

Efficacy and radiation safety in interventional radiology



World Health Organization
Geneva

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Efficacy and radiation safety in interventional radiology



Geneva
World Health Organization
2000

WHO Library Cataloguing-in-Publication Data

Workshop on Efficacy and Radiation Safety in Interventional Radiology
(1996 : Neuherberg, Germany)

Efficacy and radiation safety in interventional radiology.

Report of a joint Institute of Radiation Hygiene, Federal Health Office (Germany) and
World Health Organization workshop held in Neuherberg, Germany from 9 to 13
October 1996.

1.Radiology, Interventional—standards 2.Radiation injuries—prevention and control
3.Radiation protection 4.Occupational exposure

ISBN 92 4 154529 1

(NLM classification: WN 21)

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Preface

A joint Institute of Radiation Hygiene, Federal Health Office/World Health Organization Workshop on Efficacy and Radiation Safety in Interventional Radiology was held in Neuherberg, Germany, from 9 to 13 October 1996. The aims of this Workshop were to consider the current status, clinical efficacy, and radiation safety of interventional radiological procedures. The meeting was opened by Professor W. Burkart, Director of the Institute of Radiation Hygiene, which is a WHO Collaborating Centre.

Interventional radiology is a rapidly developing clinical speciality. The types and complexity of interventional radiological procedures have expanded over the past decade. Interventional radiology usually involves more extended periods of fluoroscopy than other diagnostic radiological examinations, and multiple use of radiography; the radiation exposure of patients and personnel involved in interventional procedures is therefore relatively high. Deterministic radiation injuries to the skin resulting from interventional radiological procedures have already been reported in the literature. However, interventional radiology now permits the effective treatment of many diseases of both cardiovascular and non-vascular origin that previously could be treated only by surgical intervention under anaesthesia at considerably greater risk to the patient. In the majority of cases, therapeutic interventional radiological procedures facilitate or replace surgery and help to reduce hospitalization time.

The objectives of the Workshop, which was financially supported by the German Government, were:

- To evaluate the current use of interventional radiological procedures in clinical practice, reviewing the most common indications for such procedures, their clinical efficacy, possible risk factors for patients, radiation dose received by patients and personnel, existing criteria for selection of equipment and quality assurance programmes, and training of medical personnel.
- On the basis of this evaluation, to develop recommendations for improving the clinical efficacy and radiation safety of interventional radiological procedures.

The report of the meeting is a further step in WHO's efforts to improve the quality and safety of diagnostic and therapeutic radiological services, with particular emphasis on reducing the radiation exposure of patients and personnel. Three earlier WHO

publications have dealt with various aspects of quality assurance within the fields of diagnostic radiology, nuclear medicine, and radiotherapy, with the same aim of improving the quality of services and reducing radiation exposure.¹ These publications were the outcome of three workshops organized by WHO jointly with the Institute of Radiation Hygiene and other organizations.

The establishment and development of interventional radiological services require a multidisciplinary approach, expensive radiological equipment, and highly qualified medical and technical personnel. It is thus extremely important for public health administrators and clinicians who are planning to establish national interventional radiological services to be fully aware of the current clinical applications of these procedures and the associated risk factors, development trends, principles of selecting the appropriate equipment and radiation dose reductions, and the training needs of personnel. It is hoped that this report will provide clear answers to many questions related to the establishment of new radiological services and contribute to the improvement of clinical efficacy and radiation safety of existing services. Many of the data contained in the report come from Germany, which has particularly comprehensive databases in this field, but they may be assumed to be fairly typical of any developed country.

¹ *Quality assurance in diagnostic radiology*. Geneva, 1982.
Quality assurance in nuclear medicine. Geneva, 1982.
Quality assurance in radiotherapy. Geneva, 1988.

1.

Clinical aspects

1.1 Introduction

Over the past 25 years, an important number of therapeutic procedures have been developed in the field of radiology, based mainly on angiographic techniques. Diagnostic procedures involving the injection of contrast media come under the heading of **invasive diagnostic radiology**. **Interventional radiology**, on the other hand, comprises invasive procedures with a predominantly therapeutic objective. This distinction is important because the requirements for informed consent and the levels of acceptable risk for diagnostic procedures are substantially different from those for therapeutic procedures. For example, the potential direct benefits, or curative effects, of an intended therapeutic intervention could carry a risk of complication that would be unacceptable for a diagnostic examination.

1.2 Definition of interventional radiology

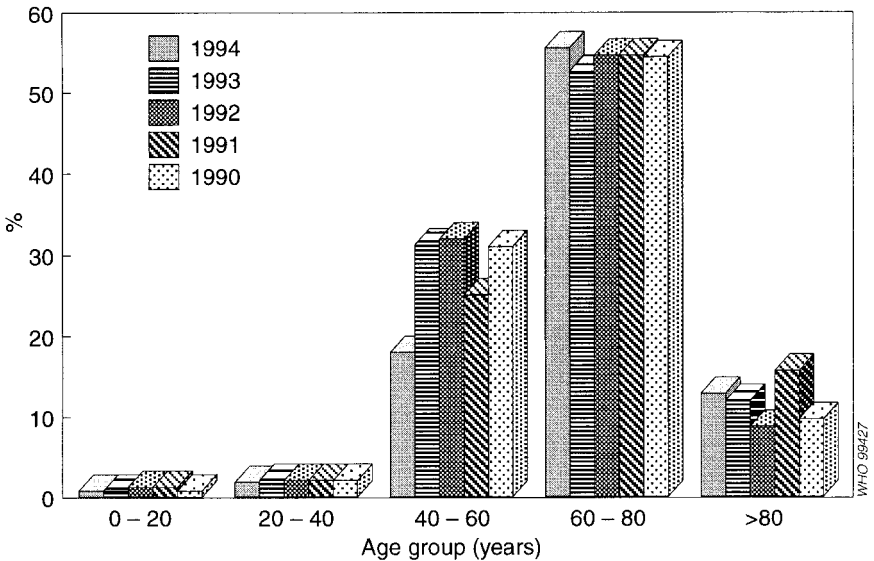
Interventional radiology comprises image-guided therapeutic interventions. Access is percutaneous and these procedures are therefore usually performed under local anaesthesia and/or sedation. Originally, guidance was provided by X-ray fluoroscopy, but more recent procedures also employ ultrasound, computerized tomography (CT), and magnetic resonance imaging (MRI) guidance. These imaging modalities are used for precise localization of the lesion before the intervention, for monitoring of the procedure, and to control and document the result.

1.3 Current world status and trends

1.3.1 Industrialized countries

Following the first report of percutaneous treatment of arteriosclerotic vascular obliterations, which was published in 1964 (1), this procedure, using X-ray fluoroscopy guidance, was started in a limited number of centres. With the introduction of balloon catheter dilatation of peripheral arteries in 1974 (2), and more particularly after the first percutaneous treatment of stenoses in coronary arteries under X-ray fluoroscopy in 1978 (3), this type of “minimally invasive therapy” has gained enormous importance in a number of industrialized countries. In the hands of cardiologists or radiologists it offers the significant advantages of requiring only a short

Fig. 1. Age distribution of patients treated with angioplasty in Germany, 1990–1994



hospital stay, local (rather than general) anaesthesia, and no open surgery or extra-corporeal circulation. These advantages have made it possible to treat isolated and multiple vascular stenoses, thereby possibly extending life expectancy.

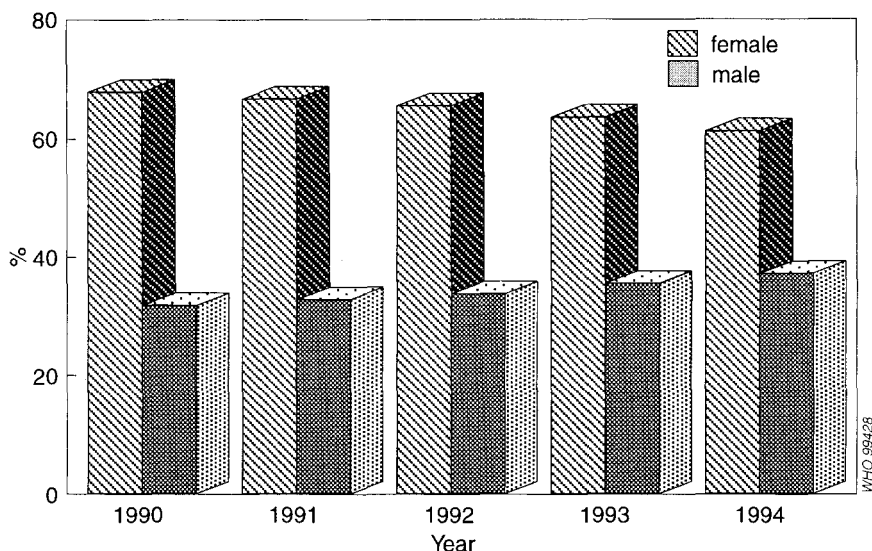
In Germany the age distribution of patients treated with angioplasty in the five years 1990–1994 showed little significant variation (Fig. 1). The sex distribution, by contrast, reveals a slowly increasing percentage of women (Fig. 2), which is attributable to changing risk factors (e.g. cigarette smoking).

Angioplastic techniques also form the methodological basis for other image-guided interventions such as transluminal embolization, organ ablation, drainage procedures, neurolysis, and transluminal implantation of various devices.

Cardiological interventions

According to data compiled by the American College of Cardiology (ACC) and the American Heart Association (AHA) (4), almost 50% of Americans die of cardiovascular diseases. A significant proportion of patients have severe clinical symptoms or potentially life-threatening lesions in the coronary arteries and are therefore candidates for revascularization procedures.

