the Health and Safety at Work etc. Act 1974 (HSWA 1974).

6.26 Mobile protective screens play an important role in staff radiation protection in interventional environments. When specified correctly they should provide an area behind which dose rates are sufficiently low that members of staff would theoretically need no additional protective equipment. Such screens should be at least 2 m high, will contain a mixture of flat and angled panels as required and should be large enough to provide sufficient shielding for all those who may need to be behind them.

6.27 Any screen designed to protect the operator must also allow clear visibility to all entrances into the room, so that in the event of unauthorised entry into the interventional room during an exposure the operator is aware immediately.

6.28 Overhead-suspended shields (Figure 6.3) are generally used in interventional procedures to reduce radiation doses to the head and upper body of those staff who may need to remain close to the patient during the performance of a procedure. They provide the most efficient way to protect the eyes of the operator if used correctly, an important consideration given the reduction in the eye dose limit to 20 mSv. Shields like this are usually mounted on the ceiling but can be attached to an adjacent wall or even on the radiological equipment itself, depending on range of procedures that are to be carried out.

Figure 6.3: Example of overhead suspension shield to reduce upper body exposure in interventional examinations



6.29 Ceiling suspended shields should be placed as near to the patient as possible, so as to interrupt as much scattered radiation as possible, and ideally the cut-out arc that is a feature of many screens should be close to the patient contour. The operator should be viewing the patient through the screen, with the screen angled to maximise the size of the X-ray shadow, and for lateral projections where the tube is close to the operator, the shield should be drawn back closer to their side. With careful positioning, ceiling suspended screens provide the most effective protection of the head and upper body. Some operators find that they limit vision and access to the patient, but it is essential for operators to use them as much as possible to prevent doses to the eye exceeding the dose limit.

6.30 There can be poor compliance in the use of protective devices by some staff. A reason given for this is the inability of staff to perform selected procedures adequately due to inconvenient/almost impossible positioning of the protective equipment. This may be due to equipment design faults or the requirements of a specific procedure.

6.31 As outlined above, the legs of interventional radiologists may receive non-trivial radiation doses (Whitby and Martin 2003). These may be substantially reduced either by the use of lead drapes hung from the table or a short mobile screen (Figure 6.4). Not all lead skirts are transferrable from one side of an X-ray table to the other, so portable screens should be available where this is an issue.

Figure 6.4: Table mounted shielding used to reduce lower body exposure in interventional radiology

6.32 All staff working in an interventional room should wear a lead apron. There are a wide range of styles of lead apron, examples being front-only, double-sided or wrap-around. Designs that do not provide complete protection for the torso must be used with caution to prevent exposure of unprotected areas. When worn correctly, a lead apron will reduce the radiation dose from scattered radiation by 95% to 99%. Weight can be an issue with lead aprons, and it is possible to use so-called light-weight aprons; when this option is chosen, it is important that the lead equivalence is known and the labelling on the product fully understood (Hiles and others 2016).

6.33 Thyroid shields can significantly reduce thyroid and effective dose and are especially important for younger people and female staff who have a greater risk from radiation induced thyroid cancer. The British Institute of Radiology (Hiles and others 2016) recommend that they should always be worn by people carrying out interventional work.

6.34 Protective eyewear (lead glasses) can reduce the radiation dose to the eye considerably. However, the amount of protection provided depends on the angle of incidence of the scattered radiation. This is especially important in IR as the interventionalist will not generally be looking directly at the patient when performing a procedure. For this reason, lead protective eyewear should preferably be of a close-fitting wrap-around design. Prescription lead glasses should be worn if the interventionalist wears spectacles. Protective eyewear does not eliminate exposure of the eye completely, since much of the radiation dose arises from scatter from surrounding tissues.

6.35 It is important that protective equipment is checked regularly for defects. In addition, staff should be taught the importance of looking after PPE, for example hanging lead aprons up to avoid creases which may lead to a defect in the lead protection. Although some staff do this routinely it has been found that this is not necessarily true for all users of the equipment.

Personal Dosimetry

6.36 IRR17 (IRR 2017) prescribe the dose limits which employers must ensure that workers do not exceed. The regulator for IRR2017 is the Health and Safety Executive (HSE). In IR procedures, consideration needs to be given to radiation doses to a) the whole body, b) the eyes and c) extremities, including fingers, hands and legs. Dose limits are expressed in terms of effective dose for whole body monitoring and equivalent dose for eyes and extremities. The relevant dose limits to be taken into consideration in IR are: whole body 20 mSv per annum, eye 20 mSv per annum, extremities (hands, including finger tips, and legs) 500 mSv per annum. Employees who are likely to receive in excess of certain constraints need to be classified. These constraints are: whole body exposures 6 mSv per annum, eye 15 mSv per annum, extremities 150 mSv per annum.

6.37 Once a staff member has notified their employer of a pregnancy, the employer must ensure that the equivalent dose to the foetus is as low as reasonably practical and is unlikely to exceed 1 mSv during the remainder of the pregnancy.

6.38 Monitoring for regulatory purposes is called compliance monitoring. Decisions on whether to issue personal dosemeters to staff for compliance monitoring purposes are based on the risk assessments that are mandated by IRR17 (IRR 2017). When whole body dose monitoring is carried out for compliance purposes and only one dosemeter is worn, the HSE recommend that the dosemeter should be worn under any lead apron. In terms of best practice, ICRP recommend that 2 dosemeters, one shielded by the apron (under apron) and one unshielded (over apron) at collar level, provide the best estimate of effective dose (ICRP 2013a). It is likely that interventionalists will need to wear both an under apron dosemeter and one for monitoring dose to the eye lens, for which the optimum position may be on the forehead or adjacent to the left eye. Other staff working with X-rays will also need to have a method for recording or estimating the dose to the eye. Authoritative operational guidance on the personal monitoring requirements for personnel working in healthcare (including interventional radiology), can be found in Martin and others (2018). An RPA, appointed in accordance with the requirements of IRR17, should be consulted on personal dose monitoring requirements.

6.39 Monitoring may be required for other purposes, for example to understand patterns of work or to identify those parts of a work practice that contribute most to the dose a member of staff receives. This type of dose monitoring may be used as part of an optimisation process to reduce staff doses to a level that is As Low As Reasonably Practicable (ALARP), in which case whole body monitors should be worn outside the lead apron.

6.40 Effective and equivalent dose, the quantities which are used to define regulatory dose limits for whole body, extremity and eye dose monitoring, are abstract quantities which cannot be measured directly. For this reason, so called ‘operational quantities’ have been defined and it is these that are used for the purpose of both environmental and personal monitoring. The quantity used in personal monitoring is Hp(d), where p means ‘personal’ and d is the depth in mm beneath tissue at which the measuring device is calibrated. Hp(d) is referred to as personal dose equivalent. In practice, 3 different depths are commonly used.

6.41 Dosemeters are calibrated to give the dose equivalent at 10 mm beneath the surface when their intended use is whole body monitoring, the dose at 3 mm for eye monitoring and at 0.07 mm for extremity (skin) monitoring. It is important that dosemeters are only used for the purpose for which they are calibrated and that they are worn when issued. Dosemeters that are used for compliance purposes must be of a type approved by the HSE and must be read by a dosimetry service that is itself approved by the HSE.

6.42 Dosemeters can be grouped into 2 broad types, passive and active.

6.43 **Passive dosemeters** are not powered and generally need to be interrogated or read using an external device. They are generally used for compliance monitoring and for identifying situations where more sophisticated (active) monitoring may be required. Passive dosemeters are fabricated for the most part using Optically Stimulated Luminescent (OSL) or Thermo Luminescent (TLD) materials. These materials require an external stimulus (light or heat) to release energy deposited in them by the incident radiation, which is then emitted as light, and they require sophisticated read out devices. OSL dosemeters typically have a threshold for detection of 10 µSv and TLD a threshold for detection of 100 µSv. Such dosemeters can be read by an external provider or in-house, and results returned for analysis. A further type of passive dosemeter that has appeared on the market relatively recently uses direct ion storage and is based on the combination of an ion chamber and a non-volatile electronic charge storage element. Internal electronics allow this type of dosemeter to ‘self-read’ with results being transferred to a logging device wirelessly. The threshold for detection is 10 µSv.

6.44 Passive dosemeters are used in IR for whole body monitoring, skin dose monitoring (using ring badges or fingertip sachets) and eye dose monitoring. Given their primary role of demonstrating compliance with annual dose limits they tend to be worn for 1 to 3 months at a time before being read out. There is therefore an inevitable delay between a radiation dose being received by the wearer of a passive dosemeter and its notification to the wearer and her/his employer. When passive dosemeters are used for compliance monitoring, and staff work for more than one employer at different sites (a common occurrence in IR), it is important that robust arrangements are made between the differing employers to ensure that adequate assessment of the annual dose to any single person can be made.

6.45 **Active or electronic personal dosemeters (APDs)** require a power source, usually a battery, and generally provide both cumulative dose and dose rate information. There is usually a real time display available for the wearer and a built-in data logging capacity that enables interrogation by a reading device subsequent to the wear period; there may also be an audible alarm if a pre-set dose rate is exceeded. When used in IR, care must be taken to ensure that the energy range of the detector in the APD is suitable for use in diagnostic radiology. The minimum threshold detection is typically of the order of 1 µSv. The use of an APD permits:

- More immediate awareness of received radiation doses than is possible with passive dosemeters.

- The potential for more sophisticated and granular analysis of dosimetry data than is possible with passive dosemeters. The reader can identify when doses were delivered since recording is carried out at discrete time intervals rather than being integrated over time.
- Consequent analysis of doses delivered at different points during individual tasks and sub-elements of tasks thus allowing optimisation (in terms of ALARP) to be facilitated.
- The potential for users to wear only one dosemeter over a monitoring period when s/he is working for more than one employer since the time when the doses were delivered can be identified.
- The potential for more frequent analysis of compliance related dose data in circumstances such as pregnancy, when more vigilance may well be required, given the lower dose limits that are applied.
- Potential for real time display on a central display. Some systems use APDs in this way to provide real time information that can be used to make staff aware of what cumulative doses and dose rates they are being exposed to during any given procedure.

6.46 Vanhavere and others (2020) carried out an evaluation of 3 types of APD in the clinical IR and IC setting across several countries. They compared APD results with those from conventional passive dosemeters, both being mounted in a holder, so that the relative position was the same. This required that the holders were worn by the same person for multiple procedures. Operators wore the holder above their lead apron, aiming for a minimum reading of 300µSv; in practice, data above 100µSv were included in the analysis. This study followed an earlier one by many of the team (Vanhavere and others 2012) which showed that, in pulsed radiation fields, the response of most APDs decreased when the instantaneous personal dose equivalent increased. The later study found that, in the majority of cases, the APDs underestimated doses below 2 mSv, although the APD/passive ratio ranged from 0.5 to 2. Above 2 mSv, the ratio tended to unity. No single factor – different energies, angular response, pulsed field response – was found to account for the differences. Different ratios for the same APD were found in some sites, however, with the APD/RPL ratio being closer to one.

6.47 Approved dosimetry services proposing to use APDs to measure radiation doses of classified workers in the UK need prior approval from HSE. No approval is required for use in monitoring doses to non-classified employees or if the APD is used in conjunction with a primary approved dosimeter by classified employees.

6.48 Evidence suggests that APDs can be used for staff education and optimisation of doses (Racadio and others 2014, Baumann and others 2015, Omar and others 2017). If used for these purposes, they should be worn over any lead protective apron.

Consequences of dose limits

6.49 Concerns have been raised that staff radiation doses may lead to limitations on the number of procedures which an individual can undertake while remaining within the dose limits. This would lead to considerations of the staffing levels required to provide a service.

6.50 From the literature, neurointerventionalists appear to be at highest risk from radiation. An interventional spinal surgeon (with 9 years of experience) was monitored during 52 consecutive fluoroscopic spine procedures, which included myelography, selective nerve root block and facet joint block, over 3 months (Yamashita and others 2017). A radiophotoluminescence glass ring dosimeter, which accumulated the radiation doses measured at the right thumb for each month, recorded 122 mSv, 120 mSv, and 126 mSv, giving a total dose of 368 mSv. Working at this level throughout the year would give an annual dose of some 1300 mSv allowing for annual leave, over twice the dose limit for the skin. An alternative interpretation of these data is that, even as a classified worker, the surgeon would reach the dose limit after only 4 months.

6.51 Neto and others (2016) measured the radiation doses to various part of the body received by the primary operator and assistant during lower limb angiography, lower limb angioplasty and EVAR. Seven staff took part and TLD measurements were made for 30 of each type of procedure.

6.52 Dosemeters were worn above shielding equipment (lead apron, thyroid shield, among others) and the results corrected by measured shielding factors to yield estimated body doses. The doses to the hands, which needed no correction, were found to be critical in terms of dose limit compliance. The median and maximum recorded doses per procedure are shown in Table 6.1, together with the maximum number of each which could be carried out in a year without exceeding the dose limit.

Table 6.1: Hand doses recorded per procedure (uSv) and maximum number of procedures carried out per year at median and maximum dose levels by an individual to remain within skin dose limits.

	Median dose (uSv)	Interquartile range (uSv)	Maximum procedures per year	
			Median	Maximum
Primary operator				
Angiography	33.1	11.7 to 149.2	>2500	>2500
Angioplasty	178.2	35.4 to 645.8	>2500	770
EVAR	2105.3	826.2 to 4,679.2	560	100
Assistant operator				
Angiography	37.5	8.5 to 84.3	>2500	>2500
Angioplasty	33.6	15.7 to 71.1	>2500	>2500
EVAR	417.7	210.3 to 5,751.3	640	90

6.53 The eye doses were recorded without shielding but, assuming appropriate eye shielding to give 60% attenuation, the maximum numbers of procedures which could be carried out by an individual to remain within the current limits are shown in Table 6.2.

Table 6.2: Maximum number of procedures carried out per year at median and maximum dose levels by an individual to remain within eye dose limits.

	Maximum procedures per year	
	Median	**Maximum**
Primary operator		
Angiography	>2,500	1,000
Angioplasty	930	390
EVAR	140	110
Assistant operator		
Angiography	>2,500	870
Angioplasty	1,790	950
EVAR	240	130

Conclusions

6.54 Wherever possible, X-ray tubes and shielding should be ceiling-mounted to enhance manoeuvrability and usability. The highest dose rates in the IR room are from radiation backscattered from the patient and positioning the X-ray tube under the couch substantially reduces doses to the head and hands of the operator, although this positioning reduces manoeuvrability.

6.55 Staff should minimise the time for which they are exposed to radiation and maximise their distance from the radiation source as is consistent with their duties At all times they should utilise shielding and personal protective equipment (for example, lead apron, thyroid shield and, if found necessary, protective eyewear) as provided by their employer.

6.56 For compliance dose monitoring, HSE recommend that. the dosemeter is worn under the lead apron. A second dosemeter, placed on the forehead or adjacent to the left eye, will be necessary to monitor the operator’s eye dose.

6.57 More information about optimisation of staff radiation doses can be obtained by wearing an additional dosemeter over the apron at chest height.

6.58 Where shown advisable, additional dosemeters may be placed on the operator’s hands.

6.59 Active personal dosemeters offer several advantages over passive dosemeters (see paragraph 6.44), principally immediate awareness of radiation dose rate. They are of value also in the development of new procedures.

6.60 Operator hand and eye doses may limit the number of procedures per year which can be carried out by an individual.

Chapter 7: Image optimisation and diagnostic reference levels

Radiation dose and image quality in IR

7.1 In patient radiation protection terms, the imperative in medical imaging is to provide images which are adequate for the clinical task or question at hand whilst delivering the minimum radiation dose to the patient. This is often thought of in terms of balancing patient dose and image quality and is termed optimisation. Achieving the optimal balance for any application requires an understanding of the way in which an image is formed and how different factors influence both the quality and the radiation dose received by the patient (Martin and others 1999).

7.2 The clinical task may be, for example, achieving the correct diagnosis from a radiograph or positioning a stent correctly during an image guided procedure. Radiation dose is directly related to image noise. Thus, the radiation dose required to produce an image that is adequate for the task will be a function of the task itself. For example, detection of a renal stone will require less radiation than accurate visualisation of an artery during cardiac cineangiography. In addition, as well as being dependent on the level of detail required and noise present in the image, the correct interpretation of the image is a subjective process, so the amount of radiation required will also be dependent on the person who is interpreting or using the image. Put succinctly, adequate assessment of an image is both task and reader dependent.

7.3 The task and reader interdependencies are the main reason that much of the focus on optimisation has concentrated on methods for reducing radiation dose. Image quality is generally assessed as a technical rather than clinical parameter, usually in a quality assurance programme as part of a compliance regime. However, there is a growing consensus that the optimisation goal goes beyond dose alone and should increasingly include more clinically relevant considerations of image quality (Samei and others 2018).

7.4 Nevertheless, there are many ways in which technical and scientific approaches to improving image quality whilst reducing patient dose can be incorporated into the design of equipment intended to be used for IR. For example, modern X-ray equipment features digital flat panel detectors and operates in pulsed rather than the traditional continuous mode. The use of short pulses of radiation results in sharper images and when combined with reduced frame rates can also result in lower patient doses for the same perceived image quality (Aufrichtig and others 1994, Balter 2014).

7.5 Flat panel detectors have the advantage of generally better dose efficiency and spatial resolution (Seibert 2019) and do not require increased dose when used in magnification mode when compared to older image intensifier-based equipment. Digital detectors also permit the implementation of image processing algorithms such as deblurring, frame averaging and edge enhancement in real time, with consequent implications for perceived image quality.

7.6 As previously described, equipment used for IR is also generally fitted with a host of dose saving features, many of which have the added bonus of improving the technical aspects of image quality. Increasingly the features come as standard equipment, but some remain optional. Common features include;

- Last image hold - which freezes the last frame viewed on the display and thus allows detail to be viewed without exposing the patient,
- Virtual collimation - which allows the X-ray collimators to be moved using last image hold images for guidance, once again reducing patient exposure,
- Additional beam filtration - which permits insertion of additional beam filtration to expressly reduce ESAK, with the intention of reducing the possibility of inducing tissue reactions.

7.7 Additional filtration can also improve image quality if employed in angiographic procedures involving contrast agents such as iodine, since it can be used to alter the energy of the X-ray beam to more adequately overlap with the k-edge of the contrast agent. This will have the effect of improving image contrast.

Optimisation of interventional procedures

7.8 Optimisation of IR procedures as for other radiology procedures requires a team approach with radiologists, radiographers and medical physics experts working together. This process starts from the specification of the equipment, continues through the testing phase and extends into clinical implementation.

7.9 Detailed specifications of performance relating to the intended clinical use of the equipment should be made when purchase is being considered. This should include the training of staff required and maintenance requirements. The specification requires input from radiologists, radiographers, radiology managers, medical physics experts (MPEs) and procurement experts.

7.10 Acceptance tests by the vendor application specialists and their performance should be verified by site staff, principally the MPE. This will involve testing of automatic dose rate control (ADRC) settings for different modes and anatomical/clinical programmes through measurements of dose and image quality. It is important to know how the ADRC works in terms of which acquisition parameters are changing and based on what algorithms, and that the automatic exposure control for individual images is operating satisfactorily.

7.11 Results of the tests should be fed back to the equipment users to provide information on dose levels. Clinical protocols should be checked for consistency with other radiology equipment operated by the healthcare organisation to ensure that there is a systemic approach to imaging.

7.12 Initial training of the operators should be provided by the representative of the installer / manufacturer (applications specialist) following acceptance and before the equipment is put into clinical use.

7.13 A quality control (QC) programme involving the measurement and analysis of aspects of equipment performance in terms of dose and image quality should be in place and MPEs with expertise in diagnostic radiology involved in interpretation of results. MPEs should understand how the systems work, their characteristics, modes of operation and image acquisition, image quality requirements and image processing for different clinical programmes and clinical uses. There should be close cooperation with equipment service engineers, and clinical staff operating and using the equipment. The QC programme should form part of a managed quality assurance programme.

7.14 Results from QC tests should be used in analysing performance of IR equipment in surveys of patient dose. Although such surveys are the means through which units giving higher doses can more readily be identified, the reasons for any anomalies can only be understood from analysis of the equipment performance data.

7.15 Clinical protocols should be configured through adjustment of settings customised to the required image quality and dose saving needs for the clinical task.

7.16 Protocols for IC examinations are usually developed at a local level and hence may vary from one department to another. The National Institute for Health and Care Excellence (NICE) has issued guidelines on the safety and efficacy of interventional procedures being carried out in the NHS (NICE 2007). All the common CHD procedures are identified, and the efficacy of each interventional procedure is discussed.