Fig. 2. Sex distribution of patients treated with angioplasty in Germany, 1990–1994



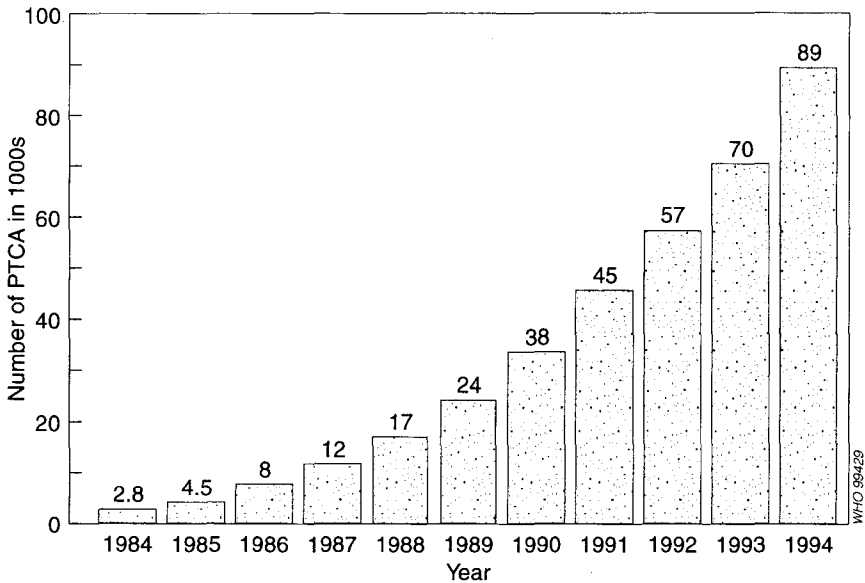
In 1983, 188 000 coronary artery bypass operations were performed in the USA; by 1986 this number had increased to 284 000. Percutaneous transluminal coronary angioplasty (PTCA) procedures increased similarly, from 32 300 in 1983 to 133 000 in 1986 (5, 6). In the early years PTCA was performed mostly in patients with single-vessel coronary disease. Subsequently, however, the technique has also been applied, with increasing success, to patients with multivessel disease, multiple sub-total stenoses in the same vessel, and complete occlusions in acute myocardial infarction, as well as in isolated high-risk patients. The number of interventions has thus risen steadily, reaching 430 000 in 1994 in the USA (7). At the same time the procedure has become more sophisticated, although this has also resulted in longer fluoroscopy times. In the Federal Republic of Germany, the number of PTCA procedures performed also rose dramatically, from 2809 in 1984 to 89 000 in 1994 (Fig. 3) (8–10).

In August 1988, the ACC/AHA published guidelines for PTCA (4), and the *Unité de Cardiologie interventionnelle* (Interventional Cardiology Unit) in Toulouse summarized the accepted indications and the criteria for selection of patients for PTCA in their Coronary Angioplasty Course in 1995 (11). These two organizations give recommendations for PTCA, both according to type of lesion (Table 1) and on the basis of the results of retrospective and prospective trials.

Table 1. Selection of patients for PTCA: key elements for reasoning

Type A lesions (success >85%; low risk)	Type B lesions (success 60–85%; moderate risk)	Type C lesions (success <60%; high risk)
<ul style="list-style-type: none"> • Discrete (<14mm length) • Concentric • Readily accessible • Non-angulated segment ($\leq 45^\circ$) • Smooth contour • Little or no calcification • Not totally occlusive • Not ostial in location • Absence of thrombus • No major branch involvement 	<ul style="list-style-type: none"> • Tubular (10–20mm length) • Eccentric • Moderate tortuosity of proximal segment • Moderately angulated segment ($>45^\circ$, $<90^\circ$) • Irregular contour • Moderate-to-heavy calcification • Total occlusion <3 months old • Ostial in location • Bifurcation lesions require double guide wires • Some thrombus present 	<ul style="list-style-type: none"> • Diffuse (>20mm length) • Excessive tortuosity of proximal segment • Extremely angulated segments ($>90^\circ$) • Total occlusion >3 months old • Inability to protect major side branches • Degenerated vein grafts with friable lesions

Fig. 3. Interventional cardiology procedures performed in the Federal Republic of Germany, 1984–1994



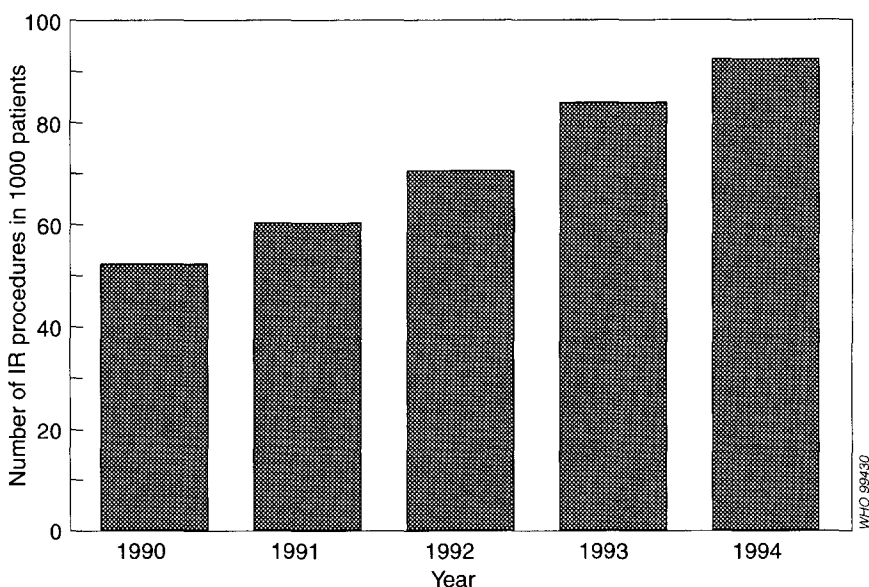
While the numbers of coronary angioplasty interventions are unlikely to increase significantly in the highly industrialized countries, catheter-guided ablations have gained in importance in recent years and continue to show an upward trend. In Germany, the number of these procedures rose from 1101 in 1992 to 2386 in 1993 (8, 9).

Radiological interventions

In most countries, interventions involving the heart and coronary arteries are performed by cardiologists, whereas other vascular interventions are carried out mainly by interventional radiologists. In some hospitals, however, vascular interventions are performed by angiologists or vascular surgeons, most of whom have had no special training in interventional radiology or radioprotection.

In 1988, a number of countries (e.g. Federal Republic of Germany, Italy, United Kingdom) started centralized registration of interventional radiology procedures (E. Zeitler, personal communication, 1995). According to the data collected, the range of vascular interventions has widened to include percutaneous transluminal angioplasty (PTA), percutaneous embolization, percutaneous chemo-embolization, foreign body extraction, vascular occlusion, percutaneous sclerotherapy, and percutaneous implantation of endoprostheses, from the cranium (neurointerventions) down to the peripheral vessels. In addition, non-vascular interventions in the bronchopulmonary,

Fig. 4. Interventional radiology procedures (excluding cardiology) in Germany, 1990–1994



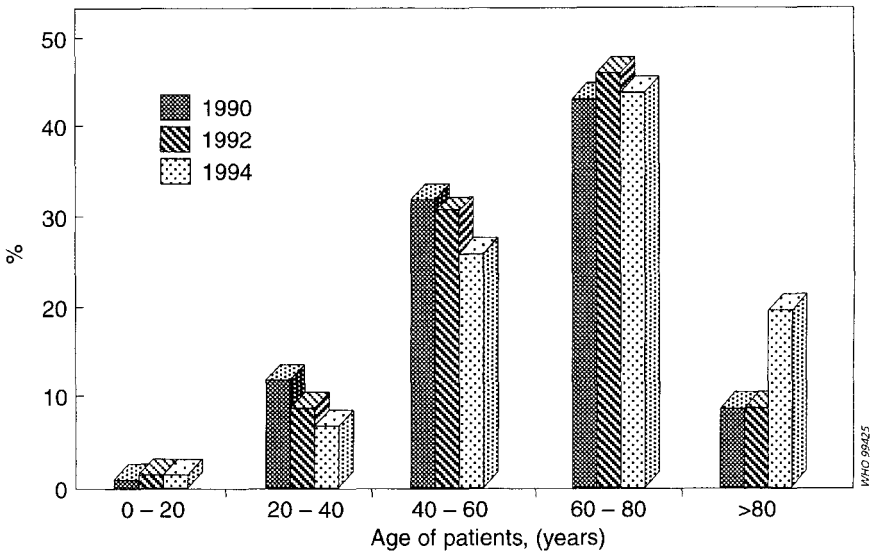
genitourinary, gastrointestinal, and musculoskeletal systems are performed not only by radiologists but also by specialists from other medical disciplines. These procedures are performed under X-ray fluoroscopy, CT, or ultrasound guidance or under endoscopic control. Registration data from Germany reveal the increasing frequency of the various procedures (Fig. 4).

The total number of vascular interventional radiology procedures is similar to the number of PTCAs. Most vascular interventions involve the pelvic and leg arteries and the renal and supra-aortic arteries; a minority involve the veins. An increase in the number of interventional procedures in the cerebral arteries is predicted, whereas interventions in the renal arteries and peripheral arteries are thought unlikely to increase appreciably (but will be performed with improved techniques). In the future, percutaneous stent application will probably find more widespread use because of better patency rates; this procedure may also involve longer fluoroscopy times.

Percutaneous embolization in congenital vascular diseases, as well as in tumours, is a very difficult technique, especially in cerebral and spinal arteries. The long fluoroscopy times involved have led to temporary epilation and erythema in a few patients.

The use of interventional radiological procedures continues to increase. In most university and city hospitals of western and central European countries, a growing

Fig. 5. Age distribution for all interventional radiology procedures in Germany, 1990–94



number of specialized physicians are capable of treating patients with percutaneous techniques instead of open surgical procedures. Japan and some other Asian countries have extensive experience with interventional radiology in the treatment of hepatic cancer, using percutaneous transcatheter embolization or percutaneous alcohol or chemotherapy administration under CT guidance. Vascular interventions such as PTA are usually carried out in patients with endangiitis. In Asian countries there has been an increase in the occurrence of atherosclerosis of the coronary and peripheral arteries, with a concomitant rise in the number of hospital departments that have started to treat patients with minimally invasive interventional radiology techniques.

The age distribution in Germany for patients treated with PTCA and for all interventional radiology procedures (Fig. 5) demonstrates that most interventional radiological procedures are performed in individuals aged between 40 and 80 years.

1.3.2 Developing countries and countries with transitional economy

In developing countries and countries with transitional economy, there is an increasing need for interventional radiology, particularly for the treatment of regionally significant diseases. This is especially true of countries such as Egypt and Turkey and certain South American countries, where a high incidence of coronary heart diseases

and peripheral arterial occlusive diseases has been observed. Certain specialized institutions in these countries offer interventional treatments as a more economical alternative to coronary or vascular surgery, but progress is essential, possibly with the support of the industrialized countries. Because the number of such specialized centres is limited, extending the availability of interventional radiology to a greater part of the population requires that the treatment be offered at smaller hospitals and health centres. This, in turn, means that the necessary prerequisites (appropriate equipment, trained personnel, and special education) must be met.

In other, especially Asian, countries (e.g. China and Indonesia), the high incidence of hepatocellular cancer is a challenge, both for early diagnosis and for subsequent interventional therapy, including chemo-embolization using fluoroscopically guided catheterization, and the administration of alcohol or other substances under CT guidance. The existing centres in these countries have to be enlarged in line with national regulations; training and further education of the personnel must be supported.

1.3.3 Developing countries without established health-care infrastructure

In developing countries that lack an established health-care infrastructure, it is essential, in view of the epidemiological and critical economic situations, to support the establishment of one centre for interventional radiology and one centre for interventional cardiology at a national level.

1.3.4 Risk of X-ray induced injuries

The increasing complexity and sophistication of interventional radiological procedures have led to a steady increase in fluoroscopy time. Total fluoroscopy time can be much longer than that for conventional diagnostic imaging, which may increase the risk of deterministic injuries.

In a small number of patients, erythema, temporary epilation, skin ulcer, and dermal fibroses have been observed after interventional therapy.¹ Local radiation exposure is influenced not only by the fluoroscopy time, but also by the dose rate and the mode of operation. Possible radiation-induced skin injuries are listed in Table 2, and the risk of fatal cancer attributable to radiation from fluoroscopy is detailed in Table 3.

The risk of deterministic and stochastic effects of radiation exposure varies for different areas of the skin. The age of patients undergoing interventional radiological procedures that involve long fluoroscopy times is also an important factor in the development of stochastic effects. The most common interventional procedures, such

¹ E. Zeitler, personal communication, 1995.

Table 2. Radiation-induced skin injuries

Skin effect/injury	Fluoroscopic “on time” (hours) to reach threshold at: ^a			Time to onset of effect ^c
	typical threshold absorbed dose (Gy) ^b	usual fluoroscopy dose rate of 0.02 Gy/min	high-level dose rate of 0.2 Gy/min	
Early transient erythema	2	1.7	0.17	hours
Temporary epilation	3	2.5	0.25	3 weeks
Erythema	6	5.0	0.50	10 days
Permanent epilation	7	5.8	0.58	3 weeks
Dry desquamation	10	8.3	0.83	4 weeks
Invasive fibrosis	10	8.3	0.83	— ^d
Dermal atrophy	11	9.2	0.92	>14 weeks
Telangiectasis	12	10.0	1.00	>52 weeks
Moist desquamation	15	12.5	1.25	4 weeks
Late erythema	15	12.5	1.25	6–10 weeks
Dermal necrosis	18	15.0	1.50	>10 weeks
Secondary ulceration	20	16.7	1.67	>6 weeks

^a Time required to deliver the typical threshold dose at the specified dose rate.

^b The SI unit for absorbed dose is the gray (Gy), where 1 Gy is equivalent to 100 rad in the traditional system of radiation units.

^c Time after single irradiation to observation of effect.

^d Onset undetected.

Table 3. Risk of fatal cancer attributable to radiation from fluoroscopy^a

Age (years)	Sex	Risk of fatal cancer ^b attributable to fluoroscopy time of:			
		1 hour	2 hours	3 hours	4 hours
1–14	Male	1:460 (1.0%)	1:230 (1.9%)	1:155 (2.9%)	1:115 (3.9%)
	Female	1:380 (1.2%)	1:190 (2.3%)	1:130 (3.5%)	1:95 (4.6%)
15–34	Male	1:640 (0.7%)	1:320 (1.4%)	1:210 (2.1%)	1:160 (2.8%)
	Female	1:500 (0.9%)	1:250 (1.5%)	1:165 (2.7%)	1:125 (3.6%)
35–54	Male	1:980 (0.4%)	1:490 (0.9%)	1:325 (1.4%)	1:250 (1.8%)
	Female	1:1087 (0.4%)	1:540 (0.8%)	1:360 (1.2%)	1:270 (1.6%)
55–74	Male	1:1220 (0.4%)	1:610 (0.7%)	1:410 (1.1%)	1:305 (1.4%)
	Female	1:1520 (0.3%)	1:760 (0.6%)	1:510 (0.9%)	1:380 (1.2%)
All	Male	1:760 (0.6%)	1:380 (1.2%)	1:250 (1.8%)	1:190 (2.3%)
	Female	1:730 (0.6%)	1:360 (1.2%)	1:240 (1.8%)	1:180 (2.4%)

^a Reproduced, with minor editorial changes, from reference 13 with permission from Excerpta Medica Inc.

^b The chance of developing a fatal cancer induced by radiation is also expressed (in parentheses) as a percentage of the spontaneous fatal malignancy rate for each age group and sex.

as PTCA and PTA, are used mainly in patient populations over 40 years of age. However, small numbers of children and young adults are also treated using interventional procedures, mainly for arteriovenous malformations, congenital diseases, and cardiac arrhythmias. Because of the life expectancy of these patients, potential stochastic effects may be important. It is therefore essential to differentiate between interventional procedures in adults, in young adults, and in children: if the procedure may involve the hazard of a high radiation exposure, this risk should be considered when informed consent is obtained.

If areas of the skin are likely to be exposed to levels of absorbed doses that approach or exceed the thresholds of skin reactions, the patient should be informed in advance about the possible effects of treatment. Since radiation doses cannot be assessed prospectively, relevant parameters should be documented for all interventional radiological procedures. This information is important for the referring physician (as well as for the patient):

- for careful planning of subsequent therapy (which may involve further exposure of the same area of skin) or of future treatments;
- to avoid further irradiation, irritation, or damaging of this area;
- to allow various procedures to be improved, thus reducing the risk of radiation injuries.

Table 4. Medical specialisms involved in interventional radiology

-
- Angiology
 - Cardiology
 - Neuroradiology
 - Gastroenterology
 - Genitourinary
 - Bronchopulmonary
 - Orthopaedics
 - Paediatric
-

1.4 Interventional radiological procedures

Diseases and symptoms that fall under a variety of medical headings may be candidates for interventional radiology. Specialists from other medical disciplines (see Table 4) will frequently refer patients for interventional radiology and be involved in subsequent treatment and follow-up (14–19). Generally, three groups of interventional treatment can be distinguished:

- cardiology
- general radiology
- neuroradiology.

1.4.1 Cardiology

Interventional radiology in cardiology involves the following procedures:

- *Percutaneous coronary revascularization* (3, 5, 6, 20–23)
 - percutaneous transluminal coronary angioplasty
 - directional coronary atherectomy
 - laser angioplasty
 - stent implantation.
- *Interventions for congenital and acquired valvular lesions*
 - percutaneous valvuloplasty
 - percutaneous atriotomy.
- *Catheter ablation of supraventricular/ventricular arrhythmias.*

Percutaneous coronary revascularization

Indications (4, 11)

If lesions can be dilated with a high degree of success and without significant risk of complications due to their location, PTCA seems to be particularly indicated in

patients with critical left coronary artery stenoses and an ejection fraction $<50\%$. However, PTCA still carries certain inherent risks or may adversely affect the quality of life, and should not be recommended when medical therapy alone is sufficient to keep patients symptom-free and free of objective ischaemia during the stress test, thallium scintigraphy, or stress echocardiography. PTCA should *not* be performed when predictable results will be significantly inferior to bypass surgery revascularization. The generally accepted indications for PTCA are:

- symptoms refractory to medical treatment;
- silent ischaemia (positive exercise-test or thallium scintigraphy and high-risk stenoses located in an artery supplying a large left ventricular myocardial area).

Patients with multivessel disease form a separate and specific subgroup. PTCA is indicated for patients in this group who have symptoms of ischaemia during exercise despite treatment with β -blockers (or calcium channel blockers), and normal or sub-normal left ventricular function (ejection fraction $>40\%$) *and*

- critical (70%), easily accessible, or suitable lesions for angioplasty in two or three major epicardial arteries serving moderate or large areas of viable myocardium;
- lesions for which angioplasty has a high chance of success (type A, or amenable to stenting) in one or two major arteries, associated with less amenable lesions (type B2 or C) in vessels subtending non-viable or small viable areas of myocardium;
- lesions with type B characteristics in two major arteries that subtend at least moderate areas of viable myocardium;
- lesions with type B characteristics in two or more epicardial arteries, but with suitable anatomy for coronary angioplasty in one or two major lesions (proximal left anterior descending artery or lesions serving large areas of myocardium);
- one type C lesion in a vessel that subtends a moderate area of viable myocardium and one or more other lesions suitable for PTCA (type A or B), not in the proximal left anterior descending artery, subtending large or moderate areas of viable myocardium.

Contraindications

Contraindications to angioplasty in patients with multivessel disease are related to conditions associated with

- a low probability of success;
- a definite increased procedural risk;
- a high probability of late cardiac events;
- presence of severe diffuse atherosclerosis, for which an alternative form of revascularization would be unequivocally more efficient;

- significant obstructions (>50%) in the left main coronary artery not protected by at least one completely patent bypass graft to the left anterior descending or left circumflex artery;
- one or more lesions of low expected success rate in major epicardial vessels serving large areas of viable myocardium, including
 - chronic old total occlusion or long-calcified lesions
 - lesions located in vessels with extreme proximal tortuosity
 - lesions involving a large side-branch that cannot be protected;
- poor left ventricular function, with the only remaining viable territory being supplied by the attempted vessel, or with type B or C lesion subtending a very large amount of myocardium equivalent to more than one major vessel territory;
- depressed left ventricular function (ejection fraction <40%) and three-vessel disease, including a proximal type B stenosis on the proximal left anterior descending artery, and acceptable risk for surgery;
- three-vessel disease including a lesion with a high risk of restenosis.

Angioplasty may sometimes be indicated, despite apparent contraindications, as a palliative treatment. Higher risks, which would be unacceptable for a less symptomatic patient, may be acceptable in severely symptomatic patients who are poor candidates for bypass surgery.

Catheter ablation of supraventricular/ventricular arrhythmias

Arrhythmic foci can be ablated using radio-frequency (RF) probes via a transluminal route. The age distribution for RF ablation in one particular cardiology centre in Germany is shown in Fig. 6. The comparative radiation exposure:effective dose equivalent is shown in Table 5.

Indications

Radio-frequency ablation is indicated in the following conditions:

- Supraventricular tachycardias
 - Wolff–Parkinson–White syndrome
 - atrioventricular nodal re-entrant tachycardia
 - atrial tachycardia/atrial flutter
 - atrial fibrillation
 - symptomatic tachycardias
 - drug-refractory tachycardias
 - side-effects of, or long-term, drug therapy.
- Ventricular tachycardias
 - one or a few monomorphic tachycardias, haemodynamically well tolerated
 - drug-refractory tachycardia
 - in addition to pacemaker catheter implantation.