Diagnostic reference levels (DRLs)

7.17 As described in paragraphs 3.3 and 5.40 to 5.43, the radiation doses received by patients undergoing interventional procedures are recorded in terms of IAK or its derivatives. The most commonly recorded quantities derived from IAK are KAP, which provides a measure of the radiation dose and beam area product entering the patient at any projection, ESAK, which provides a measure of the amount of radiation incident on the skin surface relative to air, and CAK, which provides a measure of the total amount of radiation incident on the reference position on the patient during a procedure.

7.18 It is not appropriate to apply dose limits to the patient in medical exposures since there is, by definition, a direct benefit to the patient. Instead, in the case of diagnostic examinations, guidance regarding radiation doses for different examinations is provided by the adoption of diagnostic reference levels (DRLs). DRLs are intended to act as a guide to the very indistinct border between good and normal practice and poor and abnormal practice and are often seen as the first step in the optimisation process. They are usually established from surveys of measured doses for patients of average size in hospitals, usually at national, but also at regional or local levels.

7.19 National DRLs for a range of diagnostic examinations, which do not apply to individual patient examinations, have been set in the UK at the third quartile of mean X-ray room examination doses measured in large-scale hospital surveys. ICRP (2017) have proposed that future DRLs be set in terms of the third quartile of median examination doses.

7.20 DRLs are essentially an audit tool, so an investigation or intervention might be triggered if the mean or median dose for an examination in a hospital exceeds the DRL. Conceptually, an investigation could also be triggered in the situation where doses are substantially below the DRL value. Defining the DRL in terms of the third quartile means that a dose which exceeds a DRL for any particular examination will be higher than that which the majority of radiologists agree is needed to produce images that are sufficient for the intended clinical purpose.

7.21 UK regulation requires that if an exposure intended for the individual is significantly greater or different to that intended it should be reporting to the appropriate enforcement authority. In the case of IR, one of the criteria for reporting is when the exposure is in excess of 10 times the local Diagnostic Reference Level (see paragraph 7.56).

7.22 However, whilst DRLs are very useful for diagnostic examinations they are much more challenging to implement or interpret in the case of IR because a) such procedures are by definition therapeutic, not diagnostic and b) there is a wide distribution of patient doses for any given examination. Consequently, the conventional DRL methodology is not well-suited to IR procedures (Baiter and others 2011).

7.23 As reported by ICRP (2017), procedure complexity varies for interventional procedures because of difference between patients, the lesions being treated and disease severity. For these reasons, interventional procedures demonstrate substantial variability in the amount of radiation used for individual cases due to patient, operator, type of materials and equipment factors.

7.24 ICRP (2017) recommend that even though interventional procedures are therapeutic, the term DRL is retained for use in IR since their purpose is to provide a tool for optimisation and the adoption of a different nomenclature is likely to result in confusion. They do however recommend that DRLs for interventional procedures should be developed differently from those for diagnostic procedures.

7.25 ICRP (2017) makes recommendations regarding the establishment of DRLs for interventional work that take into account procedure complexity; to date very few approaches to this have been proposed and an agreed methodology has yet to be developed. Quantities that are recommended by ICRP as being suitable for establishing DRLs are:

- KAP (the preferred metric),
- CAK at the International Standards Organisation (ISO) reference point,
- fluoroscopy time and
- the number of radiographic images obtained as part of the procedure

7.26 As an alternative to assessing complexity, another proposed approach to establishing DRLs in IR is to use data taken from a very large number of individual measurements such as those from an entire country. This type of data collection differs from the traditional approach taken, where median or mean results per X-ray room are collected, and is more suited to IR (Marshall and others 2000, Baiter and others 2011, ICRP 2017)). The summary data are termed an Advisory Data Set (ADS, (NCRP 2010)) and comparisons are made between the distribution of the ADS and that of the data set measured in an individual hospital, Health Board or Trust. Determination of the need for an investigation or report is dependent on comparison with the 75th percentile of the ADS.

7.27 If DRLs based on metrics such as KAP are to be established for IR procedures, then large groups of patients will need to be entered into survey cohorts since the amount of radiation used is dependent on procedure complexity rather than simple patient factors (ICRP 2017).

7.28 A coherent methodology for the establishment and implementation of DRLs for fluoroscopically guided interventions has yet to be developed in the UK, despite the requirement to use them for reporting purposes.

Dose Surveys, DRLs and skin dose

7.29 As outlined above, the factors that influence both patient dose and image quality depend on the patient body habitus (physique), the clinical question, the examination, the equipment used to image the patient and the person interpreting the eventual image.

7.30 Nevertheless, knowledge of the distribution of doses delivered to patients is undoubtedly the first step in the optimisation process, and because of the nature of the distribution, it can only be gained by surveys of real patient doses (not phantoms).

7.31 Patient dose surveys should be undertaken routinely, both for local audit purposes and to contribute to the setting of national DRLs.

7.32 In IR, large numbers of patients are required to demonstrate statistically significant dose differences, which may well be smaller than the spread in doses due to patient size since both differences in patients' anatomy, patient disease complexity and operator technique contribute to dose variations.

7.33 Metrics used in surveys should be representative of patient dose, the preferred quantity for IR being KAP. Ideally KAP should be transferred automatically to, and retrieved from, the RIS or other hospital information system in order to avoid issues caused by transcription errors. Preferably, use can be made of the RDSR where available.

7.34 There are no recent UK recommendations for DRLs to be used in IR. The most recent data come from a 2010 review (Hart and others 2012) of doses for various examinations and interventional procedures which was carried out by the Health Protection Agency (now PHE). For these dose surveys, reviews of the national reference doses are based on rounded third quartile values of the mean patient doses observed for common X-ray examinations or interventional procedures in a nationally representative sample of X-ray rooms. They do not take into account procedure complexity and do not use aggregated data as described in paragraph 7.17. The current suggested UK DRLs for interventional procedures are listed in Table 7.1.

Table 7.1: Current UK recommended national reference doses for IR procedures on adult patients

Interventional procedure	Dose Reference Level (DRL) (Gy cm^2)	DRL fluoroscopy time per exam[4] (mins)
Biliary intervention	43	14
Facet joint injection	6	1.4
Hickman line insertion	3	1.5
Nephrostomy	13	6.7
Oesophageal stent	13	5
Pacemaker (permanent)	7	6
Percutaneous transluminal coronary angioplasty (PTCA) (single stent)*	7	6

* Mean patient weight range 75 to 85 kg instead of 65 to 75 kg.
Values from Hart and others (2012).

7.35 For some interventional procedures the sample size was too small to derive accurate third quartile doses from the dose distribution to be used as DRLs. Hart and others (2012) believe that although the sample sizes are insufficient to be truly representative of national practice, the information may still be useful in providing a rough indication of typical practice. Instead of the third quartile mean room doses as reported in Table 7.1, the average room doses are reported for information about at least 5 hospitals, 5 rooms and 30 patients.

7.36 The Department of Medical and Occupational Radiation Protection of the German Federal Office for Radiation Protection has published a list of DRLs for 10 interventional procedures (Schegerer and others 2019), based on data collected between 2012 and 2015 and using pooled data, rather than being taken from the distribution of room means.

7.37 Several publications have looked at the issue of procedure complexity (see for example, D'Ercole and others (2012), Padovani and others (2001), Ruiz-Cruces and others (2016), Sánchez and others (2020) and Baiter and others (2011)). Most of these, but not all, have considered interventional cardiology, possibly because a) there are far more of these performed than any other IR procedure, and b) there are fewer variables involved (Miller, personal communication, 2020).

7.38 As an example of the effect of complexity of examinations, a study by Ruiz-Cruces and others (2016) concluded that the appropriate scaling factor for DRLs to take

[4] National Diagnostic Reference Levels: 22 January 2016 to 14 November 2018

complexity into account ranged between 2 and 5 for a selection of non-coronary IR investigations.

7.39 There is a paucity of data on IR DRLs in paediatrics and no national DRLs have been established for any procedure in any European country (EC 2018).

Skin dose monitoring in fluoroscopically guided procedures

7.40 Complex interventional procedures have the potential for delivering high radiation doses to the skin. Substantial numbers of radiation-induced tissue reactions, such as erythema, hair loss, and more extensive tissue damage have been reported following IR procedures (ICRP 2000, 2013a).

7.41 The threshold and severity of tissue reaction is linked to peak skin dose and the area of skin irradiated. Table 3.3 summarises the tissue reactions of ionising radiation. Skin dose will depend on the complexity of the procedure as well as the size of the patient, so procedures where there is a potential risk of exceeding a peak skin dose of 2 Gy should be identified. Procedures for which there is a risk of high skin doses are discussed in Chapter 5.

7.42 Since radiation damage takes time to repair, patients who have had repeated procedures, especially within the previous 2 to 3 months, increase the risk of skin injury (ICRP 2000, Martin and others 2017). Previous radiotherapy treatment to the area to be irradiated can also increase the risk of skin damage. The potential risks should be discussed with patients as part of the consent process.

7.43 For patients identified as being at risk, it is important that skin dose is monitored throughout the IR procedure to prevent skin injury wherever possible. Information should be provided to the operator during a procedure in order that appropriate modifications to technique (for example, changes in tube angulation, lower dose rate settings) can be used when appropriate. In addition, post procedure steps should be adopted to ensure that patients have the correct information and are provided with appropriate follow up if required.

7.44 Ideally, knowledge of the actual peak skin dose experienced by any area of the skin surface is required to estimate the risk of a deterministic skin injury. As detailed in paragraphs 5.46 to 5.48, measurement of peak skin dose is complex and usually carried out by indirect methods. The uncertainty in calculated peak skin dose can be up to +/-50% (Dabin 2020).

7.45 A range of software tools have been developed to do this in either real time or after a procedure; they are either marketed by major X-ray equipment manufacturers or produced by independent companies as part of dose management solutions or as free and open source radiation exposure monitoring for the medical physicist (OpenREM[5]). Current reports suggest that the reporting of the peak skin dose estimate is not as systematic or harmonised as it might be. A review of currently available options is presented in Malchair (2018).

7.46 Where assessments of peak skin dose are not available, it is possible to use CAK, KAP and potentially screening time thresholds for identifying those patients who may experience skin damage as a result of a fluoroscopically guided procedure. Of these CAK is the most appropriate quantity, as it relates to the air kerma level at

[5] OpenREM

the skin of the patient (Martin and others 2017) and so was the quantity used in the survey (see Chapter 8). CAK is the total IAK from an entire procedure measured at approximately the level of the skin surface and is displayed on all modern interventional equipment.

7.47 The CAK will in general exceed the peak skin dose, since, as the position of the X-ray tube is changed during procedures, different areas of the skin are irradiated. The CAK would only be a measure of the true skin dose if all the fields used overlapped. This is unlikely to occur in most specialities, provided that the operator uses different tube angulations during every procedure. One specialty where this is more likely is neuroradiology, where hair thinning and hair loss may occur more readily at lower CAK level (see for example Corrigall and others (2020)).

7.48 IR of the trunk has the potential to give much higher CAK levels, but here the relationship to peak skin dose is uncertain. Effects have not been reported for CAK values below 7 to 8 Gy. Maccia and others (2015) did not find any long-term skin injury despite a follow-up of patients when CAK was over 7 Gy. However, Guesnier-Dopagne and others (2019) reported a 9% incidence of acute radiodermatitis and a 20% chronic incidence in patients exposed at similar levels when systematic follow-ups were carried out by dermatologists. There may be many radiation-induced skin changes that are not detected unless follow-up is carried out by a dermatologist.

7.49 Consequently, translating CAK into the potential risks to patients is difficult. An attempt to provide some indicative values linking peak skin dose to both CAK and KAP is given in Table 7.2 (Jaschke and others 2020), but the ranges are necessarily large.

Table 7.2 Risks of skin effects following IR procedures

Peak skin dose (Gy)	CAK in IR of trunk (Gy)	KAP in IR of trunk (Gy cm^2)	CAK in neuro-radiology (Gy)	Risk of tissue reaction
2 to 3	3 to 8	150 to 300	2 to 5	Tissue reactions unlikely to occur
3 to 5	5 to 12	250 to 800	3 to 8	Small risk of transient erythema and epilation. Recovery from hair loss.
5 to 8	8 to 20	400 to 1200	5 to 12	Risk of erythema and epilation in some patients. Effects may appear within 2 to 8 weeks. Erythema may be prolonged.
8 to 12	12 to 30	600 to 2000	8 to 16	Transient erythema expected as a prompt effect. Skin desquamation, prolonged epilation.

7.50 ICRP recommend that in procedures involving the trunk, a CAK of 5 Gy can be used to signify a peak skin dose of 3 Gy and recommend that this value be used as a trigger above which clinical follow-up should be performed for early detection and management of skin injuries (ICRP 2013a). Recommendations given by the National Council on Radiation Protection and Measurements (NCRP 2010), based on work done by Stecker and others (2009) propose additional action levels both during and post procedure for peak skin dose, CAK, KAP and screening time, and these are shown in Table 7.3, together with specific levels for neuroradiology base on the discussion in the previous paragraph.

Table 7.3 Action levels or alerts (Adapted from Stecker and others (2009))

Dose Metric	During the procedure		Post-procedure
	Action level	Subsequent alert level (increments)	Trigger level for patient follow-up
Peak skin dose	2 Gy	0.5 Gy	3 Gy
Cumulated incident air kerma at the interventional reference point	3 Gy 2 Gy (Neuroradiology)	1 Gy	5 Gy 3 Gy (Neuroradiology)
Air kerma area product (100 cm^2 X-ray field)	300 Gy cm^2	100 Gy cm^2	300 Gy.cm^2 (cardiac and neuro interventions) 500 Gy.cm^2 (other procedures)
Fluoroscopy time	30 min	15 min	60 minutes

7.51 The trigger level of a peak skin dose of 3 Gy is based on the threshold dose for tissue reactions at which 1% of all individuals exposed demonstrate the expected tissue reaction (ICRP 2012). Therefore, exceeding the 5 Gy CAK trigger level is only likely to result in an effect in a small proportion of patients.

7.52 Alert levels may be set at lower peak skin dose, CAK and KAP level in order to alert the interventionalists that the radiation exposures are approaching the trigger level, so that they can consider possible further optimisation at an earlier stage. They may also consider whether it may be appropriate to consult more experienced colleagues.

7.53 Exceeding a peak skin dose of 3 Gy or a CAK of 5 Gy would trigger follow-up, usually 2 to 4 weeks after the procedure to identify any skin effects that might require further management. Minor skin reactions, such as transient erythema, should not require follow-up, but the patient should be asked to evaluate the skin reaction, perhaps record through a photograph, and report skin changes to the responsible physician.

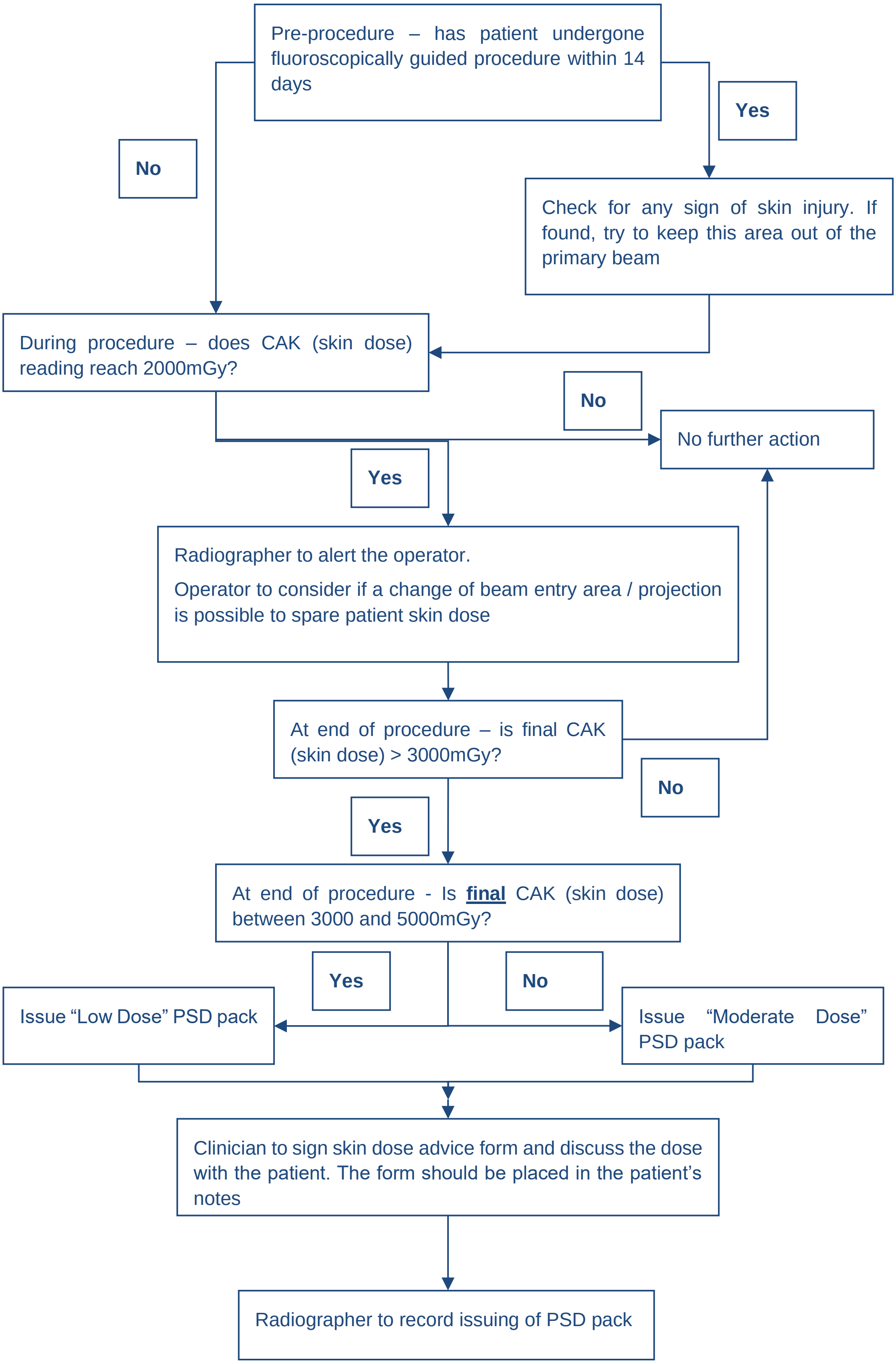


Figure 7.1: Flow diagram showing how CAK can be used as a reference level to anticipate skin damage.

7.54 An example of how this advice is implemented in one institution is shown in the flow diagram in Figure 7.1. In this instance, a caution level CAK level is set at 2 Gy and the peak skin dose reporting level is set at a conservative 3 Gy. If during a procedure the caution level is reached, the radiographer must ensure the operator (cardiologist/radiologist) is made aware. If the reporting level is reached during the procedure, a skin dose advice form is filed in the patient's notes and the patient is issued with an advice note – the advice depends on the CAK (see Chapter 8).

Reporting requirements

7.55 Guidance is available in the UK[6] on when to report radiation incidents that occur in interventional radiology. This guidance has been agreed by all 4 UK nations, but incidents are reported to different inspectorates (the Care Quality Commission in England, the Regulation and Quality Improvement Authority in Northern Ireland, Healthcare Inspectorate Wales and Healthcare Improvement Scotland). As with all procedures involving ionising radiation, accidental exposures (where an individual has received an exposure where no exposure of any kind was intended) are always reportable to the relevant inspectorate (except in England where there are threshold effective dose levels for adults and children below which it is not necessary to report the accidental exposure).

7.56 Unintended exposures are where an exposure was intended for the individual but the exposure they received was significantly greater or different to that intended. Unintended exposures are reportable to the relevant inspectorate where the ratio of the dose the patient received compared with that intended is sufficiently high. Furthermore, a foetal dose in excess of 1 mGy is reportable where there was a failure to follow the local pregnancy enquiry procedure prior to the examination. Specific to fluoroscopically guided interventions, an exposure is reportable where there has been no procedural failure but the exposure was in excess of 10 times the local Diagnostic Reference Level, or if there were observable tissue reactions worse than transient erythema as a result of the procedure.

7.57 IAEA operates a voluntary (and anonymous) self-reporting system which collates safety-related event reports as a learning resource. The SAFety in RADiological procedures (SAFRAD) database can be accessed online[7].

Conclusions

7.58 When purchasing an IR system, a detailed specification should be prepared in conjunction with all staff groups concerned which includes performance criteria, staff training and maintenance requirements. Acceptance testing, quality assurance and maintenance programmes should be drawn up.