Fig. 6. Age distribution for radio-frequency ablation

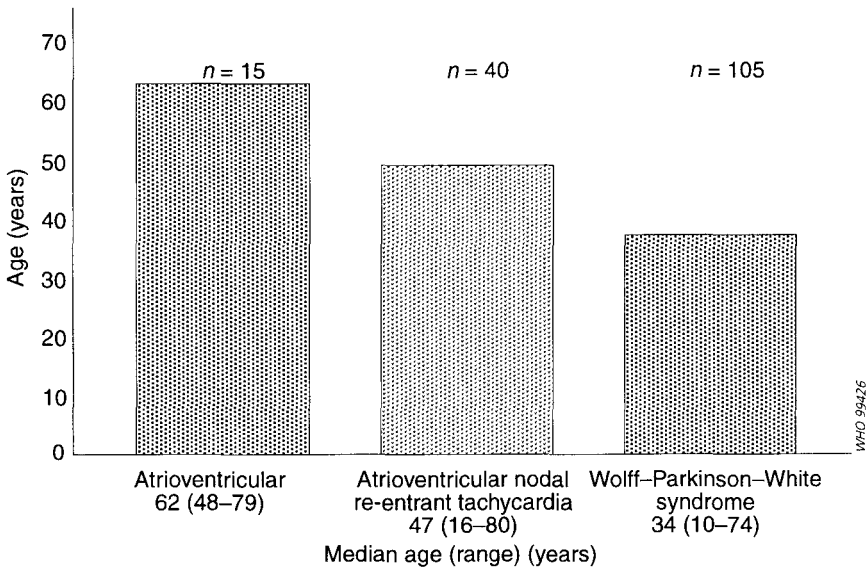


Table 5. Comparative radiation exposure:effective dose equivalent^a

Arrhythmia ablation procedure	1.7 rem ^b
Recommended annual limit for radiation workers	5.0 rem
Average annual dose in USA	0.3 rem
Medical procedures:	
coronary angiography	1.2 rem
coronary angioplasty	2.2 rem
thallium-201 scan	2.1 rem
technetium-99 radionuclide ventriculogram	0.8 rem

^a Reproduced from reference 13 with permission from Excerpta Medica Inc.

^b 100 rem = 1 Sv.

Other cardiac interventions

Percutaneous valvuloplasty instead of cardiac surgery is indicated mainly in older patients and patients at high risk. It is rarely used, however, and accounts for only 1–4% of all cardiac interventions.

1.4.2 Interventions in general radiology

The numbers of interventions in general radiology and of available techniques have increased steadily during the past decade. Highly developed instruments and increas-

ing experience have broadened the spectrum of indications, to the extent that relatively young and old patients and those with diseases in advanced stages can also now be treated. (The age distribution for all types of interventions in 46 000 patients between 1990 and 1994 in Germany is shown in Fig. 5, and the distribution of the sexes for angioplasty in Fig. 2.)

Most interventional radiology procedures are performed in patients referred by other clinicians, so that interdisciplinary cooperation is essential. During the discussions that precede signature of the informed consent, the patient should be informed about the procedure and possible alternatives, and about complications of the technique, the use of contrast media, and the radiation exposure.

Risks associated with the use of contrast media have been considerably reduced but depend to an extent on the patient's condition, including history of allergic reaction, asthma or other allergic diseases, and diseases of the kidneys.

Risks from radiation exposure must be carefully considered when interventions are performed on children and younger adults, and especially in pregnancy and when fluoroscopy is necessary. This is particularly important in radiosensitive areas of the body (such as the female breast, the eyes, the unclosed epiphysis of long bones, and the gonads); special filters should be used and high-dose fluoroscopy avoided if possible.

A wide variety of procedures are used in interventional radiology, and a complete listing of procedural variants, indications, and contraindications is beyond the scope of this report. Generally accepted indications can be found in textbooks and in the literature (1, 2, 14, 15, 17–19, 24–26). The indication must be carefully evaluated in children and young adults, particularly those with congenital atrioventricular malformations, in the treatment of varicoceles, and in young adults whenever the fluoroscopy time exceeds 60 minutes. The indications for patients receiving local thrombolysis, implantation of stents or endoprostheses, or transjugular intrahepatic portosystemic stent-shunts (TIPSS) should also be carefully evaluated. In the following paragraphs the most common interventional radiology procedures are defined and explained.

Vascular interventions

Percutaneous transluminal angioplasty

The aim of PTA is the recanalization and luminal restitution of stenosed or occluded arteries. Most PTA procedures are carried out in patients aged 40–80 years (see Fig. 1) with atherosclerotic lesions, but a smaller number of patients are treated for congenital fibromuscular dysplasia or inflammatory diseases (e.g. Takayasu disease).

For various reasons the number of PTAs continues to increase each year. Data from prospective trials, combined with more specialized and less traumatic instrumentation and a growing number of well-trained physicians, have led to wider acceptance of these therapeutic modalities, both within the medical community and by the public.

A typical indication for PTA is peripheral occlusive vascular disease in patients with claudication, pain at rest, and gangrene, but the most important is critical limb ischaemia (CLI) in stages III and IV of the Fontaine classification (27). Vascular surgery may be the better alternative for CLI provided that the patient is fit for surgery and that the resulting long-term patency offers an advantage of at least 10% over the results of PTA. Combined procedures are also possible (for example PTA of iliac artery stenoses and bypass surgery of the femoropopliteal region).

Adjuncts or concurrent interventional techniques are local fibrinolysis (pharmacological thrombolysis), percutaneous thrombectomy or thrombaspiration, percutaneous atherectomy, and stent implantation.

Complications of PTA occur in 2–5% of cases and are more common in patients with extensive disease or diabetes.

Embolization and occlusion of vessels

Embolization and occlusion of vessels are useful therapeutic procedures in arteriovenous malformations, the control of haemorrhage, tumours, aneurysms, and organ ablation. Other indications for embolization are post-traumatic and post-operative bleeding, and bleeding as a complication of radio therapy.

Arteriovenous malformations

In the hands of experts, therapeutic embolization of arteriovenous malformations is extremely successful and has a low complication rate. It is considered as the method of first choice for treatment of this condition. Open surgery is thus no longer necessary in many patients; in others, however, embolization is followed by vascular surgery.

Haemorrhage

Gastrointestinal tract. In acute gastrointestinal bleeding from duodenal ulcers, vascular malformations, or malignant tumours, embolization of the bleeding vessel by vasopressin infusion is preferred by most interventional radiologists. In selected cases coil embolization is also indicated.

Respiratory tract. Successful embolization in the respiratory tract requires the occlusion of all major feeding arteries. Embolotherapy, if properly performed, is capable of controlling massive recurrent haemoptysis in about 90% of cases.

Urinary tract. In patients with haematuria, embolotherapy is useful in selected renal arterial branches, as well as in the hypogastric artery in haemorrhage of the urinary bladder.

Tumour and organ ablation

Embolization is used to occlude the arterial supply to tumours, create ischaemia, and induce tumour necrosis, and to stop tumour growth by intra-arterial delivery of occlusive material and sclerosing solutions. As a rule, the closer to the tumour the occlusion can be achieved, the smaller is the probability of collateral circulation developing. Transcatheter embolization of neoplasms is indicated to control haemorrhage, to relieve pain by reducing tumour size, or, preoperatively, to facilitate surgical intervention.

Renal ablation may be indicated before tumour resection or as palliative therapy in renal carcinomas. It can also be the therapy of choice—and may sometimes be life-saving—in patients with ruptured kidneys. In inoperable patients this type of organ ablation can be used to devascularize shrunken kidneys (which cause malignant hypertension).

Selective splenic embolization is used to debulk an enlarged spleen in cases of hypersplenism.

After partial or complete embolization of organs, patients often suffer from the so-called “post-embolization syndrome” (severe pain, fever, and malaise). Possible complications are ischaemia and necrosis of adjacent healthy tissue.

Aneurysms

Pulmonary and renal artery aneurysms, for example, can be treated by arterial embolization. The implantation of covered stents is a new and promising alternative approach to exclude aneurysms from the circulation.

Transjugular intrahepatic portosystemic stent-shunt

TIPSS is a procedure designed to reduce portal hypertension by creating a tract between one of the hepatic veins and a large portal vein inside the liver parenchyma (28, 29). Insertion of a stent after dilatation with a balloon catheter should guarantee patency of the shunt.

The indications for TIPSS in patients with portal hypertension are recurrent variceal bleeding despite sclerotherapy, and intractable ascites; portal vein thrombosis is generally considered a contraindication.

The technical success rate of TIPSS is over 90%. Possible complications are haemorrhage, shunt stenosis, and hepatic encephalopathy.

Special venous interventions

Interventional radiology procedures may be used for implantation of vena cava filters to prevent pulmonary embolism and for percutaneous occlusion of veins to treat varicoceles or varices in different areas.

Locoregional tumour therapy

Percutaneous or intra-arterial administration of chemotherapeutic drugs (either alone or in combination with embolic materials (chemoembolization)) or use of other material, such as the Hickman catheter, can be achieved under X-ray control.

Non-vascular interventions in general radiology

Non-vascular interventions are usually performed in close cooperation with specialists from the appropriate medical disciplines.

Biliary interventions

Percutaneous transhepatic biliary interventions are indicated in patients with obstructive jaundice due to tumour compression or invasion in the biliary system, benign congenital or acquired biliary stenoses, or complications after liver transplantation.

Biliary interventions can be used for drainage of bile, stone extraction, balloon dilatation of stenotic lesions, and stent implantation.

Uroradiological interventions

Uroradiological interventions are indicated for percutaneous puncture of the kidney with urinary drainage, stone removal, and ureteral dilatation or stent implantation.

Bronchopulmonary interventions

Bronchopulmonary interventions are indicated for percutaneous drainage of pleural effusion, biopsy of pulmonary or mediastinal masses, and recanalization of bronchi using laser, balloon, or stent.

Gastrointestinal interventions

Indications for gastrointestinal interventions include transoesophageal application of stents in patients with malignant or benign stenoses, balloon dilatation of oesophageal stenoses or stenoses of the pylorus, percutaneous gastrostomy, and transrectal balloon dilatation of malignant and benign colonic stenoses.

Musculoskeletal interventions

Uses of musculoskeletal interventions include percutaneous biopsy of bone or soft-tissue tumours, drainage of abscesses, and percutaneous resection of pathological conditions (e.g. osteoid osteoma).

Pain therapy

Treatment of pain can be carried out by fluoroscopy- or CT-guided application of analgesic drugs, percutaneous sympathicolysis in the cervical and lumbar region, and neurolysis of the coeliac or trigeminal ganglion.

1.4.3 Neuroradiology

In principle, all of the vascular interventional procedures listed in section 1.4.2 can be applied to structures that supply or form part of the central or peripheral nerve systems. The following paragraphs outline the current types of neuroradiological interventional procedures (14, 17, 25).

Angioplasty of supra-aortic and cerebral arteries

Angioplasty is a successful technique in patients with stenoses in the brachiocephalic, common carotid, vertebral, and subclavian arteries. Clinical symptoms of these conditions include subclavian steal syndrome, cerebrovascular ischaemia with attacks, and ischaemia of the upper extremities.

Haemodynamically relevant stenoses with reduction of the diameter of the artery of more than 75% are an indication for neuroradiological intervention. PTA with balloon dilatation of subclavian stenoses has a primary success rate of about 90% with good clinical outcome; the clinical 5-year patency exceeds 80%. For occlusions of the subclavian artery, PTA has a primary success rate of about 60%.

Vascular surgery, which yields good long-term results in more than 80% of cases over a follow-up period of 5 years, is the preferred method in patients with occlusions of the supra-aortic arteries and no special contraindications. Indications for PTA of ostial stenoses in the vertebral arteries are vertebrobasilar insufficiency and bilateral vertebral disease. PTA gives rise to fewer complications than surgery, but long-term results have not yet been demonstrated in prospective trials.

PTA of obliterations near the carotid bifurcation

The general standard treatment for both symptomatic and asymptomatic arteriosclerotic stenoses in the internal carotid arteries is vascular surgery. Most patients are treated in stage II of cerebrovascular disease; selected patients are eligible for treatment in stage I, if they are to undergo subsequent heart surgery or surgery of aortic aneurysms. With the new sophisticated stents and other devices—for treatment of dissections that may occur after balloon PTA—PTA can be an acceptable alternative to surgery when performed in highly specialized departments. However, duplex ultrasonography, as well as CT or MRI examination of the brain, is essential before the procedure is carried out. The technical and clinical success is more than 90%, with complications observed in only about 2% of patients.

Accepted indications for PTA in arteries of the neck are fibromuscular stenoses, post-operative stenoses (>3 months after surgery), and traumatic dissections (preceded by heparin medication for 4 months). The success rate in these cases is high, but no prospective trials have been undertaken.

Embolization

The blood supply to arteriovenous malformations or brain tumours (particularly meningiomas) can be reduced by embolization and occlusion of intracerebral arteries. The same technique is also used for the treatment of epistaxis or other haemorrhage and of tumours (e.g. glomus tumours), and before surgery of the face and neck. Possible complications are stroke, tissue necrosis, or secondary inflammation, which may occur in 4–8% of cases.

Other neuroradiological interventions

Percutaneous transcatheter occlusion of cerebral artery aneurysms is an intervention that is currently under prospective trial as an alternative to neurosurgery. Tumour biopsy under CT or other stereoradiographic control, as well as percutaneous drainage of fluids under X-ray control, are standard presurgical interventions.

Special risks

Neurointerventions sometimes need very long fluoroscopy times. Temporary epilation has been observed in individual cases (30, 31), and the interventional neuroradiologist should be aware of this potential risk and ensure that the patient is adequately informed.

1.5 Organization

The introduction and performance of interventional radiology at a hospital or in a radiological practice require logistic support from medico-technical departments, personnel, and administration.

1.5.1 Rooms and equipment

For cardiovascular interventional therapy, irrespective of the medical department in which it is performed, conditions should be at least equivalent to those for invasive cardiological and angiographic diagnostics in terms of radiological equipment, furnishing of the rooms, etc.

The interventional catheterization room should have a floor area of at least 40 m². It should be equipped with a physiological recording system, a high-resolution fluoroscopic and cineangiographic X-ray unit or digital imaging system, full emergency

resuscitation equipment (including circulatory assist devices), and a full complement of drugs for treatment of possible emergencies. The room should be linked to an emergency power supply system. An electrocardiograph (ECG) unit must be available, together with facilities for control of vital parameters, including a defibrillator and pacemakers (capable of being battery operated). The lighting system should be controllable to allow either step-by-step or smooth variation in brightness. An additional lighting fixture is required for operating rooms, as well as the instrumentation for artificial respiration with oxygen, and a compressor. Air-conditioning is desirable, and there should be at least 10 electrical outlets. Electrical cables should be laid in separate channels in the floor, the wall, or the ceiling. Installation of the power supply must comply with all applicable national regulations, to ensure the safety of patients and staff at all times.

Further rooms are needed for registration, for the operator, and for preparation and follow-up of patients.

The room containing the X-ray unit must be separated from both the registration room and the monitoring room for protection from radiation, but visual contact should be possible through a lead-glass window. The rooms should also be linked by doors. The control panel of the X-ray unit, plus all important controls and instruments that do not have to be directly at hand to the interventionalist in the X-ray room (e.g. for ECG, blood analysis, radiation exposure control systems, and chronometers), should be located in the monitoring room.

Washing facilities for the physicians and nurses and for cleaning of the instruments should be installed in the preparation or after-care room, or in a separate room, close to the catheterization room.

It is also essential to have one room for the developing, processing, and evaluation of films, as well as a computer room, and archiving facilities. Changing rooms for patients and personnel, as well as a separate rest and recreation room for the personnel, are necessary. Toilets and equipment for the cleaning of urinals and bedpans must be available close to the intervention room.

The equipment of rooms for non-vascular interventions depends mainly on the existence and location of an X-ray, CT, MRI, or ultrasound unit. If there is such a unit, additional washing facilities for physicians and nurses should be planned, as well as a room for specific medical instrumentation and other devices and another for preparation and after-care of patients.

The X-ray equipment must meet national regulations and should be adequate for heart catheterization, angiocardiology, coronarography, or angiography of arteries of the trunk, neck and brain, and pelvis and leg. It should be possible to vary the direction of the beam without having to move the patient. The equipment must be

easy to move away from the X-ray table in emergency situations so that resuscitation measures can be applied.

For paediatric interventions in cardiology, neuroradiology, and general radiology, safe positioning of the patient, keeping the patient warm, and providing additional radiation protection are all essential considerations.

1.5.2 Institutions and personnel

Only physicians with several years of experience in radiology or cardiology should be employed in interventional radiology or cardiology departments. The minimum requirements to be met for the training of staff are outlined in section 3. Apart from the physician qualified in interventional cardiology or radiology, an assistant physician, a nurse, and a radiographer are needed, as is an assistant to hand on catheters, instruments, and sterile supplemental instruments. National regulations concerning working hours have to be observed for staffing the department.

A room with a team fully dedicated to interventional procedures is fully occupied if 400 examinations per year are performed. The number of interventions carried out using the same staff should not exceed 800, ensuring that the national radiation protection guidelines are adhered to.

Each interventional radiology, cardiology, or other interventional department needs specialized doctors, specialized nurses and technicians, and close cooperation with medical physicists and surgeons working in the same field. For the planning and management of the different situations, the specialist's qualification is crucial. Qualification guidelines are discussed in section 3.

1.6 Conclusions and recommendations

1. Interventional radiology is an expanding area with an important role to play in the diagnosis and treatment of many diseases of cardiovascular and non-vascular origin.
2. In most cases therapeutic interventional radiological procedures facilitate or replace surgery and help to reduce hospitalization time. Under favourable conditions, interventional radiological procedures can be performed on an outpatient basis, and—because of the minimal risk involved—are well accepted by patients.
3. Interventional radiology requires expensive radiological equipment, a multi-disciplinary approach, and a high level of professional expertise. In principle, interventional radiological services should be available in large radiological departments, in university or general regional hospitals, in cardiological and other specialized institutions, and be situated close to emergency and surgical departments.

4. Planning the establishment of interventional radiology facilities must include provision for the education of medical personnel in other radiological centres, possibly in other countries. The purchase of interventional radiological equipment in the absence of adequate training should be considered counterproductive.

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2.

Radiation safety

2.1 Introduction

Compared with other X-ray examinations, interventional radiology characteristically involves considerably prolonged periods of fluoroscopy and extended use of radiography. Doses to both patients and clinical staff are relatively high and carry the potential for detrimental effects on health; these are discussed in section 2.2. Particular awareness of this potential and attention to radiation safety are essential on the part of all those involved in interventional radiology. The aim of radiation protection must be to avoid the occurrence of deterministic effects and to reduce the risk of long-term stochastic effects (1). Adequate justification for the use of X-rays and optimal protection for patients and staff are the cornerstones of radiation safety.

In an evaluation of the efficacy of any procedure in interventional radiology the potential for radiation damage should be considered to be inherently important (2). All procedures should be justified; diagnostic and therapeutic benefits should be weighed against possible radiation damage (to both patients and staff), taking into account the benefits and risks of alternative available techniques that do not involve exposure to ionizing radiation (3). Each aspect of any interventional procedure should be optimized to ensure that the clinical purpose is achieved with the lowest radiation dose practicable. This important principle can be implemented in the design, selection, and maintenance of equipment, as well as in the use of techniques appropriate to good practice.

Optimization is facilitated by the operation of comprehensive quality assurance programmes, which should include quality control measures for the equipment and protocols for the routine assessment of doses received by both patients and staff. The results of staff monitoring should be compared with investigation levels and statutory dose limits. Although no dose limits are recommended for the exposures received by patients for medical purposes, the use of procedure-specific reference dose values allows comparison of performance and has been endorsed as a practical means of promoting optimization of protection (3). It is intended that reference dose values serve as thresholds for investigation and to prompt improvements in poor practice when appropriate. Methods of dosimetry for patients and staff are discussed in section 2.3 and methods of dose reduction in section 2.4.

The principles of justification and optimization of protection are promoted through the education and training activities discussed in section 3. Adherence to these principles will contribute to the growth and establishment of a safety “culture” (3) in both interventional radiology and other branches of diagnostic radiology.

2.2 Detrimental effects of radiation

Because the process of ionization causes changes in atoms and molecules, even if only transiently, it may sometimes damage living cells. The potential for damage is a function of the energy absorbed per unit mass (J kg^{-1}), or absorbed dose, and is expressed in gray (Gy). Absorbed dose is the fundamental dosimetric quantity in radiation protection. In general, the biological effects of irradiation on an organ or tissue depend not only on the level of absorbed dose but also on the quality of the radiation. Quality is taken into account by application of a radiation weighting factor, which yields the dose equivalent, expressed in sievert (Sv); the radiation weighting factor for X-rays is 1. Overall radiation effects may be assessed by multiplying the dose equivalents for specified tissues or organs by tissue weighting factors; summation of these individual values yields the effective dose, also expressed in sievert (1).

The quantity dose equivalent (H_T) to a tissue T was introduced by ICRP (1):

$$H_T = \sum_R W_R D_{TR}$$

where D_{TR} is the absorbed dose (Gy) to tissue T from a type of radiation R, and W_R is the radiation weighting factor for the type of radiation.

Effective dose (E) is given by

$$E = \sum_T W_T H_T$$

where W_T is the tissue weighting factor (see Table 6).

The effects of ionizing radiation on tissue are divided into two categories, deterministic and stochastic (1, 4).