7.59 It is not appropriate to implement dose limits to the patient for a given procedure, but there is a need to identify the indistinct border between normal and abnormal practice. This is provided by the Diagnostic Reference Level; DRLs are essentially an audit tool to trigger investigation if the local values are above (or substantially

[6] Significant accidental and unintended exposures under IR(ME)R; guidance for employers and duty-holders. Care Quality Commission, Healthcare Inspectorate Wales, The Regulation and Quality Improvement Authority and Healthcare Improvement Scotland (June 2019).
[7] SAFRAD database

below) the appropriate DRL. Auditing against DRLs is often considered the first step in the optimisation process.

7.60 There is a proposed international methodology for the establishment of DRLs, but this has yet to be fully implemented. The most recent work on DRLs in the UK dates from a 2010 review and did not take into account complexity or use aggregated data. Only adult values were addressed. As COMARE has found, the data on which UK DRLs could be based are not available.

7.61 Complex IR procedures can lead to a high skin dose which may trigger tissue reactions. ICRP recommend that exceeding a peak skin dose of 3 Gy should trigger patient follow-up 2 to 4 weeks post procedures.

Chapter 8: Patient pathway

8.1 Patients will be referred to the IR service from other clinical services. It is important that IR operators attend multi-disciplinary team meetings held by specialties making regular referrals to the service, which will facilitate planning of the procedure (see paragraph 5.22). Written referral guidelines should be available.

8.2 Patients will expect the procedure to be explained to them by the operator, who has the detailed knowledge to explain all treatment options, outline the process, discuss all relevant risks and answer queries.

8.3 In order to ensure adequate discussion of these issues, IR operators should hold out-patient clinics with time slots of a sufficient length. This is of particular importance in paediatric cases.

8.4 The patient record should be checked carefully for any recent (3 to 4months) procedures that may have involved high radiation doses (for example, radiotherapy, previous IR therapy) and may give rise to an increased risk of tissue reactions (see paragraph 7.42).

8.5 In almost all cases, the radiation risk will be small in comparison to clinical risks and both will be outweighed by the benefit of the procedure. All of these considerations should be clearly explained to the patient.

8.6 In terms of radiation risks, both stochastic (cancer induction) and deterministic aspects (skin reactions, hair thinning, hair loss, among others) should be addressed. This is especially important for complex cardiac procedures and neurointerventional procedures. During the latter interventions the patient eye dose has been reported to be as high as 2Gy when treating an AVM in the anterior fossa (Sánchez and others 2016), with 1 in 6 cases for correction of cerebral emboli exceeding 500 mGy.

8.7 Female patients of childbearing potential must be asked about pregnancy status, even if this has already been checked by the referrer. The guidance given by HPA (2009) should be followed.

8.8 Some centres have an extensive range of written information for each procedure (for example, Appendix D) while others rely mainly on oral discussion. For paediatric procedures, illustrative leaflets for the patient should be provided. The key is excellent 2-way communication.

8.9 In all cases, a telephone or email contact should be given for the patient to ask for any further information.

Informed consent

8.10 IR procedures are frequently employed in order to treat a serious or life-threatening condition or to provide a less invasive alternative to a procedure such as surgical intervention. In addition to an explanation of the risks of the IR procedure it is important to set this in the context of a balance of risks between the IR procedure and the underlying condition and/or alternative procedure.

8.11 IR procedures confer considerable benefit to the majority of patients but by necessity carry a degree of risk which includes the risk associated with ionising radiation. Shared decision making, consideration of risks and benefits of intervention and consent are a dynamic process that is informed by participants throughout the patient pathway. Discussion of risks and benefits within the context of shared decision making and informed consent is well established within IR practice although this process is most frequently focused on the direct risks and benefits of the intervention.

8.12 Risks related to radiation exposure are less well documented and/or discussed within many consent pathways. There is considerable evidence that risks related to radiation exposure are poorly understood and often underestimated by participants in the patient pathway including patients and referrers.

8.13 Clinicians undertaking interventional procedures should be in a position to consider and inform patients of both the direct risks of the procedure and the indirect risks such as the risks associated with radiation exposure related to the procedure. In addition to patient factors considered in diagnostic examinations, the complexity of the procedure makes establishing diagnostic reference levels for IR challenging (see paragraphs 7.22 to 7.28) In particular, for more novel complex procedures accurate established diagnostic reference levels are unlikely to be available. Nevertheless, there is a duty for practitioners to consider the radiation dose within the risks of the procedure and inform patients as appropriate. The European Directive 2013/59/ Euratom includes direction that “wherever practicable, prior to the exposure taking place, the practitioner or the referrer, as specified by Member States, ensures that the patient or his/ her representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. Similar information as well as relevant guidance shall be given to carers and comforters, in accordance with point (b) of Art. 56(5)” (EU 2013).

8.14 Legal standards that inform consent processes within the UK have changed significantly from an approach based on the ‘prudent doctor’ to one based on a ‘prudent patient’. The case of Montgomery v Lanarkshire Health Board led to a ruling by the UK Supreme Court (2015)[8] which some held to change the approach to consent, while others felt that it merely reinforced existing GMC recommendations. It did, however, formalise patient autonomy, in that it was made clear that it was not the medical professional’s role to decide what information should be given to the patient; the patient must be given whatever information they seek (Farrell and Brazier 2016, Chan and others 2017). The ruling established a duty of care to warn of material risks, the test of materiality being defined as whether “a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.”

8.15 For the reasons above, determining the significance of radiation dose for a particular patient will be challenging for clinicians. However, it should be noted that the individualised nature of consent means that dose thresholds will not be

[8] Montgomery (Appellant) v Lanarkshire Health Board (Respondent) [2015] UKSC 11 - On appeal from [2013] CSIH 3

appropriate. Particular consideration is advised for discussion and disclosure of radiation dose for procedures that incur significant dose for benign conditions or in paediatric practice.

8.16 There is a wide range in the approach to obtaining consent. In most cases requiring general anaesthesia, admission will take place in the preceding afternoon or evening and consent will be obtained then.

Post IR surveillance

8.17 ICRP (2000) suggests that patients who receive a cumulative skin dose greater than 3 Gy should have a skin assessment within 10 to 14 days of the procedure. If a skin injury is suspected, a follow-up appointment should be made with a dermatologist. Similar procedures occur in the US where patients are reviewed 30 days post procedure when the cumulative skin dose is greater than 2 Gy (NCI 2005). The American Heart Association have issued guidelines specific to IC and recommend that all patients who undergo 50 minutes of fluoroscopy are assessed for skin injury at both one and 3 month intervals post procedure. In addition, patients who are obese and have received 30 minutes of fluoroscopy time are also referred for follow-up and assessment (Hirshfeld and others 2004).

Figure 8.1: Example of advice leaflet given to patient who has potentially been exposed to a skin dose exceeding 3 Gy.

Vascular Patient Information Leaflet – MODERATE RISK

You have recently undergone a lengthy procedure at …. Hospital. During this procedure it was necessary to use an X-ray dose which is potentially large enough to cause a skin reaction. Any reaction that occurs is likely to be mild and changes are most likely to appear in the area that was examined.

Possible skin reactions include

1. Reddening or discolouration of the skin.
2. Temporary or permanent loss of hair in the irradiated area.

If you notice any changes to your skin please discuss them with the doctor during your follow up clinic appointment or contact the department.

Please follow the skin care advice below.

Skin Care Advice

- The area should be kept clean and checked regularly.
- Avoid the use of perfumed products.
- Avoid hot water - use warm water only.
- Do not scrub the area, pat dry carefully after washing.
- Avoid man-made fibres, cotton clothes and bed sheets are better.
- Ensure the areas are well moisturised. Use a plain aqueous cream, such as E45.
- Avoid shaving or waxing any damaged areas.
- Avoid direct sunlight and use a sunscreen with factor 30 or higher at all times.

8.18 An example of a UK patient advice note following a procedure where the CAK may exceed 3 Gy is shown in Figure 8.1. The issue of such forms should be documented in the patient record.

8.19 Wherever possible, appointment dates for any routine follow-up should be provided to the patient prior to discharge.

8.20 Tracking of dose indicators should be done and made part of the patient's record so that careful considerations of further exposure can be properly documented during the course of future treatment, and alternative strategies to reduce patient-specific radiation burden can be developed and implemented (Glatz and others 2014). Other imaging modalities such as echocardiography and MRI, which do not require ionizing radiation, should always be preferred for pre-and post-procedure evaluations, particularly in paediatric cases.

Conclusions

8.21 IR operators should attend MDT meetings with specialities which make regular referrals and hold out-patient clinics to explain proposed procedures to patients.

8.22 Where appropriate, pregnancy status should be ascertained prior to the procedure.

8.23 Printed leaflets, including illustrative material for paediatrics, should be provided for each procedure.

8.24 Care should be taken in discussing radiation risk when obtaining informed consent, especially for paediatric procedures or those to treat benign conditions which may incur a significant dose.

8.25 Where there is an expectation that skin doses could exceed 3 Gy, a patient advice note should be supplied and a follow-up out-patient appointment arranged.

Chapter 9: Staffing issues and governance

Workforce

9.1 Provision of IR services requires a multi-disciplinary team comprising a variable combination of radiologists, radiographers, specialist nurses, clinical physiologists, healthcare assistants (HCA) and anaesthetic staff (including operating department practitioners). The numbers and types of staff required depends to some extent on the type of procedure being performed.

9.2 Normally at least 5 members are required for a procedure to be performed in a safe manner. These include one radiologist/specialist consultant, one nurse or HCA to scrub/assist and a qualified nurse to provide sedation should that be required, a radiographer and an additional member of staff to supply equipment whilst the procedure progresses. While many patients are not sedated during IR, an increasing number of complex, time-consuming procedures are being performed under general anaesthesia requiring the presence of an anaesthetist and ODP within the room.

9.3 In order to ascertain the number of radiologists working in IR the Royal College of Radiologists' (RCR) undertakes an annual workforce evaluation; however, these surveys do not include cardiologists and other specialists who are not trained primarily in radiology. The 2018 RCR Workforce Census Report shows there to be a total of 674 interventional radiologists working within the UK (RCR 2019). This figure includes radiologists, with a primary or secondary interest in IR and so the number does not reflect whole-time equivalents. Service provision varies considerably both within each of the devolved administrations and also in different localities across the UK.

9.4 This census shows that in England there are 585 interventional radiologists, divided into 402 vascular, 116 non-vascular and 67 neuroradiologists. In Wales there are only 17 vascular radiologists and one interventional neuroradiologist (see Table 9.1) (RCR 2019). On a population basis Wales is the most under-provided country within the UK across all of the sub-specialisms. It should be noted that the accurate figures for cardiology specialists are not available from this census since the majority are trained as cardiologists and are not registered with the RCR (see paragraph 9.8 below).

9.5 The census highlights major percentage increases in interventional practitioners since 2014, in non-vascular (77.5%), neuro (67.4%) and cardiac (55.9%) sub-specialisms. This is further evidence of the burgeoning use of IR procedures across an increasingly wide range of specialisms. The more modest increase in vascular specialists may in part be related to the fact that this discipline was already better developed in 2014 and might also be linked to some vascular-trained specialists who now work primarily in the other sub-specialisms.

Table 9.1: Compilation of the Royal College of Radiologists annual census reports of 2014 to 2018

		March 2014	March 2015	% change	March 2016	% change	September 2017	% change	September 2018	% change	% change Mar 2014 to Sep 2018
Radiologist headcount											
Consultant	UK	3239	3318	2.4	3482	4.9	3656	3.3	3927	7.4	**21.2**
	England	2663	2733	2.6	2870	5.0	3050	4.2	3296	8.1	**23.8**
	Scotland	307	304	-1.0	321	5.6	320	-0.2	327	2.2	**6.5**
	N Ireland	119	121	1.7	122	0.8	124	1.1	135	8.9	**13.4**
	Wales	150	160	6.7	169	5.6	162	-2.8	169	4.3	**12.7**
Trainee	UK	1035	1323	27.8	1274	-3.7	1497	11.7	1555	3.9	**50.2**
	England	883	1120	26.8	1076	-3.9	1244	10.4	1286	3.4	**45.6**
	Scotland	92	116	26.1	117	0.9	142	14.2	149	4.9	**62.0**
	N Ireland	34	44	29.4	40	-9.1	48	13.3	51	6.3	**50.0**
	Wales	26	43	65.4	41	-4.7	63	35.8	69	9.5	**165.4**
Radiologist FTE count											
Consultant	UK	3048	3125	2.5	3226	3.2	3390	3.4	3622	6.8	**18.8**
	England	2503	2575	2.9	2664	3.5	2828	4.1	3038	7.4	**21.4**
	Scotland	288	288	0.0	298	3.5	298	0.0	303	1.7	**5.2**
	N Ireland	114	114	0.0	112	-1.8	115	1.8	126	9.6	**10.5**
	Wales	143	147	2.8	152	3.4	149	-1.3	155	4.0	**8.4**
IR subspecialists											
incl. vascular	UK	433	433	0.0	433	0.0	435	0.5	479	10.1	**10.6**
	England	357	360	0.8			359	(fte)	402	12.0	
	Scotland	42	39	-7.1			38		33	-13.2	
	N Ireland	11	12	9.1			11		14	27.3	
	Wales	23	22	-4.3			19		17	-10.5	
non-vascular	UK	80	103	28.8	103	0.0	110	6.8	142	29.1	**77.5**
	England	70	89	27.1			88	(fte)	116	31.8	
	Scotland	5	6	20.0			6		6	0.0	
	N Ireland	4	4	0.0			5		5	0.0	
	Wales	1	4	300.0			4		6	50.0	
neuro	UK	46	57	23.9	57	0.0	67	17.5	77	14.9	**67.4**
	England	40	48	20.0			62	(fte)	67	8.1	
	Scotland	3	6	100.0			3		5	66.7	
	N Ireland	1	2	100.0			2		2	0.0	
	Wales	2	1	-50.0			1		1	0.0	
cardiac	UK	111	113	1.8	113	0.0	136	20.4	173	27.2	**55.9**
	England	98	98	0.0							
	Scotland	5	6	20.0							
	N Ireland	4	4	0.0							
	Wales	4	4	0.0							

Data from RCR Censuses (RCR 2014, 2016, 2017a, 2018, 2019).

9.6 It should be noted that this is not a complete census of all clinicians who specialise in IR. For example, vascular surgeons also perform the arterial-vascular techniques described in Chapter 2. In addition, kidney access for percutaneous stone removal is increasingly performed in theatre by urological surgeons. One of the main reasons for the involvement of other specialties, is the replacement of many previously routine surgical procedures (either totally or in part) with IR (see Chapter 2). In some situations, involvement of non-radiology specialists can also be attributed to the lack of availability of a consultant interventional radiologist to assist/take ownership of the procedure. While in practise this should not be an issue, the training requirements of these non-radiology trained practitioners, particularly in the understanding of radiation risks for both themselves and their patients, need to be evaluated.

9.7 In the UK, of over 90 neurointerventional practitioners in 2019, only 1 (trained primarily as a neurosurgeon) was not an interventional neuroradiologist, although a few interventional radiologists have been or are being trained to perform thrombectomy. This is typical of many Western European countries, Canada, Australia and New Zealand, but there is a wider variation in background of neurointerventional operators in the USA and Germany.

9.8 One of the main uses of IR is in the treatment of patients with heart disease. However, the majority of these patients are treated by cardiology specialists. The British Cardiovascular Intervention Society (BCIS) commenced auditing of PCI in 1988, when some 500 procedures were carried out.

9.9 The 2017 to 2018 audit (BCIS 2019) reported the total number of consultant PCI operators (cardiologists and radiologists) as 663, with a 7% increase since 2012 as shown in Table 9.2. These data take account of those working on more than one site and, by comparing with the RCR data, suggest that there were 546 consultant cardiologists involved in providing this service in 2017 to 2018; the remainder being provided by consultant interventional radiologists.

Table 9.2: Number of consultant PCI operators (BCIS 2019)

Year	2012	2013	2014	2015	2016	2017 to 2018
Operators	621	630	659	647	660	663

9.10 The 2018 to 2019 data (BCIS 2020) show a further 4% rise in the number of operators to 693. Only 5.8% of these are female.

9.11 The gender imbalance is seen across all interventional radiology services. Reasons for this have been suggested to include radiation protection considerations, the need for high flexibility for covering on-calls and heavy workload, with the consequent difficulties in balancing roles at home and work. These factors have been evaluated in regard to females who work in diagnostic radiology, but the real reasons why few women choose IR are poorly understood (Perez and others 2016).

9.12 Although only a single case, Chen and Brunet (2020) reported on the radiation doses estimated to have been received by a neurointerventional fellow prior to and during pregnancy. No significant differences were observed in mean fluoroscopy times, procedure doses or personal radiation exposures measured by collar dosemeters before and during pregnancy. During pregnancy, an additional dosemeter was worn under 2 lead apron skirts to estimate foetal radiation exposure, recording 0mrem for all 6 months. This suggests that foetal radiation exposure need not be a matter of concern for female operators provided good radiation protection practice is followed

9.13 Another important pressure on the workforce is the need for out-of-hours (OOH) provision since a number of the procedures may need to be carried out in emergency situations, for example, embolisation to stop critical haemorrhaging, critical cardiology procedures and so on. The British Society of Interventional Radiology (BSIR, unpublished data) has recently estimated that only 45% of IR units are able to provide comprehensive OOH IR care, potentially putting many patients at risk. This is due to several factors. In some centres there are not sufficient IR consultants to provide a safe sustainable OOH rota while, in other localities, there are radiologists but not enough support staff such as nurses or radiographers.

9.14 The BSIR has indicated that a 1 in 6 on-call rota is suitable for the majority of units to function effectively, although it has been proposed that those serving a larger population should consider using a 1 in 8 on-call rota, due to a larger OOH case load. On this basis, BSIR has estimated a requirement for a further 403 Interventional Radiologists in order to provide a 1 in 6 on-call rota in each trust in the UK (the regional shortfall varying from 22 to 48% of current levels).

9.15 There does not appear to be the same shortfall in PCI services (Ludman, 2020, personal communication), perhaps because of national planning.

9.16 For those units unable to provide 24 hr OOH cover, BSIR advise that formal arrangements should be in place for a neighbouring unit to provide cover with agreed protocols for transfer of patients, but this has not currently been uniformly adopted within the UK.

9.17 These figures do not account for annual and study leave and cross cover within a department to allow for suitable recovery following an onerous on call period. Interventional radiologists will also have diagnostic imaging commitments which may or may not be related to their IR work as well as a requirement to attend multi-disciplinary team (MDT) meetings. In addition, they should have identified out-patient sessions discussing risk and obtaining patient consent, and clinical time for ward visits or follow up as well as audit and registry involvement. All these activities will obviously reduce the time available for performing IR procedures. This reduces their overall exposure times but puts additional pressure on the staff to provide a safe and sustainable service if the number of trained staff is inadequate.

Medical Physics Experts

9.18 There is an ongoing shortage of medical physicists with the necessary expertise to undertake all the tasks relating to the optimisation of procedures and carrying out of performance tests and patient dose surveys. Moreover, a significant number of radiology physicists are about to retire. More training posts are required to fulfil this need.

Training

9.19 The current RCR consultant training programme requires radiologists to complete 5 years of training. To be recognised as an interventional radiologist they are required to complete 3 full years in this sub-specialism. To meet this requirement, they commence IR training in year 4 and complete the 3 year requirement by adding an extra year in year 6. Many interventional radiologists will use year 6 to gain experience at another centre within the UK or abroad on a recognised fellowship scheme. It is seen as important that trainees are exposed to a broad spectrum of procedures allowing them to develop the necessary skills to practice at consultant level.

9.20 Regulation 15 of the IRR17 (IRR 2017) requires employers to ensure that those that work with radiation receive appropriate information and instruction. This includes the risks to health created by exposure to ionising radiation as a result of their work, the general and specific radiation protection procedures and precautions which should be taken in connection with the work with ionising radiation to which they may be assigned and the importance of complying with the medical, technical and administrative requirements of the IRR17. As this training must take account of the local circumstances and conditions, it cannot be assumed that IR trainees have received adequate training during their 5-year training programme. Thus, the employer must take steps to ensure that adequate information, instruction and training has been or is given prior to them commencing work with ionising radiations. Furthermore, the IRR17 also requires that any training and information given in accordance with Regulation 15 must be repeated at appropriate intervals and documented by the employer. For most employees, including interventional radiologists, this ‘refresher’ training should be given every 3 to 5 years.