2.2.1 Deterministic effects

Both the onset and the severity of deterministic effects vary with the absorbed dose. The threshold for dose-response is defined as the amount of radiation required to cause the effect in 1–5% of exposed individuals (5). Usually, there is a period of latency—possibly several weeks—before the effect becomes clinically apparent. This may mean that the physician who performed the procedure may not observe or be aware of the symptoms and/or signs when they occur. The majority of deterministic effects in interventional radiology are likely to result from irradiation of the skin. The

Table 6. Tissue weighting factors (W_T)^a

Organ or tissue	W_T
Gonads	0.20
Red bone marrow	0.12
Colon	0.12
Lung	0.12
Stomach	0.12
Bladder	0.05
Breast	0.05
Liver	0.05
Oesophagus	0.05
Thyroid	0.05
Skin	0.01
Bone surfaces	0.01
Remainder	0.05

^a Reproduced from reference 1 with permission from Elsevier Science.

Table 7. Radiation-induced skin injury (6, 7)

Effect	Typical threshold absorbed dose (Gy)	Latent period (weeks)
Erythema and dry desquamation	3–5	3
Epilation (temporary)	3	3
Epilation (permanent)	7	3
Telangiectasia	12	>52
Moist desquamation	>20	4
Tissue necrosis	50	3

appearance of injury is dependent not only on the cumulative dose to the skin, but also on the dose rate, fractionation of the dose, the age and characteristics of the patient, and the site of exposure. Table 7 gives some examples of the absorbed doses typically required to produce effects in the skin and adjacent tissues (6, 7), together with an indication of times to onset following a single irradiation. Physicians who perform interventional procedures must therefore be aware that significant radiation injury to skin can result from long fluoroscopy times and extended use of radiological procedures.

Deterministic effects on the lens of the eye may also be of importance and are particularly relevant to all personnel involved in interventional procedures. The lens of the eye is among the most radiosensitive tissues of the body (5). Lens opacities (cataracts) can develop within months of exposure to high doses of radiation, but may take years to develop after exposure to lower doses; the degree of visual

impairment will vary (5). The threshold for opacities sufficient to cause impairment of vision is believed to be 2–10 Sv for a single exposure to X-rays (1). For prolonged low-level exposures, the threshold is considered to be in excess of a total dose of 8 Sv (5) at a dose rate somewhat above 0.15 Sv per year (1). However, ophthalmologically detectable opacities may result from smaller doses and lower dose rates.

The special case of *in-utero* exposure must also be considered in interventional radiology; a patient and/or a member of staff may be pregnant, although this may not always be known at the time of irradiation. The principal deterministic effects on the developing embryo and fetus are death, malformation, growth retardation, and abnormal brain development leading to severe mental retardation (8). Dose thresholds for lethality vary between 0.1 Gy within the first week after conception to over 1 Gy in the second half of pregnancy (9, 10). Gross malformations are most likely to be induced by irradiation during organogenesis (2–7 weeks after conception), with a threshold between 0.2 and 0.5 Gy (11). The risk of subsequent severe mental retardation is greatest between 8 and 15 weeks' gestational age, possibly without a threshold, and from 16 to 25 weeks with a threshold of 0.6–0.7 Gy (8). In practical terms, the threshold dose in pregnant women for deterministic effects on the fetus will be around 100 mGy.

2.2.2 Stochastic effects

The probability—but not the severity—of stochastic effects varies with the dose, and there is assumed to be no threshold (4). The principal stochastic effects are carcinogenic (somatic) and heritable effects.

Cancer may be induced by irradiation of any organ of the body. The delay between exposure and manifestation of the cancer is specifically related to the type of tissue affected and to the magnitude of the dose; latency may vary from 2 years for leukaemia to 40 years or more for solid tumours. The risk of fatality varies with the organ affected. Breast tissue is particularly sensitive, with a risk coefficient 2.5 times that of thyroid tissue; skin irradiation carries the lowest risk, due in part to the low mortality (only 1%) for all skin tumours. The lifetime fatal cancer risk for whole-body irradiation, averaged over the whole population, is 5% Sv⁻¹, and total cancer risk—including non-fatal cancers—is 6.1% Sv⁻¹ (12). However, the risks are less for older patients, that is, for the majority of patients undergoing interventional procedures, since less time remains for cancer to develop before death from other causes occurs. Conversely, risks are appreciably higher for younger populations (paediatric patients). For a working population aged 18–65 years (which would include interventionists and their staff), the fatal cancer risk is estimated to be 4% Sv⁻¹ and the total cancer risk to be 4.9% Sv⁻¹. These risk coefficients apply to radiation given at low doses and low dose rates (single doses of 200 mGy or less, or higher doses delivered at rates of up to 100 mGy per hour). For higher doses, the risks are doubled (1). Risk coefficients for all cancers are given in Table 8 and for cancer in selected organs

Table 8. Risk coefficients for cancers in both sexes at low doses and dose rates and at high doses and dose rates^a

Exposed population	Risk coefficient (% Sv ⁻¹)	
	Fatal cancer	Total cancer ^b
Whole population	5.0 (10)	6.1 (12.2)
Working population	4.0 (8)	4.9 (9.8)
Individuals up to age 15 years, exposed in utero	3.0 (6)	6.0 (12.0)

^a Source: reference 1.^b Values in parentheses are for high doses and high dose rates.**Table 9. Risk coefficients for fatal cancer in individual organs, in both sexes, at low doses and low dose rates and high doses and high dose rates^a**

Organ	Fatal cancer risk coefficient (% Sv ⁻¹)	
	Whole population ^b	Working population ^b
Bone marrow	0.5 (1.0)	0.4 (0.8)
Breast	0.2 (0.4)	0.16 (0.32)
Thyroid	0.08 (0.16)	0.064 (0.128)
Skin	0.02 (0.04)	0.016 (0.032)

^a Source: reference 1.^b Values in parentheses are for high doses and high dose rates.

in Table 9; the risks are given for working populations and thus apply to all health personnel involved in interventional radiology.

The above-mentioned risk coefficients are not applicable to patients undergoing particular interventions since the age distribution for each type of procedure differs and will not conform to the age distribution of the whole population. From surveys of such age distributions, it is possible to estimate typical risks for each type of procedure. Table 10 gives the lifetime risk by age at time of exposure (1). Table 11 gives the age distributions of patients for PTCA and PTA procedures in Germany. In Table 12, the risks derived for these specific patient groups (using the data in Table 10) are compared with the risk coefficients for the whole population and for inpatients undergoing CT examinations.

Exposure during interventional radiology will be principally of the skin and any organ in the primary field. For interventionists and other health staff, significant exposure is mainly from scattered radiations; the skin and the thyroid are the main organs of

Table 10. Fatal cancer risk coefficient by age at exposure^a

Age at exposure (years)	0-20	21-40	41-60	61-80	>80	Workers 18-65
Lifetime probability of fatal cancer (% Sv ⁻¹)	11.5	5.5	2.5	1.2	0.2	4.0

^a Source: reference 1.**Table 11. Age distribution of patients undergoing PTCA and PTA procedures in Germany^a**

Procedure	Percentage by age (years)				
	0-20	21-40	41-60	61-80	>80
PTCA	0	5.8	50.8	43.4	0
PTA	0.8	1.9	30	55.2	12.1

^a Based on data supplied in a personal communication from T. Schmidt.**Table 12. Comparison of fatal cancer risk coefficients for populations of patients undergoing different procedures in Germany^a**

Procedure	PTCA	PTA	CT ^b	(Whole population)
Lifetime probability of fatal cancer (% Sv ⁻¹)	1.6	2.1	2.3	5.0

^a Based on data supplied in a personal communication from T. Schmidt.^b Inpatients.

concern for stochastic effects. Staff should be warned not to place their hands in the unattenuated primary beam since its intensity is many orders of magnitude greater than the intensity of scattered radiation.

Stochastic risk to fetuses, resulting from exposures of patients and/or health workers, must also be considered. The risk of fatal cancer after *in-utero* irradiation can at present be estimated only up to the age of 15 years; it has been assessed as 3.0% Sv⁻¹ (13). The additional risk for the rest of life may be 1-3 times this value (14), but this awaits further elucidation. High-dose X-ray procedures, which involve an absorbed fetal dose of some tens of mGy, should be avoided in pregnant patients unless there is an overriding clinical requirement. For pregnant health workers, ICRP recommends that, once pregnancy is declared, the dose to the fetus should not exceed 1 mSv during the remainder of the pregnancy (1). Estimating fetal dose is difficult, but a useful practical rule is to limit the dose to the abdominal surface of pregnant women

to 2 mSv over the same period. Under typical fluoroscopy conditions, this will keep the fetal dose below 1 mSv (15). Compliance with these limits is generally possible and, from the point of view of radiation protection, pregnancy should not usually exclude health workers from participating in interventional radiology work.

Heritable effects of radiation may result from the induction of mutations in the DNA of male and female germ cells. While these mutations have no direct consequence for the exposed individual, they may be expressed in subsequent generations as genetic disorders (1, 11, 13, 16–19). Although studies of human exposure have not shown any significant radiation-related increases in heritable effects (16, 18), evidence from animal studies suggests that a total risk coefficient of $2.4\% \text{ Sv}^{-1}$ should be applied to individuals of reproductive age as an estimate of the risk to successive generations. In a working population (18–65 years), only a fraction (assumed to be 25%) will be of reproductive capacity and the risk coefficient for this group as a whole is thus $0.6\% \text{ Sv}^{-1}$. The corresponding risk coefficient for a general population of all ages is $1\% \text{ Sv}^{-1}$.

2.3 Dose assessment

2.3.1 Patient exposure

Patient exposure during interventional radiological procedures is generally high compared with that in most diagnostic X-ray examinations. Dose levels may exceed the thresholds for deterministic effects, and the risk of stochastic effects may be an important consideration for particular groups, such as paediatric patients.

For a particular type of procedure, the dose to the patient will be determined both by the equipment and techniques used and by the patient's physical characteristics and clinical problem, which strongly influence the fluoroscopic dose rate and required exposure per radiographic image.

Equipment-related factors include:

- radiation quality (applied potential and filtration)
- type of equipment (digital or conventional)
- availability of automatic exposure control algorithms.

Procedure-related factors include:

- clinical requirements of the patient
- duration of fluoroscopy and number of radiographic exposures required for the procedure to be efficacious, which will be determined in part by the skill of the interventionist and the cooperation of the patient
- requirements for image quality.

In practice, patient exposure may be characterized to a varying extent by a range of different parameters, including fluoroscopy time, number of radiographic exposures (acquired images or cine frames), localized surface dose, dose–area product, and effective dose. Published dose data relating to different types of procedure are summarized in Tables 13–16; these illustrate both mean exposure levels and the significant variations observed between individual patients and between different hospitals. In general, fluoroscopy times (Table 13) are appreciable and skin doses (Table 14) approach or exceed the thresholds for deterministic effects shown in Table 7. Values of effective dose for interventional procedures (Table 16) typically exceed those for the common diagnostic X-ray examinations shown in Table 17 (20, 21). Further detailed analyses of patient exposure during embolization and angioplasty in Germany in 1994 are given in Tables 18 and 19 respectively; these include quartile values for the distributions of the mean doses observed at individual hospitals. Such survey data are particularly relevant to the establishment of reference dose values for interventional procedures, as discussed further in section 2.4.3.

Fluoroscopy time is easy to record but provides only a broad indication of patient exposure. However, recording fluoroscopy time may be particularly useful for comparing the performance of individual interventionists. Other factors in addition to fluoroscopy time may also contribute significantly to overall patient dose during radiographic procedures. Assessment of the localized dose to skin is important for controlling deterministic effects, although it is not a useful indicator of stochastic risk. Cumulative surface dose may be measured directly using a thermoluminescent dosimeter (TLD) (35) or film (42) positioned within the most heavily irradiated region for the particular type of procedure. Alternatively, estimates of maximum surface dose can be made from knowledge both of the conditions of exposure during the procedure and of the characteristics of the X-ray equipment. Absorbed dose to the skin may also be inferred from measurements of dose–area product.

Cumulative dose–area product is relatively easy to monitor using, for example, a suitably calibrated, large-area ionization chamber fitted to the diaphragm housing of each X-ray tube (22, 43). Dose–area product provides a practical indication of overall patient exposure relevant to the assessment of stochastic risk (see Fig. 7). It may be used to derive estimates of effective dose using coefficients specific to the type of technique and anatomical site of examination (44, 45). Some illustrative factors relating to different types of procedure are given in Table 20.

As part of quality assurance, assessment of patient dose is an essential element in optimizing protection. Monitoring of fluoroscopic time and dose–area product, together with estimates of localized surface dose, represents a useful dosimetric approach that will facilitate control of patient exposure. Appropriate reference dose values play a particularly important role in promoting the reduction of unnecessary exposures. Reference doses in relation to dose reduction are discussed further in section 2.4.

Table 13. Fluoroscopy times, per procedure, for patients undergoing interventional radiology

Procedure	Mean fluoroscopy time (minutes)	Fluoroscopy time range (minutes) ^a		Reference
		Individual patients	Individual hospitals	
PTCA	11.5	2.4–28	5.8–18	V. Neofotistou ^b
	30	9–70	—	22
	—	60 (max.)	—	23
	—	56 (max.)	—	24
	11	92 (max.)	—	25
	31.3	—	—	26
	43.8 ^c	—	—	26
	31 ^d	8–62	—	27
PTA	43 ^e	3–53	—	27
	12.8	0.1–180	8.5–28.4	T. Schmidt ^b
	19.7	5.3–26	—	28
	41.7 ^f	—	—	V. Neofotistou ^b
TIPS	6	—	—	Faulkner & Broadhead ^b
	46	—	—	29
RF ablation	42	27–108	—	V. Neofotistou ^b
	50	31 (SD)	—	30
	21.4	142 (max.)	—	31
	—	190 (max.)	—	32
	28	3–109	—	Faulkner & Broadhead ^b
Valculoplasty	53 ^g	40–120	—	33
Lysis	21	—	—	29
Embolization	24	0.3–155	8.6–52.1	T. Schmidt ^b
	37.4	8.1–58	—	28
	47.5 ^h	—	—	V. Neofotistou ^b
	28.5 ⁱ	—	—	V. Neofotistou ^b
	23 ^j	1–75	—	Faulkner & Broadhead ^b

^a Minimum and maximum values or standard deviation (SD).

^b Personal communication.

^c Laser PTCA.

^d Total occlusion.

^e Subtotal stenosis.

^f Leg.

^g Children.

^h Liver.

ⁱ Kidney.

^j Neurological.

Table 14. Localized absorbed dose to skin, per procedure, for patients undergoing interventional radiology

Procedure	Mean absorbed dose (Gy)	Absorbed dose range (Gy) ^a		Reference
		Individual patients	Individual hospitals	
PTCA	—	1–5 ^b	—	34
	1	43 (max.)	—	23
	0.1 ^c	1 (max.)	—	35
	0.15 ^c	0.05–0.30	—	22
	0.46 ^{b,d}	—	—	27
	0.39 ^{b,e}	—	—	27
PTA	0.45 ^b	0.003–6.3	0.3–0.99	T. Schmidt ^f
RF ablation	—	8.4 ^b (max.)	—	32
	0.9 ^b	6.2 (max.)	—	31
	0.07 ^c	1.4 (max.)	—	36
Embolization	1.1 ^b	0.013–7.0	0.39–2.3 ^b	T. Schmidt ^f
	—	0.2–1.4 ^{c,g}	—	37
	0.5 ^{c,h}	—	—	35
Biliary drainage	2.1 ^c	—	—	35

^a Minimum and maximum values.^b Estimated (maximum likely) data for static beam.^c Measured data.^d Total occlusion.^e Subtotal stenosis.^f Personal communication.^g Cerebral.^h Hepatic.

2.3.2 Occupational exposure

Occupational exposure is of greater concern in interventional than in diagnostic radiology since health personnel are usually nearer to the patient, and therefore close to the unattenuated primary beam for longer. Moreover, the clinical condition of a patient often necessitates the presence of more health workers. Individuals stationed at the patient's side during interventional radiology procedures are close to the source of scattered radiation (i.e. the patient) and may thus be exposed to high dose rates. A typical radiation dose distribution around the patient is illustrated in Fig. 8 (46). The requirement for easy access to the patient and the design of equipment may compound the problem; in particular, the use of lead screening curtains may be impractical, and the over-couch X-ray tube/under-couch image intensifier geometry

Table 15. Dose-area product (DAP), per procedure, for patients undergoing interventional radiology

Procedure	Mean DAP (Gy cm ²)	DAP range (Gy cm ²) ^a		Reference
		Individual patients	Individual hospitals	
PTCA	93	33–402	55–206	V. Neofotistou ^b
	28.5	20–50.5	—	22
	42	266 (max.)	—	25
	87.5	67–122	—	35
	110	40–340	—	38
	143	83 (SD)	—	39
PTA	58	0.5–810	38–128	T. Schmidt ^b
	68.5	22–150	—	28
	43.5	5–184	—	38
	65.1	—	—	Faulkner & Broadhead ^b
TIPS	354	—	—	35
RF ablation	116	26–217	—	V. Neofotistou ^b
	56.4 ^c	12–184	—	Hoffman, Gerth & Steinbeck ^b
	77.5 ^d	13–367	—	Hoffman, Gerth & Steinbeck ^b
	97.3 ^e	9–532	—	Hoffman, Gerth & Steinbeck ^b
	103	7–516	—	Faulkner & Broadhead ^b
Valvuloplasty	44 ^f	—	—	33
	56 ^g	—	—	33
Embolization	130	2–850	47–290	T. Schmidt ^b
	121	34–286	—	26
	391	93–918	—	38
	114 ^h	7–394	—	Faulkner & Broadhead ^b
	81.7 ⁱ	—	—	35
Biliary drainage	68.9	30–163	—	35

^a Minimum and maximum values or standard deviation (SD).

^b Personal communication.

^c Atrioventricular (AV).

^d Atrioventricular nodal re-entry.

^e Wolff–Parkinson–White (WPW).

^f For infants (<1 year).

^g Children (1–16 years).

^h Neurological.

ⁱ Hepatic.

Table 16. Effective dose, per procedure, for patients undergoing interventional radiology

Procedure	Mean effective dose (mSv)	Range of effective dose (mSv) ^a		Reference
		Individual patients	Individual hospitals	
PTCA	28.9	7.5–57	8.9–51	V. Neofotistou ^b
	10	1400 (max.)	—	23
	22	—	—	30
PTA	7	0.05–100	4.5–15	T. Schmidt ^b
RF ablation	17	—	—	30
Embolization	20	0.2–140	7.5–46	T. Schmidt ^b
	—	6–43	—	38
	10.6 ^c	—	—	40, 41

^a Minimum and maximum values.^b Personal communication.^c Cerebral.**Table 17. Typical effective dose in common diagnostic radiological examinations in the United Kingdom^a**

Examination	Typical effective dose (mSv)	
	CT	Conventional
Head	1.8	0.1
Thoracic spine	5.8	1.1
Chest	8.3	0.04
Abdomen	7.2	1.4
Lumbar spine	3.6	2.2
Pelvis	7.3	1.0
Intravenous urography	—	4.6
Barium meal	—	4.6
Barium enema	—	8.7

^a Reproduced, with permission, from references 20 and 21.

that is sometimes used may mean increased exposure levels for staff (40). The circumstances of exposure particular to interventional radiology necessitate a more comprehensive approach to the monitoring of occupational doses. This approach should involve the assessment of doses to unshielded organs as well measurements on the trunk under a lead apron. Monitoring should be targeted: workload, equipment,

Table 18. Analysis of patient exposure to radiation during embolization procedures in Germany in 1994^a

Category	Sample size	Analysis	Fluoroscopy time (minutes)	Surface dose (Gy)	Dose-area product (Gy cm ²)	Effective dose (mSv)
Patients	800	Mean	24	1.10	130	20
		SD	18	0.81	100	16
		Min.	0.3	0.013	1.5	0.2
		Max.	155	7.00	850	140
Hospitals	16	Min.	8.6	0.39	47	7.5
		25%	15.4	0.69	85	14
		50%	18.0	0.81	100	16
		75%	29.1	1.30	160	26
		Max.	52.1	2.30	290	46

^a Based on data supplied in a personal communication from T. Schmidt.**Table 19. Analysis of patient exposure to radiation during angioplasty procedures in Germany in 1994^a**

Category	Sample size	Analysis	Fluoroscopy time (minutes)	Surface dose (Gy)	Dose-area product (Gy cm ²)	Effective dose (mSv)
Patients	6200	Mean	12.8	0.45	58	7
		SD	9.5	0.33	43	5
		Min.	0.1	0.003	0.5	0.05
		Max.	180	6.30	810	100
Hospitals	16	Min.	8.5	0.30	38	4.5
		25%	11.7	0.41	53	6.5
		50%	13.9	0.49	63	7.5
		75%	18.1	0.63	81	10
		Max.	28.4	0.99	128	15

^a Based on data supplied in a personal communication from T. Schmidt.

procedures used, and levels of dose-area product are all useful predictors (47), and staff doses correlate reasonably well with dose-area product (48). The success of any monitoring strategy depends critically on the full cooperation of staff in wearing dosimeters correctly.