9.21 All operators must receive initial training in patient radiation management when beginning work in the interventional radiology suite (ICRP 2009b). Radiation safety training should include review of the potential adverse effects of radiation on patients and staff, and evaluation of factors that affect patient and staff doses, and measures that can be taken to reduce dose. Operators should be informed how to estimate patient dose using the DICOM Dose Reports or other surrogate parameters of radiation exposure (Stecker and others 2009). There should be close cooperation with MPEs who can advise on dose levels delivered by different equipment programme options. Trainees and experienced interventional radiologists should have a close awareness of radiation dosage and be looking for opportunities to minimise exposure. Training should also include understanding of the most important tissue reactions and the radiation dose levels, at which they may occur (ICRP 2000).

9.22 Operators should undergo adequate training in interventional techniques prior to performing interventional procedures under the supervision of an experienced operator until they are judged capable of performing procedures by themselves. Simulators may be used for training in catheterization techniques and how to manage radiation dose (Willaert and others 2011, See and others 2016, Keefe and others 2018). Simulators enable techniques to be repeated, allowing trainees to increase their procedural efficiency, and thereby reduce complication rates and radiation exposure.

9.23 Miller and others (2010), ACC (2016), Morishima and others (2016), Sheyn and others (2008) and Vano and others (2006) suggest that educating staff about best practice and radiation protection is the best way to ensure the ALARA principle is maintained. Major improvements in practice were reported after the implementation of a safety education initiative in the paediatric interventional suite. Minor changes to practice, for example, increased collimation, use of last-image-hold and decreased panning during imaging, all contributed to the overall dose reduction to patients and staff. There is a need for periodic refresher training in techniques and update training in radiation protection and dose levels. Such training should be given by a combination of specialists, radiologists / clinicians, medical physicists, and radiographers.

9.24 Similarly, for clinicians not trained as radiologists who are performing IR procedures (for example, vascular surgeons, urologists and cardiologists), there is a clear need for training in all relevant aspects of ionising radiation and protection. Several recognised courses including on-line courses, have become available since introduction of the initial IR(ME)R 2000 regulations (IR(ME)R 2000).

Regulation of radiation exposure during a working life

9.25 Several members of staff will be present during a procedure, they will be exposed to ionising radiation to varying degrees depending on their role and in particular where they are required to stand within the IR suite to perform their duties. Another major factor contributing to working-life exposure is the number of interventional sessions that an individual consultant performs. This varies considerably between hospitals and between practitioners, with some doing up to 8 sessions weekly. Clearly the number of sessions will be a determinant of the total dose received. The same applies to non–medical IR staff, although some of these will rotate between different types of imaging within a department, for example, radiographers. However, many nurses are routinely assigned to work continually with an IR suite.

9.26 The interventionalist is most at risk from incidental radiation exposure since he/she works immediately adjacent to the patient. This group also are more likely to spend a considerable proportion of their working life in this role. Over the course of his or her career, an IR practitioner is exposed to an estimated 50 mSv to 200 mSv of ionizing radiation. The brain is subject to higher-intensity exposure, given the proximity of the head to the radiation source. In the past, career exposure to the head was estimated to be some 1,000 mSv (Picano and others 2012), but this was a figure derived from an estimate of the unshielded dose. The combination of modern x-ray units and shielding will have reduced this figure substantially.

9.27 Interventionalist staff often have a significant case load and will typically spend over 60% of their working week in the interventional radiology suite (see above). With the burgeoning of IR techniques that have clear clinical benefit, the work load is inevitably set to increase and will result in a potential increase in radiation exposure of staff (within the bounds of available working time), ameliorated by comprehensive radiation protection measures (discussed in Chapter 5).

Classification of staff exposed to radiation in the workplace

9.28 Regulation 21 of the IRR17 (IRR 2017) states that 'the employer must designate as classified persons those of its employees who are likely to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for the skin or the extremities' (see also paragraphs 432 to 436 of the ACoP and guidance to the IRR17 L121 'Work with Radiation' (HSE 2018)).

9.29 It is important to note that the requirement to classify persons is not just based on likely routine exposures but also the exposures that a person could receive as a result of a radiation accident. Thus, if the employer's radiation risk assessment has identified reasonably foreseeable accidents where a person could receive more that the specified classification thresholds, either as a result of that accident or likely to be incurred as a result of any remedial action, then that person must be classified. This is despite their possibly low routine exposures.

9.30 The classification thresholds are not dose 'limits' or dose action levels. The overarching requirement of the IRR17 is that all exposures should be ALARP and that should be the principal aim of radiological protection (IRR 2017). Action to reduce exposures should not just be taken because a person is approaching the thresholds that would require that person to be classified. Restricting exposures to levels which are ALARP should be a continuing and constant process. Furthermore, classifying a person does not mean that that person is free to incur higher radiation exposures than others – the ALARP principal still applies.

Conclusions

9.31 The RCR census results show a marked increase in the number of radiology trainees in both 2017 and 2018, with an average increase of approximately 50% between 2014 and 2018 across the UK. The numbers of consultants, however, rose only by some 20% in the same period.

9.32 The data for interventional radiologists demonstrate an increase of 30% between 2014 and 2018; to this must be added an unknown number of practitioners from other clinical specialities. In particular, by comparing RCR numbers with those from BCIS, it is estimated that there are some 550 cardiologists involved in PCI.

9.33 A significant gender imbalance is seen across all IR services.

9.34 With the exception of PCI services, only half of UK IR units are able to provide comprehensive out-of-hours services.

9.35 Even for those completing the current 5-year RCR consultant training programme additional local training may be necessary. There is a clear need for formalised training for those from other clinical specialities. Employers also must provide refresher training at suitable intervals.

9.36 Employers must designate as 'classified persons' those staff who are thought likely to exceed the dose constraints set out in IRR17.

9.37 There is need for more training posts to counter the predicted shortage of medical physicists who have the necessary expertise to undertake all the tasks relating to the optimisation of procedures.

Chapter 10: Survey of IR practice in the UK 2015 to 2017

Introduction

10.1 As noted in the preface, the Subcommittee found that there were few data available about the use of IR in the UK. It was decided that the only way forward was to develop a questionnaire (Appendix E) and distribute it to a sample of hospitals around the UK.

10.2 As with all surveys, there is a compromise to be made between requesting detailed information, which makes the reply very time consuming, and the expected response rate. This was felt to be a particular problem in requesting radiation dosimetry data, since the equipment used presents this in different ways, making completing a standard questionnaire difficult, depending on the information type requested.

10.3 Table 2.1 separated the various types of procedure into 3 categories – radiology, cardiology and neuroradiology since these may be carried out in different locations in a hospital and under different management arrangements.

10.4 While the RCR Clinical Radiology UK workforce census reports gave information on the numbers of radiologists working in IR, there are also a considerable number of other medical staff involved such as cardiologists, vascular surgeons and neurosurgeons. The survey sought data on both consultant and junior staff from all disciplines. The RCR reports do not record the total number of sessions worked or the maximum number of sessions worked by an individual, which are important in estimating potential radiation dose exposure, and so these questions were included.

10.5 The IR team incorporates other members; radiographers and nurses will usually be present, with staff such as physiological measurement technicians and clinical physiologists participating in a range of procedures. The same data were requested for these 3 groups as for the medical staff.

10.6 Equipment questions were limited to the number of rooms, type of installation (single plane or biplane) and year of installation.

10.7 There are ongoing studies on how best to monitor staff doses and so a limited number of questions were asked, including one on the recently introduced real-time dosimetry systems.

10.8 Since the risk to paediatric patients from a given dose of ionising radiation is greater than for adults (see Chapter 3), these procedures were separated out.

10.9 Although some modern equipment records detailed information on patient dosimetry, it was decided only to request data on CAK, separately for adult and paediatric studies. This was split into 4 bands, commencing with CAK levels mandating patient follow-up procedures in the USA and EU.

10.10 Since regulations relating to permitted eye dose have been amended recently, data on staff eye doses was requested in a separate section. This was split into 5 bands.

10.11 Since IR procedures are carried out in most hospitals it was thought important to spread the survey across all types. Hospitals were classified as large (major teaching centres), medium or small using data provided by DHSC. A range of hospitals with a broad geographic distribution across the UK were selected to receive the questionnaire. Only limited data were received, despite reminder efforts.

Survey distribution

Radiology

10.12 In the surveyed units, a total of 4 to 40 sessions were provided each week by between 2 and 14 consultant radiologists, with an individual maximum of between 2 and 8 sessions per week. In addition, the service was supported by between 0 and 7 consultants from other disciplines, who contributed a total of up to 14 sessions per week.

10.13 Between 1 and 5 junior radiology staff participated in the service with an individual maximum of 10 sessions per week.

10.14 The number of radiographers involved ranged from 6 to 29, the maximum number of sessions worked by an individual being 2 to 14 per week.

10.15 The nurse pool providing the service varied from 3 to 47, the individual maximum lying between 4 and 12 sessions per week.

10.16 Just under half of units reported input from other staff such as physiological measurement technicians and clinical physiologists. Their numbers ranged from 2 to 12, the total number of sessions provided being 3 to 16 per week.

10.17 Units comprised between 1 and 5 IR rooms; only one-third of units had biplane equipment (and then not in all rooms). Seventeen percent of equipment was less than 2 years old, 44% between 2 and 5 years old, 30% between 6 and 8 years old and 9% greater than 8 years old.

a) Vascular IR

10.18 The total number of adult procedures increased by 6.1% between 2015 and 2017. The highest CAK for a vascular adult procedure was reported as greater than 8,000 mGy. The percentages of CAK above 2000 mGy is shown in Table 10.1. There were no reports of CAK above 2,000 mGy for paediatric studies.

Table 10.1: Percentages of cumulative air kerma doses (CAK) above 2,000 mGy for vascular investigations

Cumulative air kerma (mGy)	2016	2017
2000 to 3000	0.27	0.99
3000 to 5000	0.14	0.55
5000 to 8000	0.04	0.18
>8000	0.09	0.06

10.19 Only 0.2% of renal dialysis procedures recorded the highest CAK of between 2,000 and 3,000 mGy. Percentages of non-vascular procedures recording a CAK above 2,000 mGy are shown in Table 10.2.

Table 10.2: Percentages of non-vascular procedures leading to a CAK greater than 2,000 mGy

Cumulative air kerma (mGy)	2016	2017
2000 to 3000	0.60	0.77
3000 to 5000	0.40	0.03
5000 to 8000	0	0
>8000	0	0

10.20 None of the respondent sites made use of real-time dosimetry systems for staff. The highest eye dose recorded was in the range 20 to 50 mSv. The percentages of recorded eye dose in each category is shown in Table 10.3.

Table 10.3: Percentages of recorded eye doses in each category

Eye dose (mSv)	2015	2016	2017	2018
5 to 10	6.7	5.5	6.0	6.6
10 to 15	1.4	2.3	1.7	1.6
15 to 20	0	1.4	0.4	1.6
20 to 50	0	0.5	0	0

Cardiology

10.21 Larger units had 3 or 4 rooms, with smaller units restricted to one; all utilised single-plane installations. Equipment had been installed or refurbished since 2011.

10.22 Services were provided by between 12 and 19 consultant staff on the larger sites, where a total of between 30 and 40 sessions per week were carried out. On smaller sites, between 4 and 6 consultants were involved, providing a total of 4 to 10 sessions. The maximum number of sessions conducted by an individual consultant was 2 to 5 per week,

10.23 The maximum number of sessions attended by an individual radiographer lay between 4 and 10 per week, with a similar figure for nursing staff.

10.24 The total number of procedures carried out rose by 7% between 2015 and 2017, with increases of 56% in percutaneous valve insertion and 24% in electrophysiological mapping/ablation.

10.25 The highest recorded CAK for adult procedures was in the range 5,000 to 8,000 mGy and the percentages of studies resulting in doses above 2,000 mGy in 2016 and 2017 are shown in Table 10.4.

Table 10.4: Percentage of studies resulting in cumulative air kerma greater than 2,000 mGy

Cumulative air kerma (mGy)	2016	2017
2000 to 3000	0.9	0.7
3000 to 5000	0.2	0.3
5000 to 8000	0.02	0.03

10.26 Around one-third of units employed real-time dosimetry.

10.27 The highest eye dose recorded was in the range 20 to 50 mSv. The percentages of eye dose in each range are shown in Table 10.5.

Table 10.5: Percentage of recorded eye doses in each category

Eye dose (mSv)	2015	2016	2017	2018
5 to 10	5.3	4.4	2.9	5.7
10 to 20	1.3	2.9	1.0	0
20 to 50	1.3	0	0	0

10.28 Data provided by BCIS show that, in 2017 to 2018, 102,258 adult PCI procedures were undertaken in 118 centres (98 NHS, 20 private) and 100,294 procedures in 2018 to 2019. The total workload breakdown is shown in Table 10.6 and PCI numbers by country in Table 10.7.

Table 10.6: UK PCI data for 2017 to 2018 and 2018 to 2019

	Number of centres	PCI 2017 to 2018	PCI 2018 to 2019
NHS Interventional	98	101,057	99,253
Private interventional	20	1,201	1,041
Total	**118**	**102,258**	**100,294**

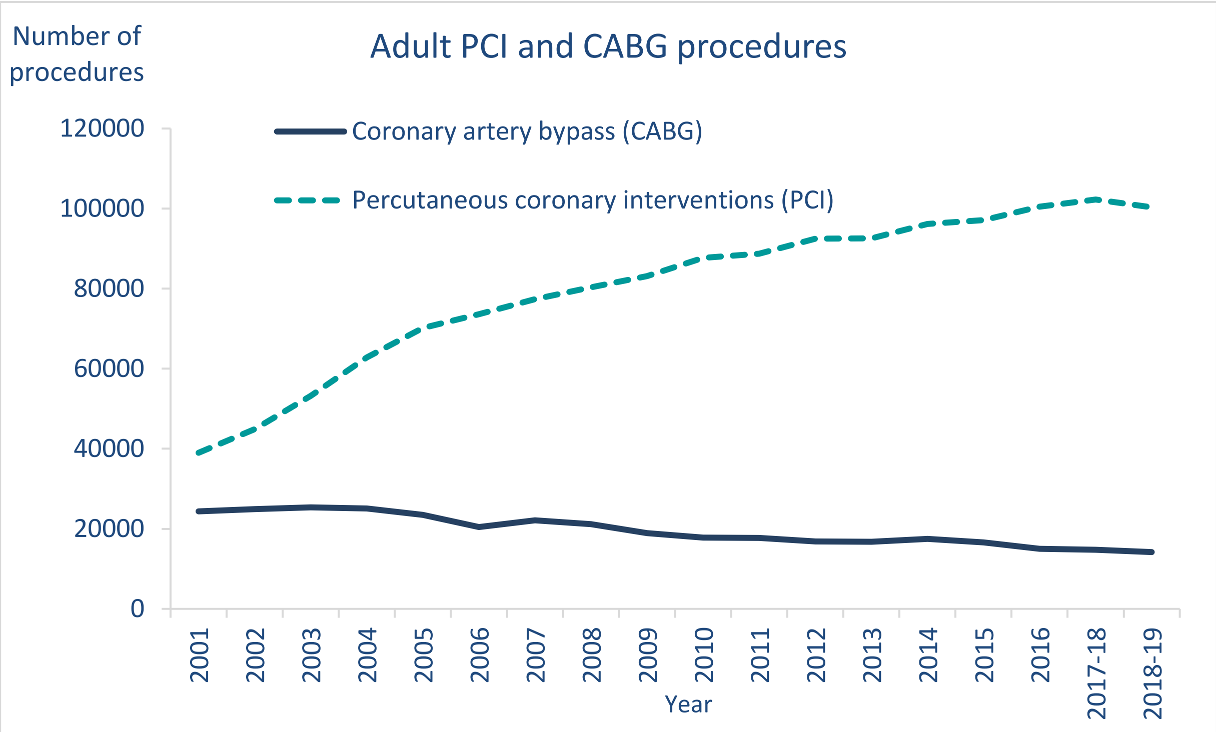
Table 10.7: Adult PCI numbers by country for 2017 to 2018 and 2018 to 2019

Country	Type	PCI 2017 to 2018	PCI 2018 to 2019
England	NHS	83,482	81,559
	Private	1,074	954
Scotland	NHS	8,998	9,007
	Private	75	50
Wales	NHS	4,356	4,720
	Private	52	37
Northern Ireland	NHS	4,221	3,967

10.29 The great majority of centres reported that fewer than 0.05% of patients required emergency cardiac surgery due to failure or partial failure of the PCI.

10.30 Figure 10.1 shows the numbers of adult PCI procedures and coronary artery bypass graft surgery (CABG) operations performed in the UK between 2001 and 2018 to 2019. It can be seen that there was a steep increase between 2001 and 2006 in PCI, with a slower, but fairly steady, rate of increase since then. The overall increase over the whole period is approximately 250%, while the increase between 2015 and 2018 is 5.3%, with a decrease of 1.9% in 2018 to 2019. The number of CABG procedures has been dropping since 2004 and is now some 40% less than in 2001.

Figure 10.1: Numbers of adult PCI and CABG procedures undertaken in the UK (BCIS 2020)



10.31 The increase in PCI numbers in the early years is much greater than the drop in CABG numbers, perhaps indicating that the new technique was employed primarily to treat patients with early signs of disease. Figure 10.1 shows that the number of PCI procedures increased by 10.6% between 2012 and 2017 to 2018, while the number of operators increased by 7% (Table 7.2). This suggests that a limiting factor on growth is the number of operators.

Interventional Neuroradiology

10.32 This specialism is only provided by a limited number of centres within the UK (currently 28); data were obtained from 4 major institutions.

10.33 Three or 4 consultants provided the service, carrying out a total of 4 to 12 sessions per week with a maximum individual commitment of between 4 and 6 sessions. There were 1 or 2 junior staff inputting a maximum of 10 sessions.

10.34 The radiography pool varied between 12 and 16, with a maximum individual commitment of 4 to 12 sessions. Between 7 and 26 nurses were involved, the maximum number of sessions being 10 to 12 per week.

10.35 Data on paediatric procedures were returned by only one site, showing no difference in numbers between 2015 and 2017. There were no instances of CAK above 2,000 mGy.

10.36 The total number of adult procedures increased by over 7% between 2015 and 2017. The largest increase was for mechanical thrombectomy in stroke cases, demonstrating a 40% increase between 2016 and 2017.

10.37 The average number of procedures per consultant ranged from between 37 and 80 per annum in 2015 to between 62 and 94 in 2017.

10.38 The highest recorded CAK for adult procedures was in the range 5000 to 8000 mGy and the percentages of studies resulting in doses above 2,000 mGy in 2016 and 2017 are shown in Table 10.8.

Table 10.8: Percentage of studies resulting in cumulative air kerma (CAK) greater than 2,000 mGy

Cumulative air kerma (mGy)	2016	2017
2000-3000	1.2	2.6
3000-5000	0.5	1.0
5000-8000	0.2	0.1

10.39 All units provided under apron badges to staff in the IR room, with collar badges generally issued only to interventional radiologists. Only one unit used a real-time dosimetry system routinely.

10.40 In terms of eye dose, there were no recorded doses above 10 mSv between 2015 and 2018, while less than 25% of doses were greater than 5 mSv in any year.

Conclusions

10.41 There are few data on the provision of IR services across the UK. This makes it difficult to evaluate trends in clinical practice, establish staffing requirements for the various staff groups involved and plan future service provision.

10.42 The lack of patient dose data hinders the establishment of national DRLs for IR procedures.

10.43 From the surveyed sites, the maximum number of IR sessions per week was 8 for consultants, 10 for trainees, 14 for radiographers and 12 for nurses.

10.44 Some 90% of the equipment on the surveyed sites was 8 or fewer years old.

10.45 The proportions of surveyed procedures in 2018 leading to a patient CAK in excess of 3Gy, and thus requiring follow-up were 0.8% for vascular IR, 0.3% for non-vascular IR, 0.3% for IC and 1.1% for INR.

10.46 No operators in IC or INR recorded eye doses in excess of 15 mSv in 2018, the level at which staff require to be classified. Eye doses between 15 and 20 mSv were recorded in 1.6% of vascular and non-vascular staff in the same year.

Chapter 11: International comparisons

Introduction

11.1 In 2014 there were 48 radiologists per million population in the UK (RCR 2015), compared to 92 per million in Germany, 112 per million in Spain and 130 per million in France.

11.2 An on-line survey of interventional radiology services was distributed to 1180 radiology departments across Europe by the European Society of Radiology (ESR) and the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) in 2017 (ESR and CIRSE 2019). There were 98 answers (response rate 8.3%) from 21 nations.

11.3 Fifty-one responses came from hospitals with more than 800 beds, 28 from hospitals with 400 to 799 beds, 15 from hospitals with 200 to 399 beds and 4 hospitals with less than 199 beds provided an answer. Ninety-five percent were from teaching hospitals that employed radiologists-in-training.

11.4 In terms of total radiology staffing, there was a reasonable gender balance; 42% of hospitals had more than 50% female radiologists, but the great majority of interventional staff were male.

11.5 Sixty out of 97 hospitals operated an out-of-hours service, somewhat higher than in the UK.

11.6 In 45 of the 72 hospitals providing a neurointerventional service, procedures were performed by interventional neuroradiologists. Interventional radiologists were directly involved in 19 departments. There were, however, 8 hospitals in which neurointerventional services were provided by other specialists, such as neurosurgeons, cardiologists, traumatologists, or neurologists.

11.7 Cardiac interventional procedures were performed in 84 hospitals, the service being provided by cardiologists or cardiac surgeons in 83. In only one case was the service run by interventional radiologists.

11.8 The workload of IR practitioners is not confined to performing procedures. Bundy and others (2020) surveyed 263 US interventional radiologists for signs of burnout using the Maslach Burnout Inventory. Some 95% worked more than 40 hours per week, with approximately 30% working in excess of 60 hours per week. Evidence of burnout was assessed to be present in over 70%.

Elective abdominal aortic aneurysm repair

11.9 Jetty and Husereau (2012) reported that the proportion of repairs in Canada carried out by EVAR rose from 11.5% in 2005 to 35.5% in 2009.

11.10 Using data only from Ontario, Salata and others (2018) found a significant difference in EVAR rates between men and women. The proportion of repairs carried out by EVAR in men rose from around 8% in 2003 to 63% in 2016, with the cross-over point being reached in 2010. For women, however the proportion was 9% in 2003 and only reached 50% in 2016. The authors suggested that a partial reason for the slower uptake in women was related to a size mismatch between the endograph delivery systems and the smaller sizes of the femoral and iliac arteries in women; they expected this to improve with newer hardware developments.

11.11 The same group (Salata and others 2019) analysed their 2003 to 2016 data to find 4,010 matched pairs of patients, one of whom had undergone EVAR and the other an open repair. The mean follow-up was 4.4 years with a maximum of 13.8 years. The EVAR group demonstrated a higher 1-year survival rate (94% vs 91%) but there was no significant difference in long-term survival. The EVAR patients, however, showed a substantially better long term major adverse cardiac event free survival (32.6% versus 14.1%).

11.12 The 2019 Annual Report from the UK National Vascular Registry (Waton and others 2019) noted that the proportion of procedures carried out by EVAR rose from 54% in 2009 to 66% in 2013 and has remained stable since. The 30-day mortality rate was 0.4% for EVAR and 3.2% for open procedures.

11.13 The UK Health Technology Assessment report (Patel and others 2018) followed up 1,252 patients recruited to the EVAR-1 trial between 1999 and 2004 (626 each treated by EVAR or open procedure) over a mean of 12.7 years. They found early lower mortality in the EVAR group, but a worse longer-term outcome with 9.3 deaths per 100 person-years versus 8.9 in the open procedure group. They also suggested that EVAR had a higher lifetime cost (mean £19,672 vs £15,876). It was noted that the current position may be more favourable to EVAR given the development of improved devices.

11.14 In the Netherlands, a retrospective study of some 2000 patients treated between 2007 and 2012 is being carried out (Geraedts and others 2020). This aims to determine the appropriateness of postoperative surveillance as well as long-term outcomes.

11.15 A 2016 survey of Australasian vascular surgeons(Lo and others 2016) found that some 70% of elective abdominal aortic aneurysm repairs were carried out by EVAR but that only 25% of ruptured aneurysms were repaired by endovascular procedures (REVAR). Eighty percent of respondents identified a lack of endovascular facilities (including appropriate anaesthetic facilities) as responsible for the difference, with 55% also reporting a lack of ancillary staff. Over 75%, however, felt that REVAR offered a reduced intraoperative blood loss, a lower complication rate and a shorter length of stay.

Cardiology

11.16 Table 11.1, derived from Barbato and others (2020) shows the number of adult PCI procedures carried out per million population across European countries and is an amalgamation of2016 and 2017 data. It can be seen that the UK has a lower rate than most European countries.

Table 11.1: Numbers of PCI procedures per million population (2016 or latest year) (Barbato and others 2020)

PCI procedures	Countries
Under 1,000	Romania, Egypt
1,000 to 1,499	UK, Spain
1,500 to 1,999	Denmark, Greece
2,000 to 2,499	Sweden, Netherlands Belgium
2,500 to 2,999	Slovenia, France, Italy, Turkey
More than 3,000	Switzerland, Poland, Germany

11.17 Table 11.2 derived from Barbato and others (2020) depicts the number of interventional cardiologists per million population among European countries and again the UK features a lower ratio than most other countries.

Table 11.2: Numbers of interventional cardiologists per million population (2016 or latest year) (Barbato and others 2020)

Interventional cardiologists	Countries
Under 10	Romania, Egypt
10 to 14	UK, Netherlands, Sweden
15 to 19	Spain, Poland, Denmark, Italy, Slovenia
20 to 24	Turkey, France, Greece, Belgium
25 to 29	Switzerland
More than 30	Germany

11.18 Table 11.3 derived from (Barbato and others 2020) shows the number of hospitals per million population which have continuous availability of catheterisation laboratories across European countries.

Table 11.3: Numbers of catheter laboratories available 24/7 per million population (2016 or latest year) (Barbato and others 2020)

Number of laboratories	Countries
Less than 1	Denmark, Egypt
1.0 to 1.9	UK, Netherlands, Slovenia, Spain
2.0 to 2.9	Sweden, Greece
3.0 to 3.9	Italy, France, Switzerland
Greater than 4	Poland, Belgium, Germany

11.19 The NCRP (NCRP 2019) conducted a survey of the radiation doses associated with medical exposures in the USA in 2016. A wide range of data sources were utilised, including a comprehensive literature survey, returns from various US government agencies, data from professional societies and commercial surveys. The data were found to be inherently fragmentary in nature and not collected by the sources on a uniform basis.

11.20 It was estimated that the number of non-cardiac interventional fluoroscopy procedures carried out in the USA declined from 12 million in 2006 to 4.6 million in 2016. The main reasons for the apparent drop lie in the definitions used in 2006 and procedures which then used fluoroscopy but which do not now do so. The associated per capita effective dose reduced from 0.20 to 0.13 mSv.

11.21 The number of cardiac interventional fluoroscopy procedures reduced from 4.6 million in 2006 to 4.1 million in 2016, with more coronary diagnostic and percutaneous interventions being carried out as a single procedure. The per capita effective dose reduced from 0.23 to 0.12 mSv.

11.22 Comparing extrapolations from several sources, an estimate of 850,000 PCI procedures were carried out in the USA in 2016, compared to some 500,000 in 2009 (NCRP 2009).

11.23 It was noted that, as a result of a programme of dose reduction measures, there had been a drop of approximately 50% in patient dose for the most complex PCI procedures since 2016.

11.24 The US data show an increase of 70% between 2009 and 2016, compared to 21% in the UK.

11.25 Taking the 2016 data for both countries, the numbers of PCI procedures per million population were approximately 2,630 for the USA and 1,530 for the UK.

11.26 Giustino and others (2020) reported data from the EXCEL (Evaluation of XIENCE Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization) trial in the USA. This trial randomised 1,900 patients to either PCI or CABG and, during 3-year follow up, there were 346 repeat revascularisations required. These occurred in 12.7% of PCI patients vs 7.6% of CABG patients.

Neurointervention

11.27 Endovascular therapy is established as the standard of care for patients suffering acute ischaemic stroke. The UNMASK EVT survey was carried out by Ospel and others (2020) to establish how endovascular therapy decisions made by physicians under the constraints of local resources differed from those they would have made in the absence of any constraints. A total of 607 physicians took part, of whom 218 were from North America and 136 from 25 European countries.

11.28 A ‘resources gap’ was defined as the difference between the ideal (no constraints) and actual rates of endovascular therapy. The deficit in resources was <5% for the majority of North American states/provinces and European countries. In Europe, Austria, the Czech Republic, Estonia, Norway and Romania recorded deficits between 5 and 20%. The largest deficits recorded from the North America/Europe group were 30% for Poland and 33% for the UK.

11.29 The numbers of respondents per European country were low (9 from the UK) and there were no data to establish the reason(s) for the resources gap. The latter did not correlate with either GDP per capita or healthcare metrics. and it was suggested that local factors such as on-call availability or regional/national factors such as an insufficient network of comprehensive stroke centres could be responsible.

11.30 As noted in paragraph 2.43, the UIA caseload in the UK is well below that of other countries.

11.31 In 2013, the National Confidential Enquiry into Perioperative Deaths (NCEPOD) report, 'Managing the Flow? A review of the care received by patients who were diagnosed with an aneurysmal subarachnoid haemorrhage', highlighted the need for 7-day INR services for ruptured cerebral aneurysm treatment and although progress has been made, not all regions are yet able to provide this (NCEPOD 2013).

Oncology

11.32 As noted above (see paragraph 2.62), transarterial chemoembolization (TACE) is accepted as the mainstay of treatment for hepatocellular carcinoma. Young and others (2019) carried out an online survey of techniques used by practising members of the 5 largest interventional radiology societies in Chinese and English. A total of 1,160 responses were obtained from 62 countries.

11.33 Significant differences in practice were found. Doxorubicin was more widely used as the cytotoxic agent in North America, Europe and South Korea than in Japan and China (p=0.0001). There were differences also in how the dose of cytotoxic agent was determined. For single and multiple carcinomas, drug-eluting bead TACE was most popular in North America and Europe, while conventional TACE was most popular in Japan, Korea and China (both p=0.0001).

DRLs

11.34 In Ireland, national DRLs are derived for the most common procedures using the European Commission methodology as set out in RP-109 and RP-130. The Medical Exposure Radiation Unit (MERU) of the Irish HSE collects data from multiple locations on the median patient dose for 30 patients for each procedure. From this, the 75th percentile of the dose distribution is chosen as the DRL. These are approved by the National Radiation Safety Committee and published in the MERU Patient Radiation Protection Manual[9]. The DRLs are updated regularly (Table 11.4).

[9] MERU Patient Radiation Protection Manual

Table 11.4 Irish National DRLs (HSE 2017)

Examination	DRL in DAP($Gycm^2$)
Colon	13
Biliary tract	16
Cerebral procedures (for example embolization)	62
Cardiac studies	55
PTCA	75
All peripheral procedures	30
All pelvic or abdominal procedures	70

11.35 In Germany, DRLs for diagnostic and IR procedures were updated in 2018 (Schegerer and others 2019). Values for 9 IR procedures were added. Data (DAP and fluoroscopy time) were collected for tens of thousands of procedures carried out between 2012 and 2017 from a range of sources. In accordance with ICRP recommendations (ICRP 2017), the DRLs were defined by the 75th percentile of the dose distributions, although the results were checked for plausibility and against values from other countries. The new values are shown in Table 11.5, the 75th percentile of reported fluoroscopy time being included for guidance.

Table 11.5: DRL values and fluoroscopy times for IR procedures in Germany

Type of procedure	DRL ($Gy.cm^2$)	Fluoroscopy time (min) 75th percentile
Recanalization of cerebral artery	180	35
EVAR of cerebral artery	250	54
PCI	48	13
Combined CA and PCI	55	13
TAVI	80	18
EVAR		
· thoracic aorta	230	19
· infrarenal abdominal aorta	230	33
· suprarenal abdominal aorta	230	52
TACE	230	25
PTA of		
· pelvis	90	17
· thigh and knee	40	18
· lower leg and foot	25	31

Table 11.6: Reference levels and fluoroscopy times for IR procedures in France.

Type of procedure	DRL (Gy.cm^2)	Fluoroscopy time (min) 75th percentile
Cerebral angiography (all)	90	11
1 cerebral vessel	30	4
2 cerebral vessels	75	7
More than 2 cerebral vessels	105	13
Spinal angiography	185	26
Embolisation in the head for aneurysm	190	58
Embolisation in the head for AVM	285	68
Lower limb arteriography without stenting	75	6
Hepatic chemoembolisation	250	28
Bronchial artery embolisation	135	38
Uterine fibroid embolisation	175	29
Uterine artery embolization (postpartum haemorrhage)	255	22
Renal artery embolization	325	25
TIPS	185	39
Vertebroplasty (all)	70	11
1 vertebra	60	9
2 vertebrae	60	10
More than 2 vertebrae	110	14

11.36 A similar survey was conducted in France (Etard and others 2017), collecting data from 36 hospitals and covering some 4,600 procedures carried out in 2015. Over 90% of the studies were carried out on systems fitted with flat panel detectors. Air Kerma area product and fluoroscopy time were obtained for 10 to 30 patients for each of 15 types of procedure with large variations in patient dose for the same procedure being noted. As per ICRP guidance (ICRP 2017) the reference levels were calculated as the 75th percentile of the distribution and are shown in Table 11.6.

11.37 Data on PCI dosimetry in France were published by Georges and others (2017), based on data from over 42,000 patients in 61 hospitals. The suggested reference level was 78 Gy.cm^2, with a 75th percentile fluoroscopy time of 15 minutes.

11.38 Heilmaier and others (2017) published locally-generated DRLs from a single hospital in Switzerland, based on adult patient studies carried out in 2014 to 2016. Each procedure was split into 'simple', 'standard' and 'difficult' categories by the operators, leading to low sample numbers in each category.

11.39 Difficulties in comparing data from different sites were emphasised, particularly differences in equipment and the exact definitions of procedures.

11.40 An extract from the data produced is shown in Table 11.7, DRLs being set from the rounded 75th percentile.

Table 11.7: Suggested DRLs from Heilmaier and others (2017)

Type of procedure	DRL ($Gy.cm^2$)	Mean fluoroscopy time (min)
EVAR		
· standard	185	17
· difficult	350	46
SIRT		
· standard	175	24
TACE		
· standard	210	20
· difficult	310	35
Renal artery embolization		
· standard	105	24
· difficult	195	25
Pelvic PTA		
· simple	50	4
· standard	60	7
· difficult	95	22
Femoral PTA		
· simple	8	5
· standard	20	12
· difficult	55	19
Lower leg PTA		
· simple	3	7
· standard	6	9
· difficult	25	17

Conclusions

11.41 The UK has a significantly lower number of radiologists per million population than most European countries.

11.42 A lower proportion of UK IR services are able to provide a comprehensive out-of-hours service than those in other European countries.

11.43 The UK has one of the lowest numbers of interventional cardiologists, IC facilities and PCI procedures proportional to population in Europe, although the latter may be a consequence of different reimbursement systems.

11.44 In a North America-European survey, the largest ‘resource gap’ in the provision of interventional neuoradiology services was found to be in the UK.

11.45 The data suggest that there is an unmet need for several procedures in the UK.

11.46 The UK lags behind several European countries in developing DRLs for IR procedures, although an internationally agreed methodology has yet to be established.

Chapter 12: Conclusions

12.1 The development of IR has revolutionised the therapeutic interventions for many medical conditions and IR is now used in a wide range of clinical specialities. These interventions have now superseded conventional surgical techniques and/or provided treatments which were previously not possible.

12.2 The ability to perform many procedures using IR (fluoroscopic imaging) allows treatments to be carried out in a minimally invasive manner and with a much-reduced need for prolonged anaesthesia. This allows for many patients to be treated as day cases, significantly reducing the requirement for hospitalisation and the need for post-operative intensive care. Patient recovery is also much quicker.

12.3 The efficiency of these techniques allows for many frail and elderly patients the opportunity to have life-saving interventions that were previously not possible.

12.4 Radiologists and radiographers who perform IR techniques have specialised training in the use of radiation for a wide range of purposes. However, consultants trained in other disciplines also increasingly use IR techniques. These staff also require specific training in all of the factors associated with the safe use of procedures involving ionising radiation.

12.5 Workforce evaluations by the RCR and BSIR suggest that the current numbers of staff trained in IR procedures are insufficient, compromising the availability of treatments to patients. In addition, the low numbers of trained staff increases their workload and potential radiation exposure.

12.6 In comparison to majority of European countries the UK is poorly provided with sufficient specialist cover to provide a 24/7 IR service.

12.7 Clinical outcomes in INR are well demonstrated to be linked favourably to higher volume practice and there is some evidence that doses are also. The appropriate control of patient and staff doses will be achieved best in high volume, well-equipped centres with the appropriate equipment infrastructure and governance/audit procedures in place. With better staffed rotas, staff doses are more widely distributed as well as trending lower with reduced average exposures per procedure compared to those for smaller, less well staffed, lower volume units.

12.8 Given that these large units are not geographically perfectly distributed then networking and patient transfer to such units is a pragmatic way to ensure 24/7 INR provision for all while also maximising clinical outcomes and reducing overall costs and radiation exposures.

12.9 Recommendations 1 and 10 of the NCEPOD report, ‘Managing the Flow? A review of the care received by patients who were diagnosed with an aneurysmal subarachnoid haemorrhage’ (NCEPOD 2013) highlight the need for the establishment of networks between secondary and regional units and the provision of 7-day INR services for ruptured cerebral aneurysm treatment. These have not been fully implemented across the UK.

12.10 As with any procedure there is a risk of complications associated with each intervention but in the vast majority of IR interventions the risks are much reduced as compared with previous conventional surgical/therapeutic interventions.

12.11 IR interventions use fluoroscopic imaging which involves exposure of patients to low doses of ionising radiation. The possible associated stochastic risk, mainly of cancer, is low and for most patients these risks are minimal compared to the benefits accruing from the IR procedure.

12.12 Infants and children are more radiosensitive than young adults to the induction of cancer by radiation, although the increased risk is small in comparison to the benefits of IR procedures. Children form only a small proportion of the total population receiving IR; however, this effect of age at exposure should be borne in mind.

12.13 Tissue reactions (deterministic effects) may become apparent following exposure to ionising radiation, normally above a threshold of 0.5 Gy; for most patients this is unlikely as they are seldom observed below absorbed doses of 2 Gy and the vast majority of IR procedures result in doses that are well below this level. In procedures in which local tissue doses may be higher than 1 Gy, it will be prudent to include a follow-up protocol and to provide additional advice to the patient.

12.14 Tissues that may be particularly affected by tissue reactions in IR procedures are the skin, the lens of the eye and the cardiovascular system, although cataract and CVD may not conform to the classical definition of effects occurring above a dose threshold.

12.15 As with all techniques involving exposure to ionising radiation every effort should be made to reduce patient doses the risk in accordance with the ALARP principle.

12.16 As yet, there is no industry standard method for the automated calculation and recording of patient dose associated with each procedure. It should be common practice for the dose information from each procedure to be included in the electronic patient record. This would facilitate practitioners in the planning and justification of subsequent exposures.

12.17 It is noted that there are international efforts to harmonise the output of skin dose maps.

12.18 IR procedures are complex, requiring a number of specialist professionals, normally about 5 to 8, to be present during the procedure. All of these individuals will be exposed to a low dose of ionising radiation during each procedure; consequently, over a working lifetime they will have a cumulative dose that requires close monitoring. For this reason, all possible precautions should be in place to minimise exposure.

12.19 The wearing of protective equipment provided by the employer is a legal requirement. The wearing of appropriate dosemeters is also a legal requirement. Passive dosemeters are most commonly utilised, but APDs offer significant advantages as set out in paragraph 6.36. APDs can be used to particular benefit by staff working on more than one site and/or for more than one employer to indicate the dose received on each.

12.20 It is not appropriate to apply dose limits to the patient in medical exposures since there is, by definition, a direct benefit to the patient. Instead, the adoption of DRLs is intended to act as a guide to the very indistinct border between good and normal practice and poor and abnormal practice as part of the optimisation process. They are usually established from surveys of measured doses for patients in different hospitals, usually at national, but also at regional or local levels.

12.21 National DRLs for a range of diagnostic examinations, which do not apply to individual patient examinations, have been set in the UK at the third quartile of mean X-ray room examination doses measured in large-scale hospital surveys. ICRP (2017) have proposed that future DRLs be set in terms of the third quartile of median examination doses.

12.22 DRLs are essentially an audit tool, so an investigation or intervention might be triggered if the mean or median dose for an examination in a hospital exceeds the DRL. Conceptually, an investigation could also be triggered in the situation where doses are substantially below the DRL value.

12.23 The continuous refinement of DRLs allows for improvements to be made in driving dose reduction, in line with the ALARP principle.

12.24 As yet, few UK DRLs have been proposed for IR procedures and there is a particular lack in the paediatric field. ICRP (2017) has discussed this topic in depth and has suggested the implementation of interventional DRLs using either complexity analysis or alternatively large data sets. The UK should develop, in collaboration with international partners, a consistent methodology taking into account ICRP recommendations that can be used to define and generate interventional DRLs.

12.25 The Subcommittee initially sought to establish what data were available to it, including basic information on the range and numbers of procedures being undertaken, the types of staff groups, the numbers of staff and the range of radiation doses to patients and staff involved in service delivery. Despite wide enquiries, it was found that few data were available.

12.26 In light of this situation, the Subcommittee found it necessary to carry out a sample survey of hospitals across the UK, using the questionnaire shown in Appendix D. This was designed to collect only data germane to the remit. Regrettably, only a small proportion of sites approached made returns, although the figure was in line with other postal surveys.

12.27 In order to inform decisions on service delivery, data such as those collected via the survey are key and mandatory returns from all UK sites (both NHS and private) should be required.

12.28 There is a range of rare genetically-inherited autosomal recessive conditions (Table 3.4) which have been identified that are known to display a markedly increased sensitivity to radiation. In addition, there are some dominantly-inherited autosomal disorders, such as Gorlin syndrome, which show the same sensitivity. These rare conditions are particularly relevant when considering radiation exposures of children.

12.29 If a patient presents with one of these syndromes, caution should be exercised in the use of radiation-related procedures. Prior to the use of any procedure, the advice of a clinical geneticist/expert in radiosensitivity disorders may be advisable.

12.30 The majority of IR inventions in children are used to correct CHD. The cardiac interventions received by these children carry much less risk than previous open-heart surgical techniques. However, since these individuals are likely to have a productive and unfettered life following the corrective intervention, the possible risk of the exposure to ionising radiation should be acknowledged and doses entered carefully in the patient record to facilitate follow-up.

12.31 The continued development of techniques in paediatric IR should be supported, together with research into methods of further radiation dose reduction.

12.32 Staff working in IR suites have specific training requirements that include a knowledge and understanding of the risks associated with IR.

12.33 Modern IR systems are highly complex and dependent upon software control. Although extensive manuals may be available (often through the internet), it is important that all staff understand and are familiar with all facets of the operation of the equipment prior to use. This is facilitated by practical courses offered by manufacturers or suppliers.

12.34 Where procedural protocols can be amended by local staff, care must be taken to ensure that the equipment performs as expected and the local MPE consulted before use on patients.

12.35 When employing locally-amended protocols, it is important to ensure that these have been reloaded correctly following any maintenance or upgrade of the equipment, since the latter may involve a reset to the original manufacturer’s settings.

Chapter 13: Recommendations

13.1 This report considers the available evidence on radiation dose issues associated with the use of interventional radiology (IR), both for staff and patients. It is acknowledged that the range of IR procedures is likely to continue to expand and the report provides recommendations which consider the potential future requirements for facilities, equipment and staff in this field. The following recommendations should be reviewed and developed as more evidence becomes available.

Recommendation 1

13.2 COMARE recommends that all healthcare staff undertaking image guided procedures in the UK should have completed a course of formal training including radiation protection for staff and patients. Existing courses should be updated regularly and, where necessary, new courses established through liaison between the Department of Health and Social Care (DHSC), the Health Departments of the devolved administrations and appropriate professional organisations. All existing and future IR training curricula should include the radiation dose structured report (RDSR).

Recommendation 2

13.3 DHSC and the Health Departments of the devolved administrations should consult with relevant professional organisations and Health Education England, NHS England and NHS Improvement (or the corresponding devolved organisations) to recommend minimum acceptable staffing arrangements for IR service provision including out of hours services. In the context of this report, this may reduce individual radiation doses, while it may also attract more staff to the field.

Recommendation 3

13.4 NHS England and the Health Departments of the devolved administrations should ensure that recommendations 1 and 10 of the NCEPOD “Managing the Flow? A review of the care received by patients who were diagnosed with an aneurysmal subarachnoid haemorrhage” report (NCEPOD 2013) relating to the establishment of networks and of 24/7 IR service provision are fully implemented across the UK.

Recommendation 4

13.5 Current IR equipment is capable of automatic patient dose reporting and production of real time skin dose maps. COMARE recommends that the UK supports international efforts to harmonise outputs, with manufacturers adopting standard measurement methods and ensuring that these can be downloaded to PACS/RIS for inclusion in the patient record.

Recommendation 5

13.6 The Committee recommends that the use of real-time electronic personal dosemeters (APDs) should be promoted for all staff. They offer particular benefit during training and in the development/introduction of novel IR procedures.

Recommendation 6

13.7 COMARE recommends the rapid establishment and reinforcement of national IR DRLs, especially for paediatric IR procedures. The UK should collaborate with ICRP and international partners to develop an agreed methodology. Resources should be made available to enable Public Health England and its equivalents in the devolved administrations to include IR procedures in UK dose surveys to provide standardised data to support regular updating of national DRLs.

Recommendation 7

13.8 The Committee recommends that DHSC and the Health Departments of the devolved administrations should include within regulations a requirement for health care providers (both NHS and private) to submit IR procedure numbers, summarised patient and staff dose data and staffing data modelled on Appendix E annually.

Recommendation 8

13.9 COMARE continues to recognise the importance of the radiosensitivity of high-risk groups as a factor in a range of clinical applications involving ionising radiation. The Committee reiterates the recommendation made in the 16th COMARE report (COMARE 2014; Recommendation 1, page 69) that the UK is actively involved in further research in this area. Professional bodies and medical and scientific societies should continue to provide educational opportunities to increase the understanding of clinical staff regarding all of the potential risks to patients, and not just the dose received, from radiological procedures. This is particularly relevant for children who receive repeat exposures to medical interventions that involve the use of ionising radiation. In addition, staff should be aware of the increased susceptibility to ionising radiation to individuals with rare, predominantly autosomal recessive genetic disorders.

Recommendation 9

13.10 The Committee recommends that appropriate grant-funding bodies support further research into paediatric IR procedures and associated radiation doses, particularly those associated with the treatment of congenital heart disease (CHD), since these patients may undergo multiple higher dose procedures.

Recommendation 10

13.11 The Committee reiterates recommendation 7 from its 16th Report, that optimisation of protocols offers significant potential for dose reduction. This can best be achieved at local level through active promotion and cooperation between professional groups. COMARE recommends that in conjunction with the production of new regulations for medical exposures, DHSC provides supporting guidance on optimisation, including a requirement for radiology services to consider formally appointing a team of radiation protection champions, consisting of a radiologist, a radiographer and a medical physicist.

Recommendation 11

13.12 Equipment manufacturers have a significant role to play in contributing to the overall safety regime for IR when introducing new technology and in training for staff, which is essential to maximise the benefits of new technology. COMARE recommends that purchasers include this in all procurement and on-going maintenance contracts.

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Appendix A: Abbreviations and Glossary

Acronym	Meaning
ADRC	automatic dose rate control
AEC	automatic exposure control
AF	adult female
ALARA	as low as reasonably achievable
ALARP	as low as reasonably practicable
AM	adult male
APD	active personal dosimeter
ASD	atrial septal defect
a-Si	amorphous silicon
AVM	arteriovenous malformation
BCIS	British Cardiovascular Intervention Society
BHF	British Heart Foundation
BIR	British Institute of Radiology
BSC	best supportive care
BSIR	British Society of Interventional Radiology
CA	coronary angiography
CABG	coronary artery bypass graft surgery
CAK	cumulative air kerma
CHD	congenital heart disease
CMOS	complementary metal-oxide-semiconductor
COMARE	Committee on Medical Aspects of Radiation in the Environment
CRC	colorectal cancer
CRYO	cryotherapy
CSF	cerebrospinal fluid
CT	computed tomography
CTO	chronic total occlusion
DAP	dose area product
DEB	drug eluting bead
DHSC	Department of Health and Social Care
DICOM	Digital Imaging and Communications in Medicine
DIMOND	Digital Imaging: Measures for Optimising Radiological Information Content and Dose
DNA	deoxyribonucleic acid

Acronym	Meaning
DRL	diagnostic reference level
DSB	double strand break
E	effective dose
ECG	electrocardiogram
ECMO	extracorporeal membranous oxygenation
ECRP	endoscopic retrograde cholangio-pancreatography
EGFR	epidermal growth factor receptor
EP	electrophysiology
ESAK	entrance surface air kerma
EVAR	endovascular aneurysm repair
f/s	frames per second
FEVAR	fenestrated endograft
FGI	fluoroscopically guided intervention
GA	general anaesthetic
GI	gastrointestinal
GUCH	grown up congenital heart disease
Gy	Gray
HCA	healthcare assistant
HCC	hepatocellular carcinoma
HPA	Health Protection Agency
HSE	Health and Safety Executive
HVL	half value layer
IAK	incident air kerma
IC	interventional cardiology
ICD	implantable cardioverter-defibrillator
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
IFN	interferon
ILI	isolated limb infusion
ILP	isolated limb perfusion
INR	interventional neuroradiology
IR	interventional radiology
IR(ME)R	Ionising Radiation (Medical Exposures) Regulations
IRE	irreversible electroporation

Acronym	Meaning
IRR	Ionising Radiation Regulations
ISO	International Standards Organisation
IVC	inferior vena cava
JoPIIRR	Justification of Practices Involving Ionising Radiation Regulations
KAP	kerma area product
kV	kilovolt
LAO	left anterior oblique
mAs	milliamp-seconds
MCRC	metastatic colorectal cancer
MDT	multi-disciplinary team
MIRD	medical internal radiation dose
MRI	magnetic resonance imaging
MWA	microwave ablation
NCAP	National Cardiac Audit Programme
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
NICE	National Institute for Health and Care Excellence
ODP	operating department practitioner
OOH	out of hours
OSL	optically stimulated luminescence
PA	posterior-anterior
PACS	picture archiving and communication system
PCI	percutaneous coronary intervention
PDA	patent ductus arteriosus
PHE	Public Health England
PIC	paediatric interventional cardiology
PICC	peripherally inserted central catheter
PPCI	primary percutaneous coronary intervention
PPE	personal protective equipment
PPI	permanent pacemaker insertion
PSD	peak skin dose
PTC	percutaneous transhepatic changiography
PTCA	percutaneous transluminal coronary angiography
RAO	right anterior oblique
RCR	Royal College of Radiologists

Acronym	Meaning
RDSR	radiation dose structured report
RFA	radiofrequency ablation
RIG	radiologically inserted gastronomy
RILD	radiation-induced liver cancer
RIS	radiological information system
RoI	Republic of Ireland
RPA	radiation protection adviser
RPS	radiation protection supervisor
SABR	stereotactic ablative radiotherapy
SACT	systemic anti-cancer therapy
SAH	subarachnoid haemorrhage
SIRT	selective internal radiotherapy
SNR	signal to noise ratio
SSNP	Sentinel Stroke National Audit Project
STEMI	segment elevation myocardial infarction
SV	Sievert
TACE	trans arterial chemo-embolisation
TEVAR	thoracic endovascular aortic repair
TIPS	transjugular porto-systemic shunt creation
TLD	thermos luminescent dosimeter
TNF	tumour necrosis factor
µGy	micro-Gray
µSv	micro-Sievert
UIA	unruptured intracranial aneurysm
VAD	ventricular assist devices
VIR	vascular interventional radiology

Term	Definition
ABLATION	The surgical removal of body tissue
ABSORBED DOSE	The quantity of energy imparted by ionising radiation to a unit mass of matter such as tissue. Absorbed dose has the units of joules per kilogram ($J\ kg^{-1}$) and the specific name gray (Gy), where 1 Gy = 1 $J\ kg^{-1}$
AIR KERMA	The amount of Kerma in a specified mass of air; measured in Gray (Gy)

Term	Definition
ALARA	As low as reasonably achievable: the principle of radioprotection stating that whenever ionising radiation has to be applied to humans, animals or materials exposure should be as low as reasonably achievable
ALARP	As low as reasonably practicable: the principle used in radiation protection in the UK that doses to people should be as low as possible once all the 'reasonable' methods of dose reduction have been employed
ANEURYSM	An excessive localised swelling of the wall of an artery
ANGIOGRAM	An X-ray of one or more blood vessels, used in diagnosing pathological conditions
ATHEROSCLEROSIS	A disease of the arteries characterised by the deposition of fatty material on their inner walls.
BARIATRIC	A patient having obesity, with a body mass index that is equal to or greater than 30.
BENIGN	Non-cancerous or non-malignant. A benign tumour may grow but it does not invade surrounding tissue or spread to other parts of the body
BILIARY	Relating to bile or the bile duct
CARCINOGEN	An agent that causes cancer
CARCINOMA	A cancer arising in the epithelial tissue of the skin or of the lining of the internal organs
CARDIAC	Pertaining to the heart
CARDIOLOGIST	A doctor who specialises in the study or treatment of heart diseases and heart abnormalities
CATARACT	An opacity, partial or complete, on the lens of the eye which may impair vision and, if dense enough, can cause blindness
CATHETER	A flexible tube inserted through a narrow opening into a body cavity, particularly the bladder, for removing fluid
CHEMOTHERAPY	The treatment of disease by the use of chemical substances, especially the treatment of cancer by cytotoxic and other drugs
COLLIMATION	All the optical elements in an instrument being on their designed optical axis
COMPUTED TOMOGRAPHY (CT)	A special radiographic technique that uses a computer to assimilate multiple X-ray images into a 2-dimensional cross-sectional image
CONCOMITANT	Naturally accompanying or associated with
CONGENTIAL	Present from birth
CONTRAST AGENT	A substance that is introduced into or around a structure and, because of the difference in absorption of X-rays by the contrast medium and the surrounding tissues, allows radiographic visualisation of the structure
DESQUAMATION	Skin peeling

Term	Definition
DETERMINISTIC	A deterministic health effect has a severity that is dependent on dose and is believed to have a threshold level below which no effect is seen
DIAGNOSTIC	Concerned with the diagnosis of illness or other problems
DIAGNOSTIC REFERENCE LEVELS (DRLs)	Dose levels in medical radiation diagnostic practices for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment
DIALYSIS	The clinical purification of blood by dialysis, as a substitute for the normal function of the kidney
DOSE	A measure of the amount of radiation received. More strictly it is related to the energy absorbed per unit mass of tissue (see Absorbed Dose). Doses can be estimated for individual organs or for the body as a whole
DOSE-AREA PRODUCT (DAP)	A measure of radiation risk calculated by multiplying the absorbed dose by the area irradiated (in Gy per cm^2)
DOSIMETER	A device used to measure an absorbed dose of ionizing radiation
EFFECTIVE DOSE	Effective dose is the sum of the weighted equivalent doses in all the tissues and organs of the body. It takes into account the biological effectiveness of different types of radiation and variation in the susceptibility of different organs and tissues to radiation damage. Thus it provides a common basis for comparing exposures from different sources. Unit = sievert (Sv)
ELECTROCARDIOGRAM (ECG)	A record or display of a person's heartbeat produced by electrocardiography
EMBOLISATION	The artificial or natural formation or development of a blood clot, air bubble, piece of fatty deposit, or other object which has been carried in the bloodstream to lodge in a vessel and cause an embolism
EPIDEMIOLOGY	The study of factors affecting health and illness of populations, regarding the causes, distribution and control
EPIGENETIC	Relating to or arising from non-genetic influences on gene expression
EPILATION	The removal of hair by pulling it from the roots or hair loss due to chemical damage or exposure to ionising radiation
EQUIVALENT DOSE	The quantity obtained by multiplying the absorbed dose by a factor to allow for the different effectiveness of the various ionising radiations in causing harm to tissue. Unit = sievert (Sv)
ERYTHEMA	Superficial reddening of the skin, usually in patches, as a result of injury or irritation causing dilatation of the blood capillaries
FLUOROSCOPY	An imaging technique that uses X-rays to obtain real-time moving images of the interior of an object
GRAY (Gy)	The international (SI) unit of absorbed dose. One gray is equivalent to one joule of energy absorbed per kilogram of matter such as body tissue
HAEMORRHAGE	An escape of blood from a ruptured blood vessel

Term	Definition
IMMUNOLOGICAL	Relating to the structure and function of the immune system
INCIDENCE	This is the number of new cases of a disease arising in a population over a specific period of time, usually one year
INTERVENTIONAL RADIOLOGY	A range of techniques which rely on the use radiological image guidance (X-ray fluoroscopy, ultrasound, computed tomography or magnetic resonance imaging) to precisely target therapy
INVASIVE	Involving entry into the living body (as by incision or by insertion of an instrument)
IONISING RADIATION	Radiation that is sufficiently energetic to remove electrons from atoms in its path. In human or animal exposures ionising radiation can result in the formation of highly reactive particles in the body which can cause damage to individual components of living cells and tissues
IRRADIATION	The process by which an item is exposed to radiation, either intentionally or accidentally
ISO-CENTRE	The intersection of the central scan plane with the axis of rotation of the X-ray tube and detector around the patient
JUSTIFICATION	Consideration that a medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation
LATENCY PERIOD	The interval between exposure to a carcinogen, toxin, or disease-causing organism and development of a consequent disease
LESION	A region in an organ or tissue which has suffered damage through injury or disease, such as a wound, ulcer, abscess, or tumour
LEVEL 1A	Systematic review (with homogeneity) of (multiple) RCTs
MAGNETIC RESONANCE IMAGING (MRI)	The use of nuclear magnetic resonance of protons to produce proton density images
MALIGNANT	Cancerous growth, a mass of cells showing uncontrolled growth, a tendency to invade and damage surrounding tissues and an ability to seed daughter growths to sites remote from the primary growth
MEDIAN	Denoting the middle term (or mean of the middle 2 terms) of a series arranged in order of magnitude
METABOLIC	Relating to or deriving from the metabolism of a living organism
METASTASES	The development of secondary malignant growths at a distance from a primary site of cancer
MODALITY	The method of application of a therapeutic agent or regimen

Term	Definition
MONTE CARLO METHODS	Monte Carlo methods are a statistical approach for modelling X-ray interactions in and through tissue, and are used to determine an estimate of radiation dose
MORBIDITY	The condition of being diseased
MORTALITY	Death
MUTATION	A permanent transmissible change in the genetic material, which may alter a characteristic of an individual or manifest as disease
NECROSIS	The death of most or all of the cells in an organ or tissue due to disease, injury, or failure of the blood supply
NEONATE	An infant less than 4 weeks old
NEURORADIOLOGIST	A radiologist who specializes in the use of radioactive substances, X-rays and scanning devices for the diagnosis and treatment of diseases of the nervous system
NON-IONISING RADIATION	Any type of electromagnetic radiation that does not carry enough energy per quantum (photon energy) to ionise atoms or molecules
OCCLUSION	The blockage or closing of a blood vessel or hollow organ
OPERATOR	Any person who is entitled to carry out the practical aspects of a medical exposure
OPTIMISATION	Consideration that a medical exposure be conducted as efficiently and effectively as possible using the lowest reasonably practicable radiation exposure, consistent with the intended purpose. The optimisation process consists of a chain of responsibilities extending from appropriate manufacture, selection and maintenance of equipment to the exposure parameters selected for the individual examination
PAEDIATRIC	Of, or relating to, the medical care of children
PATIENT DOSE	The ionising radiation dose to a patient or other individual undergoing a medical exposure
PERCUTANEOUS	Made, done, or effected through the skin
PERFUSION	The passage of fluid (such as blood) through a specific organ or area of the body (such as the heart)
PHANTOM	Object generally comprised of tissue substitute materials used to simulate a patient or part thereof
PICTURE ARCHIVING & COMMUNICATION SYSTEM (PACS)	PACS (picture archiving and communication system) is a standard healthcare technology for short- and long-term storage, retrieval, management, distribution and presentation of medical images
POSITRON EMISSION TOMOGRAPHY (PET) SCAN	A diagnostic examination involving the acquisition of physiological images based on the detection of radiation through the emission of positrons. The positrons are emitted from a short-lived radionuclide incorporated into a metabolically active substance administered to the patient prior to the examination

Term	Definition
PRACTITIONER	A registered health care professional, who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements
PROGNOSIS	A prediction of the probable course and outcome of a disease and the prospects of recovery as indicated by the nature of the disease and the symptoms of the case
QUARTILE	Each of 4 equal groups into which a population can be divided according to the distribution of values of a particular variable
RADIATION PROTECTION ADVISER (RPA)	An RPA is an expert in radiation protection, certified as competent by an HSE approved body, to advise the employer in radiation safety for the public and staff (under the Ionising Radiations Regulations 1999, IRR99)
RADIATION PROTECTION SUPERVISOR (RPS)	An RPS is a line manager, or person of similar status, working in and having knowledge of the equipment and practices in a radiation controlled area – appointed under IRR99 to ensure local rules are adhered to in that area
RADIOGRAPHER	A trained healthcare professional typically certified or licensed to produce medical imaging (such as X-rays or CT scans) for diagnosis or screening
RADIOLOGIST	A medically qualified doctor who specialises in the use of imaging techniques (X-rays, ultrasound, CT, MR, fine needle biopsy and so on) for diagnosis (diagnostic radiologist) or one who specialises in the use of imaging techniques in assisting treatment – for example, in inserting catheters into blood vessels or in choking the blood supply of a tumour by injection of a type of glue (interventional radiologist)
RADIOLOGY INFORMATION SYSTEM (RIS)	A radiology information system is networked software used for managing radiological records and associated data in multiple locations. It is often seen used in conjunction with a picture archiving and communication system (PACS) to manage workflow
RADIONUCLIDE	A type of atomic nucleus which is unstable, and which may undergo spontaneous decay to another atom by emission of ionising radiation (usually alpha, beta or gamma)
RADIOSENSITIVITY	The relative susceptibility of cells, tissues, organs, organisms, or any other substances to the effects of radiation
RADIOTHERAPY	The treatment of disease with ionising radiation. The purpose of radiotherapy is to deliver an optimal dose of either particulate or electromagnetic radiation to a particular area of the body with minimal damage to normal tissues. The source of radiation may be outside the body of the patient (external radiotherapy) or it may be a radionuclide that has been implanted or instilled into abnormal tissue or a body cavity
RESECTION	The process of cutting out tissue or part of an organ

Term	Definition
RISK	The probability that an event will occur, that is, that an individual will become ill or die before a stated period of time or age. This is also a non-technical term encompassing a variety of measures of the probability of a (generally) unfavourable outcome
SENSITIVITY	A measure for assessing the results of diagnostic and screening tests. Sensitivity is the proportion of people who test positive for a disease that have that disease. A highly sensitive test will essentially rule out those who do not have disease
SEPSIS	A serious condition resulting from the presence of harmful microorganisms in the blood or other tissues and the body's response to their presence, potentially leading to the malfunctioning of various organs, shock, and death
SIEVERT (Sv)	The international (SI) unit of effective dose obtained by weighting the equivalent dose in each tissue in the body with the ICRP-recommended tissue weighting factors and summing over all tissues. Because the sievert is a large unit, effective dose is commonly expressed in millisieverts (mSv) – one millisievert is one-thousandth of one sievert. The average annual radiation dose received by members of the public in the UK is 2.7 mSv
SOMATIC	Relating to all tissue cells the body, as distinct from germ cells
STENOSIS	The abnormal narrowing of a passage in the body
STENT	A splint placed temporarily inside a duct, canal, or blood vessel to aid healing or relieve an obstruction
STOCHASTIC	Stochastic effect or 'chance effect' is a classification of radiation effects that refers to the random, statistical nature of the damage. The severity is independent of dose. Only the probability of an effect increases with dose
TORSO	The main part of the human body, without the limbs and head; the trunk
TOXINS	Poisons of plant or animal origin, especially one produced by or derived from microorganisms and acting as an antigen in the body
TUMOUR	Mass of tissue formed by unregulated growth of cells; can be benign or malignant
ULTRASOUND	The use of ultrasonic waves for diagnostic or therapeutic purposes, specifically to visualise an internal body structure, monitor a developing foetus, or generate localised deep heat to the tissues
URINARY	Relating to or denoting the system of organs, structures, and ducts by which urine is produced and discharged, in mammals comprising the kidneys, ureters, bladder, and urethra
VASCULAR	Of, relating to, or containing blood vessels
VISCERAL	Relating to the internal organs in the main cavities of the body

Term	Definition
X-RAY	An image obtained using high energy radiation with waves shorter than those of visible light. X-rays possess the properties of penetrating most substances (to varying extents), of acting on a photographic film or plate (permitting radiography), and of causing a fluorescent screen to give off light (permitting fluoroscopy). In low doses X-rays are used for making images that help to diagnose disease, and in high doses to treat cancer

Appendix B: Organisation of an IR suite

B.1 IR involves a wide range of complex treatment protocols which inevitably requires a dedicated IR facility designed to treat specific indications (for example, cardiac, neuro, among others). An IR suite normally comprises several distinct areas including a patient preparation/recovery area, plant room(s), radiation protection equipment storage room, scrub facility, clean utility, dirty utility/disposal area and one or more IR rooms, each with a control room.

B.2 The IR facility should be designed to accommodate patients with disabilities as well as space for the transfer of patients from a stretcher to the equipment in the IR room. Access doors and patient support tables should be designed to cope with bariatric patients.

B.3 Attention should be paid to the décor to provide a calming atmosphere, particularly in paediatric units.

B.4 The IR room(s) require a sterile environment. IR suites should be constructed to full operating theatre standards. This has implications for surface finishes, airflow and filtration, temperature and humidity control. Electrical backup must be available. IR equipment can generate a high heat load, which affects the capacity of the air handling system. Advice contained in Health Building Note 6 (NHS-Estates 2001) should be followed.

B.5 It is crucial to allow sufficient space for an IR suite to operate in a safe and efficient manner. Not only must there be adequate space for the equipment, staff and consumables, but access and space for emergency responders.

B.6 Adequate patient preparation and recovery areas must be provided which have the capacity to cope with any surge in case volumes, unexpected delays or adverse events. This will have oxygen, suction, PACS access, monitoring equipment and basic resuscitation equipment.

B.7 Most procedures will be undertaken with sedation, except in INR where most are performed under general anaesthesia (GA). Sedation will be done either on the ward or within the IR suite preparation/recovery room. Sedated patients will require monitoring of blood pressure, oxygen saturation and electrocardiogram (ECG) during interventional procedures, possibly using trolley-mounted monitoring equipment. Only a small number of procedures, such as those involving children or more complex procedures, will require GA.

B.8 Adequate radiation shielding must be incorporated into the walls and, where appropriate, floor and ceiling of the IR room, as agreed with the local RPA. This will be dependent primarily upon the equipment installed and expected workload. Floor and ceiling loading calculations should account for shielding as well as equipment.

B.9 Floor-mounted IR equipment is usually secured by anchored bolts in the floor; less common is a through-bolt design with a plate on the underside of the floor slab. Ceiling-mounted IR equipment is usually supported from a universal grid of Unistrut steel attached directly to the ceiling slab. Such a grid usually extends over most of the ceiling area so that it does not need to be amended when equipment is changed. The ceiling grid also facilitates the mounting of moveable shielding screens and ancillary equipment and so is much more flexible than floor mounting; it is to be preferred for a single-plane installation.

B.10 The C-arms are sensitive to mechanical vibration and so any nearby sources should be isolated or eliminated.

B.11 Medical oxygen, medical compressed air and medical vacuum, together with nitrous oxide and active anaesthetic gas scavenging, should be provided from wall-mounted outlets or a ceiling-mounted pendant.

B.12 The IR room should contain PACS viewing systems for review of relevant images before, during, or after procedures. Bulk storage of consumables will be sited within the support area, but storage should be provided within the IR room for basic and common procedural equipment (for example, needles, wires, catheters) as well as critical equipment (for example, coils).

B.13 Each IR room should be equipped with a power injector and there should be a backup available in the near vicinity. Power injectors have clear advantages in terms of image quality and radiation dose to both staff and patients (Layton and others 2006). They also reduce contrast usage.

B.14 Each IR room should have a real-time colour duplex ultrasound system. The dirty utility area should contain facilities to clean the ultrasound probes.

B.15 The general lighting should be coordinated with the patient table and tube stand to ensure that fluoroscopic imaging perception is not adversely affected. Locally controlled variable lighting levels should be provided to avoid reflection on monitoring screens.

B.16 For paediatric units, the ambience of the special procedures suite, pre-procedure rooms, and anaesthetic bay should be made as child-friendly as possible. This includes using comforting lighting, allowing parents to accompany the child into the anaesthetic bay, and providing reassuring media, such as posters, toys, music, or other distractions.

B.17 The control room should be immediately accessible from the IR room, but also have direct access from outside the suite. There should be clear views of the entire IR room. Typically, 2 workstations per IR room are necessary, each connected to the PACS and Radiology Information System (RIS). One of the patient monitors must be powered independently of the X-ray equipment to allow continuous monitoring of the patient should a malfunction of the X-ray system occur.

B.18 An appropriate area must be provided for storage of radiation safety equipment such as lead aprons, thyroid shields and glasses that are properly apportioned to the number of staff and operators. Sufficient space is needed to ensure that wrinkling or folding of lead aprons does not occur.

B.19 A high quality fixed angiographic X-ray system is required. Most manufacturers offer a range of equipment tailored to particular applications. Single plane systems are still the most common, with bi-plane essential in neurological applications. The smallest focal-spot size provided on typical dual focal-spot x-ray tubes is larger than necessary for small paediatric patients. A triple focal-spot X-ray tube with nominal sizes of 0.3, 0.6, and 1 mm provides more flexibility for paediatric applications.

B.20 Originally, the X-ray output was continuous, but modern systems employ a variable-rate pulsed mode. Combined with a last-image-hold facility, where the last image of a series is left on the display for the operator to study, this leads to lower doses for both staff and patients. Higher frame rates are often needed to accommodate the more rapid heart rates of small children.

B.21 Image intensifier systems have been superseded by the amorphous silicon (a-Si) flat panel detector. Compared to image intensifiers, the flat detector's more direct signal conversion path with no optical lens results in uniform image brightness and no geometric distortion. The solid-state detector provides greater reliability and no image degradation over time. By its design, the flat-panel detector produces a digital signal, offering the possibility of further image processing.

B.22 More recently, the uneven atomic structure of the a-Si detector has been replaced by complementary metal-oxide-semiconductor (CMOS) technology using crystalline silicon, which has fewer power requirements, resulting in a general lower noise level compared to a-Si technology.

B.23 Due to the smaller pixel sizes of the CMOS detector (100 µm x 100 µm) with less dark current, a higher spatial resolution as well as a greater sensitivity can be achieved, which leads to images that are less grainy and dim. Using pixel binning, the output signal-to-noise ratio (SNR) and thereby also the dynamic range can be improved considerably. This allows a significant reduction in patient dose while maintaining a clinically-acceptable image quality. The ultra-fast readout technology of the new crystalline silicon detector allows for higher frame rates in 3D imaging, up to 99 f/s, with a low radiation dose of 6 nGy per pulse. (Siemens)

B.24 Flat panels are available in a range of sizes. Large view systems have been developed specifically for oncology applications.

B.25 Detailed specifications of performance relating to the intended clinical use of the equipment should be made when purchase is being considered. This should include the training of staff required and maintenance requirements. The specification requires input from IR operators, radiographers, radiology managers, medical physics experts (MPEs) and procurement experts.

B.26 Acceptance tests of new IR equipment must be carried out to ensure that the IR equipment supplied has provided what has been ordered, that it functions according to the manufacturer's and purchaser's specification and is safe to use. The MPE and radiation protection adviser will be involved in these tests.

B.27 All equipment must be subject to a scheduled maintenance programme. Where computer-controlled equipment which permits user-defined protocols is in use, it is important to ensure that the latter are reloaded properly following maintenance procedures, which may have reset systems to manufacturers' default settings.

Appendix C: Total number of cases submitted to the National Congenital Heart Disease Audit (NCHDA) in financial years 2003 to 2017

Year	Surgical	Hybrid	Catheter			Diagnostic catheter	Total
			Interventional	EP/Pacing	ICD		
2003 to 2004	4,497	0	2,928	-	-	-	7,425
2004 to 2005	4,346	0	3,032	-	-	-	7,378
2005 to 2006	4,638	3	3,490	-	-	-	8,131
2006 to 2007	4,794	7	3,769	-	-	-	8,570
2007 to 2008	4,771	10	3,616	-	-	-	8,397
2008 to 2009	4,949	14	3,910	-	-	-	8,873
2009 to 2010	5,262	6	3,963	-	-	-	9,231
2010 to 2011	5,852	6	4,310	-	-	-	10,168
2011 to 2012	5,710	29	4,498	-	-	-	10,237
2012 to 2013	5,849	16	4,372	-	-	-	10,237
2013 to 2014	6,024	50	3,720	944	109	-	10,847
2014 to 2015	5,662	62	3,511	1,037	117	-	10,389
2015 to 2016	5,630	53	3,731	1,347	126	1,631	12,518
2016 to 2017	5,642	48	3,837	1,459	154	1,878	13,018

Reference - NCAP (2018a)

Note: Primary Extracorporeal Membranous Oxygenation (ECMO), Ventricular Assist Devices (VAD) and lung transplants are counted as surgical activity; interventional, Electrophysiology(EP)/Pacing and Implantable cardioverter-defibrillator (ICD) devices are counted as catheter procedures, collated separately until 2013/14 financial year. Hybrid procedures are those with a combination of surgical and transluminal catheter interventions undertaken at the same time in the operating theatre. Diagnostic catheter data were included in the data set from 2015 to 2016 onwards.

Appendix D: Reproduction of a procedure information leaflet from Guys and St Thomas' NHS Foundation Trust

NHS
Guy's and St Thomas'
NHS Foundation Trust

Having a trans-catheter closure of your atrial septal defect

This leaflet aims to answer your questions about having the hole in your heart (known as an atrial septal defect or ASD) closed. It explains the benefits, risks and alternatives to the procedure, as well as what you can expect when you come to hospital.

If you have any further questions or concerns, please speak to a doctor or nurse caring for you.

What is an ASD?

You have been diagnosed with an atrial septal defect (ASD), which is a hole between the upper two chambers in the heart. These chambers are known as the atria and collect the blood returning from the body. If you have an ASD the blood doesn't flow correctly, which can lead to problems such as shortness of breath, migraines and strokes.

What happens during an ASD closure?

A small device made up of two umbrellas joined at the centre is put into the hole to close it up. The procedure normally takes about an hour and is performed under general anaesthetic, which means you will be unconscious (asleep) when it takes place. Please ask for a copy of our leaflet **Having an anaesthetic**, if you would like one.

Before the surgeon starts to repair the hole, the doctors will assess it using a small ultrasound probe that is put down your throat. This probe is known as a 'transoesophageal echocardiogram'.

Once the team is happy that they can close the hole, they will insert a catheter (fine tube) into a vein in your groin. The catheter is then passed to your heart. Inside the catheter there is a tiny balloon that the team will use to measure the exact size of the hole so that they can choose the best device to close it.

The device is folded so it can fit through a long tube called a 'sheath'. It is then put through the catheter in your groin and passed to your heart. We use x-rays and the probe in your throat to make sure the device is in the correct position. Once in place, the two umbrellas open on either side of the hole in the heart to close it.

Occasionally the hole may not be closed completely by the device, leaving a small leak. This may close on its own in the future.

showing we care

Why should I have an ASD closure?

The treatment aims to close the hole in your heart to prevent you from having problems with blood clotting or a stroke. If you have already had such problems, the aim is to prevent them from happening again.

What are the risks?

We may be unable to repair the hole in the way described above. If the ultrasound probe we put down your throat at the start of the procedure shows that the hole is not suitable for device closure because of its size, position and the surrounding tissue/rim, we will not be able to repair the hole at this time. We will tell you immediately and you should be able to go home on the same day. We will then put you on the waiting list for surgery.

The device may not hold in place. When the device is opened and released, there is a small chance it may dislodge because the tissue/rim around the hole is floppy. This happens in less than 2 in 100 cases. If this happens we will try to retrieve the device, but it may be difficult to withdraw it fully back into the sheath. If we cannot retrieve the device, you may need to have an open heart operation to remove the device from the heart, and the hole would be closed at the same time by the normal surgical method.

During any procedure of this kind, there is the risk of a stroke caused by a blood clot or air passing from the sheath, through the bloodstream and to the brain. This occurs in less than 1 in 100 cases. We minimise this risk by giving heparin during the procedure to keep the blood thin. Other precautions are also taken to reduce the likelihood of air passing through the heart.

You may get some bruising after the procedure, which could extend down your thigh. Some bruising is normal but if you are concerned you should seek medical advice.

What are the alternatives?

In the past, the only way of closing these holes was by an open heart operation. During an open heart operation the function of the heart and lungs is taken over by a bypass machine and the surgeon closes the hole directly with stitches or patch material.

Surgery is a very successful and safe method, but it does leave a scar on the chest. In women, the surgeon may perform the operation through a cut across the lower chest, producing a better cosmetic result in the longer term.

In the last few years, the method described in this leaflet (operating through a catheter placed in your groin) has become available as an alternative to surgery.

You are free to choose between the surgical and the non-surgical methods to close the hole. Your decision will in no way affect the care you receive in our hospitals.

How can I prepare for my ASD closure?

You will be contacted by a member of the cardiac team to arrange your admission.

Information about what you need to do and what you should bring with you can be found in the information sheet that will be sent to you before your admission. Your admission letter should give you instructions for taking your medicines before you come into hospital.

Will I feel any pain?

The procedure takes place under a general anaesthetic, so you will not feel any pain during the operation. After the procedure, you may experience some very mild discomfort in your groin (where the catheters were inserted) but this should quickly pass.

What happens after the procedure?

For the first few hours after your procedure you will be attached to a cardiac monitor. This is a machine that is mounted on the wall behind your bed. You will have stickers on your chest that will be wired up to the monitor. This allows us to see your heart rate and rhythm. Likewise we monitor the oxygen level in your blood using a small electrical sensor attached to your finger.

After we have closed the hole using the device, you will need to stay a further night in hospital. The day after your procedure, you will have two heart scans known as an 'echo' and an 'ECG'. If all is well you can then go home.

What do I need to do after I go home?

We recommend that you are accompanied by a friend or relative on your journey home.

You will be given a letter to give to your GP. This will detail what has happened to you in hospital and which tablets you are on. You will need to take aspirin and clopidogrel to thin your blood and stop large clots forming on the device. How long you need to take these for will vary. Please make sure you know how long you should continue taking these medicines for before leaving hospital. You will be given a card explaining why you are taking this combination of medicines, and for how long you should take them.

When you go home you should be back to full activity, including driving, within the week. If you have a physical job we will advise you on when you can go back to work.

Will I have a follow-up appointment?

We will invite you back to the clinic three months after the procedure. Providing all is well, you will then need to come back for yearly check-ups (which will include placing an ultrasound probe in your throat).

Contact us

If you have any questions or concerns about your ASD closure, please contact the following staff / wards (Monday to Friday, 9am to 5pm):

Secretary to consultant cardiologist **t:** 020 7188 1049
Becket Ward, 5th floor, East Wing **t:** 020 7188 8839
Stephen Ward, 7th floor, East Wing **t:** 020 7188 8843

If you have any queries outside of these hours please contact your GP or NHS 111 (see below).

For more information leaflets on conditions, procedures, treatments and services offered at our hospitals, please visit www.guysandstthomas.nhs.uk/leaflets

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Useful sources of information

Pharmacy Medicines Helpline
If you have any questions or concerns about your medicines, please speak to the staff caring for you or call our helpline.
t: 020 7188 8748 9am to 5pm, Monday to Friday

Your comments and concerns
For advice, support or to raise a concern, contact our Patient Advice and Liaison Service (PALS). To make a complaint, contact the complaints department.
t: 020 7188 8801 (PALS) **e:** pals@gstt.nhs.uk
t: 020 7188 3514 (complaints) **e:** complaints2@gstt.nhs.uk

Language and accessible support services
If you need an interpreter or information about your care in a different language or format, please get in touch.
t: 020 7188 8815 **e:** languagesupport@gstt.nhs.uk

NHS 111
Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.
t: 111

NHS Choices
Provides online information and guidance on all aspects of health and healthcare, to help you make choices about your health.
w: www.nhs.uk

Get involved and have your say: become a member of the Trust
Members of Guy's and St Thomas' NHS Foundation Trust contribute to the organisation on a voluntary basis. We count on them for feedback, local knowledge and support. Membership is free and it is up to you how much you get involved. To find out more, please get in touch.
t: 0800 731 0319 **e:** members@gstt.nhs.uk **w:** www.guysandstthomas.nhs.uk/membership

Leaflet number: 2904/VER3
Date published: January 2018
Review date: January 2021

A list of sources is available on request

Appendix E: Survey of interventional radiology (IR) practice in the UK 2015 to 2017 - Questionnaire

Survey of interventional radiology (IR) practice in the UK 2015 to 2017

This survey is being carried out in order to produce a report requested by UK Health Departments and your assistance would be greatly appreciated. The questionnaire has been split into 3 sections to reduce the workload on any one individual and we should be grateful if you could pass these to the appropriate person.

If dosimetry information is maintained centrally (i.e. by the radiation protection section) please forward a copy of the document to them also for completion.

The data are requested for calendar years.

Contact details will be retained only until compilation of the data is complete and the names of contacts and hospitals involved will not be published in the report.

Please return the completed document, by 30 November 2018, to the COMARE Secretariat at comare@phe.gov.uk.

Hospital:

Address:

Age range for paediatric procedures:

Section 1 - Radiology

Staffing and Rooms

1. Number of consultant radiologists participating in IR service:	
2. Estimated total number of consultant IR sessions per week:	
3. Maximum number of IR sessions by an individual consultant per week:	
4. Number of junior radiologists participating in IR service:	
5. Estimated total number of junior staff IR sessions per week:	
6. Maximum number of IR sessions by an individual junior per week:	

7. Number of other consultants (that is, vascular surgeons) participating in IR service:	
8. Estimated total number of consultant IR sessions per week:	
9. Maximum number of IR sessions by an individual consultant per week:	
10. Number of other junior staff participating in IR service:	
11. Estimated total number of junior staff IR sessions per week:	
12. Maximum number of IR sessions by an individual junior per week:	

13. Number of radiographers (all grades) participating in IR service:	
14. Estimated total number of IR sessions per week:	
15. Maximum number of IR sessions by an individual radiographer per week:	

16. Number of nurses (all grades) participating in IR service:	
17. Estimated total number of IR sessions per week:	
18. Maximum number of IR sessions by an individual nurse per week:	

19. Number of other staff (that is, physiological measurement technicians or clinical physiologists) participating in IR service:	
20. Estimated total number of IR sessions per week:	

21. Number of rooms equipped for IR:		
22. Number of dedicated IR rooms within radiology:	Single Plane	Biplane
23. No of hybrid rooms:		
24. Please supply the year of installation of each room in the row below		

Radiation Monitoring:

25. Do you provide under apron badges to staff in your IR rooms?	
26. Do you provide collar badges to staff in the IR rooms?	
27. Do you use a real time dose monitoring system such as Philips Dosewise or Raysafe I2/I3 in your IR rooms?	

Hospital: **Person returning survey:**

Contact details (email, telephone):

Estimated total numbers of procedures carried out on adult patients each calendar year

	2015	2016	2017
Vascular			
Peripheral angioplasty/stent			
Aortoiliac angioplasty/stent			
Endovascular stent graft- abdominal aorta			
Endovascular stent graft- thoracic aorta			
Gastrointestinal embolisation			
Transjugular portosytemic shunt			
Central venous catheter or port insertion			
Selective Internal Radiotherapy (SIRT)			
Transcatheter chemoembolisation			
Pulmonary Arterial Venous Malformation			
Nephrolithotomy (in dept. or theatre)			
Uterine Fibroid Embolisation			
Prostatic embolisation			
Stroke intervention – coil embolisation			
Stroke intervention – mechanical thrombectomy			
Other			
Renal dialysis intervention			
Fistula angioplasty/stent			
Fistula thrombectomy			
Dialysis line insertion			
Other			
Non vascular			
Nephrostomy Insertion			
Ureteric stent insertion			
Percutaneous Nephrolithotomy (inc. in theatre)			
Percutaneous Gastrostomy			
Gastrointestinal stent insertion			
Biliary drainage/stenting			
Vertebroplasty			
Other			

Estimated total numbers of procedures carried out on paediatric patients each calendar year

	2015	2016	2017
Vascular			
Central venous catheter or port insertion			
Other			
Renal dialysis intervention			
Fistula thrombectomy			
Dialysis line insertion			
Other			
Non vascular			
Nephrostomy Insertion			
Other			

Cumulative Air Kerma Survey

	2016		2017	
	Adult	**Paed**	**Adult**	**Paed**
Vascular				
No of patients with CAK >2000 & < 3000 mGy				
No of patients with CAK >3000 & < 5000 mGy				
No of patients with CAK > 5000 & < 8000 mGy				
No of patients with CAK > 8000 mGy				
Renal dialysis intervention				
No of patients with CAK >2000 & < 3000 mGy				
No of patients with CAK >3000 & < 5000 mGy				
No of patients with CAK > 5000 & < 8000 mGy				
No of patients with CAK > 8000 mGy				
Non vascular				
No of patients with CAK >2000 & < 3000 mGy				
No of patients with CAK >3000 & < 5000 mGy				
No of patients with CAK > 5000 & < 8000 mGy				
No of patients with CAK > 8000 mGy				

Eye Dose Survey* (please supply what data you can)

	2015	2016	2017	2018 to date
Vascular				
No. of staff monitored for eye dose				
No. with eye dose >5 ≤10 mSv				
No. with eye dose > 10 ≤15 mSv				
No. with eye dose >10≤ 20 mSv				
No. with eye dose >20 ≤ 50 mSv				
No. with eye dose >50 mSv				
Renal dialysis intervention if monitored separately				
No. of staff monitored for eye dose				
No. with eye dose >5 ≤10 mSv				
No. with eye dose > 10 ≤15 mSv				
No. with eye dose >10≤ 20 mSv				
No. with eye dose >20 ≤ 50 mSv				
No. with eye dose >50 mSv				
Non-vascular				
No. of staff monitored for eye dose				
No. with eye dose >5 ≤10 mSv				
No. with eye dose > 10 ≤15 mSv				
No. with eye dose >10≤ 20 mSv				
No. with eye dose >20 ≤ 50 mSv				
No. with eye dose >50 mSv				

*Please record the quantity that you record in terms of compliance with the Ionising Radiations Regulations 1999 or 2017 as applicable. If your monitoring regime or work practice makes it difficult to distinguish between modalities, please enter 'AF' for the modality already accounted for.

Section 2 – Cardiac

Staffing and Rooms

1. Number of consultant cardiologists and radiologists participating in IR service:	
2. Estimated total number of consultant IR sessions per week:	
3. Maximum number of IR sessions by an individual consultant per week:	
4. Number of junior cardiologists and radiologists participating in IR service:	
5. Estimated total number of junior staff IR sessions per week:	
6. Maximum number of IR sessions by an individual junior per week:	

7. Number of radiographers (all grades) participating in IR service:	
8. Estimated total number of IR sessions per week:	
9. Maximum number of IR sessions by an individual radiographer per week:	

10. Number of nurses (all grades) participating in IR service:	
11. Estimated total number of IR sessions per week:	
12. Maximum number of IR sessions by an individual nurse per week:	

13. Number of other staff (that is, physiological measurement technicians or clinical physiologists) participating in IR service:	
14. Estimated total number of IR sessions per week:	

15. Number of rooms equipped for IR:		
16. Number of dedicated IR rooms within cardiology:	Single Plane	Biplane
17. No of hybrid rooms:		
18. Please supply the year of installation of each room in the row below		

Radiation Monitoring:

19. Do you provide under apron badges to staff in your IR rooms?	
20. Do you provide collar badges to staff in the IR rooms?	
21. Do you use a real time dose monitoring system such as Philips Dosewise or Raysafe I2/I3 in your IR rooms?	

Hospital:

Person returning survey:

Contact details (email, telephone):

Estimated total numbers of procedures carried out on adult patients each calendar year

	2015	2016	2017
Interventional Cardiology			
Coronary angioplasty/stent			
Pacemaker insertion			
Electrophysiological mapping/ablation			
Percutaneous valve insertion			
Other			

Estimated total numbers of procedures carried out on paediatric patients each calendar year

	2015	2016	2017
Interventional Cardiology			
Pacemaker insertion			
Electrophysiological mapping/ablation			
Percutaneous valve insertion			
Other			

Cumulative Air Kerma Survey

	2016		2017	
	Adult	Paed	Adult	Paed
Interventional Cardiology				
No of patients with CAK >2000 & < 3000 mGy				
No of patients with CAK >3000 & < 5000 mGy				
No of patients with CAK > 5000 & < 8000 mGy				
No of patients with CAK > 8000 mGy				

Eye Dose Survey* (please supply what data you can)

	2015	2016	2017	2018 to date
No. of staff monitored for eye dose				
No. with eye dose >5 ≤10 mSv				
No. with eye dose >10≤ 20 mSv				
No. with eye dose >20 ≤ 50 mSv				
No. with eye dose >50 mSv				

*Please record the quantity that you record in terms of compliance with the Ionising Radiations Regulations 1999 or 2017 as applicable.

Section 3 – Neuroradiology

Staffing and Rooms

1. Number of consultant radiologists participating in IR service:	
2. Estimated total number of consultant IR sessions per week:	
3. Maximum number of IR sessions by an individual consultant per week:	
4. Number of junior radiologists participating in IR service:	
5. Estimated total number of junior staff IR sessions per week:	
6. Maximum number of IR sessions by an individual junior per week:	

7. Number of radiographers (all grades) participating in IR service:	
8. Estimated total number of IR sessions per week:	
9. Maximum number of IR sessions by an individual radiographer per week:	

10. Number of nurses (all grades) participating in IR service:	
11. Estimated total number of IR sessions per week:	
12. Maximum number of IR sessions by an individual nurse per week:	

13. Number of other staff (that is, physiological measurement technicians or clinical physiologists) participating in IR service:	
14. Estimated total number of IR sessions per week:	

15. Number of rooms equipped for IR:		
16. Number of dedicated IR rooms within neuroradiology:	Single Plane	Biplane
17. No of hybrid rooms:		
18. Please supply the year of installation of each room in the row below		

Radiation Monitoring:

19. Do you provide under apron badges to staff in your IR rooms?	
20. Do you provide collar badges to staff in the IR rooms?	
21. Do you use a real time dose monitoring system such as Philips Dosewise or Raysafe I2/I3 in your IR rooms?	

Hospital:

Person returning survey:

Contact details (email, telephone):

Estimated total numbers of procedures carried out on adult patients each calendar year

	2015	2016	2017
Interventional Neuroradiology			
Coil embolisation aneurysm			
Embolisation of AVM			
Spinal AVM embolisation			
Stroke intervention – coil embolisation			
Stroke intervention – mechanical thrombectomy			
Other			

Estimated total numbers of procedures carried out on paediatric patients each calendar year

	2015	2016	2017
Interventional Neuroradiology			
Embolisation of AVM			
Spinal AVM embolisation			
Other			

Cumulative Air Kerma Survey

	2016		2017	
	Adult	Paed	Adult	Paed
Interventional Neuroradiology				
No of patients with CAK >2000 & < 3000 mGy				
No of patients with CAK >3000 & < 5000 mGy				
No of patients with CAK > 5000 & < 8000 mGy				
No of patients with CAK > 8000 mGy				

Eye Dose Survey* (please supply what data you can)

	2015	2016	2017	2018 to date
No. of staff monitored for eye dose				
No. with eye dose >5 ≤10 mSv				
No. with eye dose >10≤ 20 mSv				
No. with eye dose >20 ≤ 50 mSv				
No. with eye dose > 50 mSv				

*Please record the quantity that you record in terms of compliance with the Ionising Radiations Regulations 1999 or 2017 as applicable. If your monitoring regime or work practice makes it difficult to distinguish between modalities, please enter 'AF' for the modality already accounted for.

Appendix F: The Committee on Medical Aspects of Radiation in the Environment

F.1 The Committee on Medical Aspects of Radiation in the Environment (COMARE) was established in November 1985 in response to the final recommendation of the report of the Independent Advisory Group chaired by Sir Douglas Black (Black 1984). COMARE's terms of reference are:

> "to assess and advise Government and the Devolved Authorities on the health effects of natural and man-made radiation and to assess the adequacy of the available data and the need for further research"

F.2 In the course of providing advice to Government and the devolved authorities for over thirty years, COMARE has published to date 18 major reports and many other statements and documents mainly related to exposure to naturally occurring radionuclides, such as radon and its daughters, or to man-made radiation. The most recent published COMARE report provided a review of the health effects, benefits and risks arising from the use of ionising radiation in dual-energy X-ray absorptiometry (DXA) scans in sports performance assessments.

F.3 The Department of Health and Social Care asked COMARE to review the evidence on the issues with radiation doses associated with interventional radiology for both staff and patients. Issues to be considered in the report included differences in equipment and training which can lead to higher doses, the legislation concerning classified workers and the protocols involved in producing clinically acceptable images for treatment. COMARE reconstituted its Medical Practices Subcommittee, with a new membership consisting of committee members and external experts, to conduct this work. The Subcommittee's terms of reference are:

> "to advise COMARE on the health effects arising from medical and similar practices involving the use of ionising and non-ionising radiation through assessment of the available data and to inform COMARE of further research priorities."

F.4 When the Subcommittee had finished its review, the report was presented to COMARE for consideration by the full committee, with the aim that the information would be presented to the Department of Health and Social Care in due course. That information is contained in this, our nineteenth report.

COMARE Reports

Eighteenth report	Medical radiation dose issues associated with dual-energy X-ray absorptiometry (DXA) scans for sports performance assessments and other non-medical practices, Chilton, July 2019.
Seventeenth report	Further consideration of the incidence of cancers around the nuclear installations at Sellafield and Dounreay. PHE, Chilton, September 2016.
Sixteenth report	Patient radiation dose issues resulting from the use of CT in the UK. PHE, Chilton, August 2014.
Fifteenth report	Radium contamination in the area around Dalgety Bay. PHE, Chilton, May 2014.
Fourteenth report	Further consideration of the incidence of childhood leukaemia around nuclear power plants in Great Britain. HPA, Chilton, May 2011.
Thirteenth report	The health effects and risks arising from exposure to ultraviolet radiation from artificial tanning devices. HPA, Chilton, June 2009.
Twelfth report	The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals. HPA, Chilton, December 2007.
Eleventh report	The distribution of childhood leukaemia and other childhood cancer in Great Britain 1969 to 1993. HPA, Chilton, July 2006.
Tenth report	The incidence of childhood cancer around nuclear installations in Great Britain. HPA, Chilton, June 2005.
Ninth report	Advice to Government on the review of radiation risks from radioactive internal emitters carried out and published by the Committee Examining Radiation Risks of Internal Emitters (CERRIE). NRPB, Chilton, October 2004.
Eighth report	A review of pregnancy outcomes following preconceptional exposure to radiation. NRPB, Chilton, February 2004.
Seventh report	Parents occupationally exposed to radiation prior to the conception of their children. A review of the evidence concerning the incidence of cancer in their children. NRPB, Chilton, August 2002.
COMARE and RWMAC* joint report	Radioactive contamination at a property in Seascale, Cumbria. NRPB, Chilton, June 1999.
Sixth report	A reconsideration of the possible health implications of the radioactive particles found in the general environment around the Dounreay nuclear establishment in the light of the work undertaken since 1995 to locate their source. NRPB, Chilton, March 1999.
Fifth report	The incidence of cancer and leukaemia in the area around the former Greenham Common Airbase. An investigation of a possible association with measured environmental radiation levels. NRPB, Chilton, March 1998.

* Radioactive Waste Management Advisory Committee.

Fourth report	The incidence of cancer and leukaemia in young people in the vicinity of the Sellafield site, West Cumbria: further studies and an update of the situation since the publication of the report of the Black Advisory Group in 1984. Department of Health, London, March 1996.
COMARE and RWMAC* joint report	Potential health effects and possible sources of radioactive particles found in the vicinity of the Dounreay nuclear establishment. HMSO, London, May 1995.
Third report	Report on the incidence of childhood cancer in the West Berkshire and North Hampshire area, in which are situated the Atomic Weapons Research Establishment, Aldermaston and the Royal Ordnance Factory, Burghfield. HMSO, London, June 1989.
Second report	Investigation of the possible increased incidence of leukaemia in young people near the Dounreay nuclear establishment, Caithness, Scotland. HMSO, London, June 1988.
First report	The implications of the new data on the releases from Sellafield in the 1950s for the conclusions of the Report on the Investigation of the Possible Increased Incidence of Cancer in West Cumbria. HMSO, London, July 1986.

* Radioactive Waste Management Advisory Committee.

COMARE Membership

Chairman

Dr C Gibson BA MSc PhD FIPEM
Medical Physicist

Present members

Dr J Barrett BSc MB ChB FRCP FRCPE FRCR OBE
Clinical oncologist

Professor F de Vocht BSc Ir MSc PhD
Population Health Sciences, Bristol Medical School, University of Bristol

Professor J Harrison BSc PhD FSRP
Faculty of Health and Life Sciences, Oxford Brookes University

Dr M Hill
University of Oxford

Dr R Kemp BA, MSc, PhD, MRTPI
Independent Risk Communication Consultant

Dr C Martin BSc PhD FinstP FIPEM FSRP CRadP
University of Glasgow

Professor S Martin
University of Nottingham

Dr R McNally
Newcastle University

Professor P Pharoah BM BCh PhD DPH MFPH FRCP
Cambridge Cancer Centre, University of Cambridge

Professor G Smith

Professor J Smith
University of Portsmouth

Professor M Sperrin
Royal Berkshire NHS Foundation Trust

Professor D Sutton BSc, MSc, PhD, CSci, FIPEM, FBIR
NHS Tayside & University of Dundee, Ninewells Hospital, Dundee, Scotland

Professor R Taylor MA FRCPE FRCP FRCR
College of Medicine, Swansea University

Professor M Toledano BA MSc PhD DLSHTM DIC FHEA
School of Public Health, Imperial College

Dr C Westcott

Former members who served during preparation of this report

Dr P Darragh MD PhD MSc FRCP FFPHM
Public Health Agency for Northern Ireland, Belfast

Professor B Howard MBE
Centre for Ecology and Hydrology, Lancaster Environment Centre

Professor P Marsden MSc PhD FSRP MIPEM MInstP CRadP
UCL Hospitals NHS Foundation Trust, London

Professor S McKeown MA PhD FRSB CBiol
School of Biomedical Sciences, Ulster University, Coleraine

Dr T Nunan MD FRCP FRCR
Nuclear medicine physician

Professor K Prise BSc PhD
Centre for Cancer Research and Cell Biology, Queen's University Belfast

Professor M Pearce BSc MSc PhD
Institute of Health and Society, Newcastle University, Newcastle upon Tyne

Dr P Riley MRCP FRCR
Department of Interventional Radiology, Queen Elizabeth Hospital Birmingham

Professor R Wakeford BSc PhD CSci CPhys FInstP CStat CEng MNucI CRadP HonFSRP
Institute of Population Health, University of Manchester

Ms H Warner
Lay Member

Professor P Warwick BA MSc PhD DSc CChem FRSC
Centre for Environmental Studies, Loughborough University

Secretariat

Dr S Mann BSc DPhil CEng MIET (Scientific)
Dr E Petty BSc PhD (Scientific)
Mrs S Watson (Minutes)
Mrs S Deacon (Administrative)

Assessors in attendance representing the following organisations

Department for Business, Energy & Industrial Strategy
Department for Communities and Local Government
Department for Education
Department of Health and Social Care
Department of Health (Northern Ireland)
Environment Agency
Food Standards Agency
Food Standards Scotland
Health and Safety Executive
Ministry of Defence
Nuclear Decommissioning Authority
Office for Nuclear Regulation
Office for National Statistics
Public Health England
Public Health Scotland
Scottish Environment Protection Agency
Scottish Government
Welsh Government

COMARE Medical Practices Subcommittee (IR) Membership

Chair	**Professor A Elliott** BA PhD DSc CPhys FInstP FIPEM ARCP University of Glasgow
Vice Chair	**Professor S McKeown** MA PhD FRSB CBiol School of Biomedical Sciences, Ulster University, Coleraine
Members	**Professor D Sutton** BSc, MSc, PhD, CSci, FIPEM, FBIR NHS Tayside & University of Dundee, Ninewells Hospital, Dundee, Scotland
	Dr P Riley MRCP FRCR Department of Interventional Radiology, Queen Elizabeth Hospital Birmingham
	Professor R Taylor MA FRCPE FRCP FRCR College of Medicine, Swansea University
	Ms H Warner Lay Member
	Dr S McFadden FCR, PhD Diagnostic Radiography and Imaging, School of Health Sciences, University of Ulster
	Dr I Robertson MbChB, MRCP, FRCR, EBIR Consultant Interventional Radiologist Greater Glasgow and Clyde NHS
	Dr J Jansen PhD PHE CRCE, Didcot
	Professor P White BSc MB ChB MSc MD FRCR Newcastle University Translational and Clinical Research Institute & Dept. of Neuroradiology, Newcastle Upon Tyne Hospitals NHS Foundation Trust
Assessors	Department of Health and Social Care Health and Safety Executive
Secretariat	**Dr S Mann** BSc DPhil CEng MIET (Scientific) **Dr E Petty** BSc PhD (Scientific) **Mrs S Deacon** (Administrative)