Local radiation doses to hands, eyes, or the thyroid can be measured using thermoluminescent or electronic dosimeters or films. Effective dose can be estimated from an appropriate combination of measurements made behind and in front of personal shielding (48–50). Such monitoring data provide a quantitative indication of the effectiveness of protection strategies. The measurements obtained should be critically reviewed in the context of investigation levels and statutory dose limits; the latter

Table 20. Illustrative factors relating dose–area product and effective dose by anatomical region and general type of interventional procedure

Application	Normalized effective dose (mSv Gy ⁻¹ cm ²)	Reference
Region		
Head	0.02	T. Schmidt ^a
Thorax	0.12	T. Schmidt ^a
Abdomen	0.27	T. Schmidt ^a
Pelvis	0.24	T. Schmidt ^a
Leg	0.02	T. Schmidt ^a
Angioplasty		
General	0.12	T. Schmidt ^a
Embolization		
General	0.16	T. Schmidt ^a
Cerebral	0.087	40, 41
PTCA		
—	0.21	V. Neofotistou ^a
60kV ^b	0.15	45; S.H. Stern ^a
90kV ^c	0.30	45; S.H. Stern ^a
120kV ^d	0.40	45; S.H. Stern ^a

^a Personal communication.^b HVL = 2.5 mm Al.^c HVL = 4.0 mm Al.^d HVL = 5.5 mm Al.

should never be exceeded. International recommendations for the annual limits on occupational exposures are summarized in Table 21.

Published data on the doses received by health staff involved in interventional procedures are summarized in Tables 22 and 23 and are illustrative of the typical levels of exposure per procedure. The variations in doses shown for a given general type of procedure may be partly explained by differences in methods of dosimetry; in practice, however, doses also depend on the equipment and technique used, the physical characteristics of the patient, the experience of the operator, and the application of dose-reduction measures.

In a small number of cases, doses may be much higher than the average values shown, and the use of personal electronic dosimeters can then be valuable in giving real-time dose information. Such dosimeters may be particularly useful for monitoring pregnant staff; dose to the abdomen can be assessed for compliance with the special limit (Table 21).

Interventional radiology carries the potential for significant occupational exposure, and adequate training of staff in radiation protection and optimization strategies is

Fig. 7. Schematic representation of determination of dose–area product

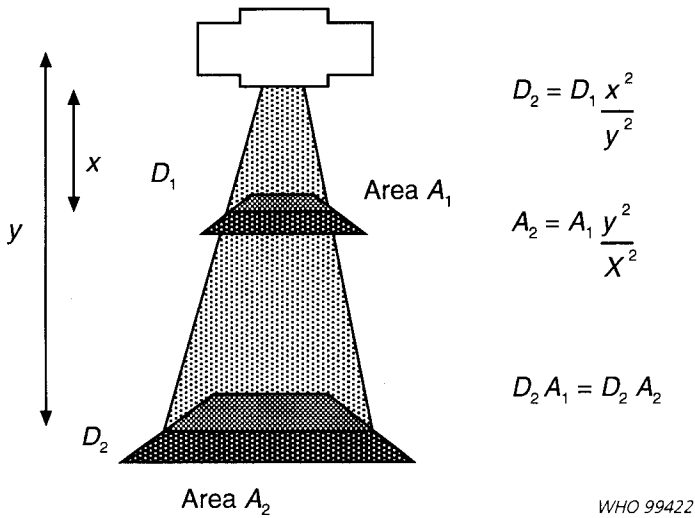


Table 21. Recommended annual limits on dose for occupational exposures^a

Application	Annual dose limit (mSv)
Effective dose	20 ^b
Equivalent dose	
Lens of eye	150
Skin	500 ^c
Hands and feet	500 ^c
Pregnancy	
Surface of abdomen	2 ^d

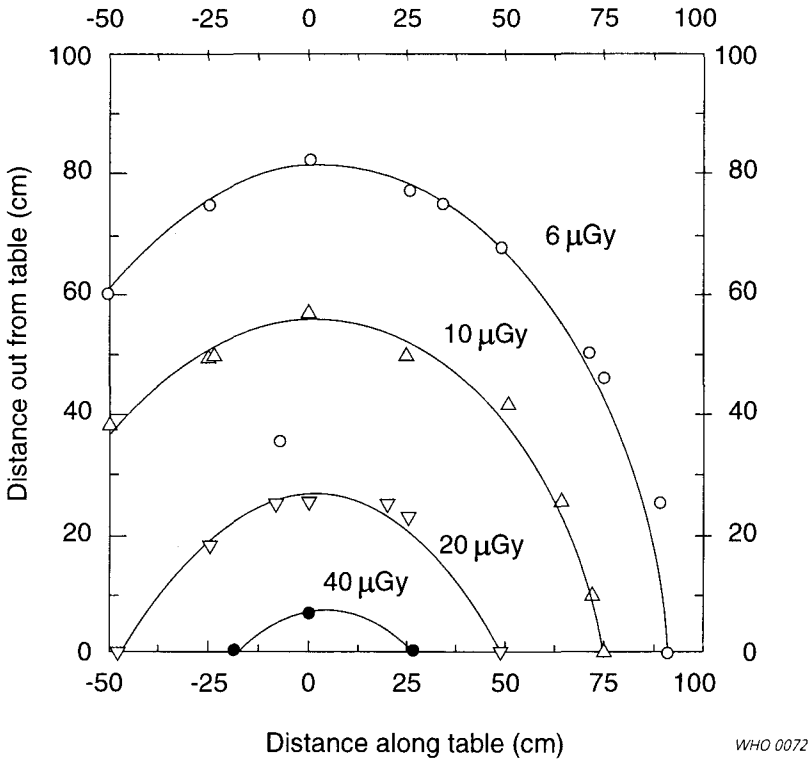
^a Source: reference 1.

^b Averaged over defined periods of 5 years, with no more than 50mSv in a single year.

^c Although the limitation on effective dose provides sufficient protection for the skin against stochastic effects, an additional limit on equivalent dose (500 mSv) is required for localized exposures in order to prevent deterministic effects.

^d Over duration of declared pregnancy.

Fig. 8. Distribution of scattered radiation dose at the couchside around the patient^a



^a Reproduced from reference 46 with the permission of the publisher.

clearly vital. Annual doses to individuals will obviously depend on workload, and exposures for some staff may well exceed investigation levels, which are set at fractions (such as three-tenths) of the dose limits. For non-cardiac procedures, hand dose is likely to be the limiting factor, since the thyroid and eyes can be shielded. Protection of the eyes is likely to be the most important consideration in cardiac procedures since hands can, with care, be kept well away from the unattenuated primary beam (47).

Measures to reduce occupational exposure in interventional procedures are discussed in section 2.4.4.

Table 22. Levels of occupational exposure during interventional radiology: typical doses, per procedure and by category of staff, for cardiac procedures

Procedure	Category of staff	Eye dose (μGy)	Hand dose (μGy)	Thyroid dose (μGy)	Effective dose (μSv)	Reference
PTCA	Cardiologist ^a	16–45	38–72	—	4.6	V. Neofotistou ^b
	Cardiologist ^b	178–200	190–240	—	23	V. Neofotistou ^b
	Cardiologist	470	1100	—	50	24
	Cardiologist	130	160	80	5–10	51
	Technician	150	—	—	—	51
RF ablation	Cardiologist	320 ^c	—	—	18 ^a (28 ^{d,e})	30
	Nurse	—	—	—	2	30
	Cardiologist	300	1000	—	—	52
	Cardiologist	—	1000	160 ^c	—	36

^a Normal-dose group.^b High-dose group.^c Without additional shielding.^d For manipulation of catheter from femoral area; effective dose is doubled for manipulation from subclavian vein.

Table 23. Levels of occupational exposure during interventional radiology: typical doses, per procedure and by category of staff, for non-cardiac procedures

Procedure	Category of staff	Eye dose (μGy)	Hand dose (μGy)	Thyroid dose (μGy)	Effective dose (μSv)	Reference
PTA	Radiologist	—	500	211	—	28
TIPS	Radiologist	—	—	—	25–30	53
Biliary	Radiologist ^a	300	1290	—	—	54
	Radiologist ^b	3100	35 000	—	—	54
Urinary	Radiologist	300	520	—	—	54
	Urologist	—	340	—	—	55
Percutaneous drainage	Radiologist	—	180 (3–1310)	—	—	56
	Radiologist ^a	—	130	—	—	56
	Radiologist ^b	—	320	—	—	56
General practice	Interventionist	—	—	—	3	57
	Interventionist	—	1500 (0–5500)	—	—	58
Embolization	Radiologist	14	19	—	25 ^c	40, 41
	Scrub nurse	13	—	—	9.5 ^c	40, 41
	Radiographer	—	—	—	3.9 ^c	40, 41
	Radiologist	200	500	—	25	37
	Radiographer	150	100	—	20	37
	Radiologist	—	250	240	—	28

^a Experienced.

^b Inexperienced.

^c Measured by electronic personal dosimeter above lead apron. True effective dose will be about 20 times less.

2.4 Dose reduction

Interventional radiology may result in relatively high radiation doses to both patients and health-care staff. It is therefore essential, while continuing to fulfil clinical objectives, to make every effort to avoid or minimize deterministic radiation effects and to minimize stochastic effects. General principles and recommendations for the protection of patients undergoing prolonged fluoroscopic procedures have been formulated by the Food and Drug Administration in the USA (59).

When available, non-ionizing or complementary imaging procedures should be considered as alternatives to the use of X-rays. For example, biopsies and therapeutic drainage can often be performed by a well-trained physician using ultrasound or magnetic resonance imaging. For other types of procedure, such as endoscopic retrograde cholangiopancreatography, the use of a modern X-ray unit equipped with an ultrasound scanner or a flexible endoscope will allow localization to be achieved with a lower radiation dose to the patient.

Interventionists should be aware of the broad interrelationship between patient and occupational exposure. The amount of scattered radiation received by staff is often related to the dose-area product for the patient (60). Efforts to reduce patient dose generally benefit everyone present in the X-ray room. However, certain measures that could shorten procedures and reduce patient dose would actually increase occupational exposure; these might include, for example, an interventionist briefly introducing his or her hand into the primary beam or removing a ceiling-mounted lead-glass screen in order to improve patient accessibility. It is important that staff are sufficiently well trained in radiation protection to be able to judge the true benefit of dose-reduction measures.

2.4.1 Techniques for reducing patient dose

Dose reduction should be considered with due regard to the clinical purpose of the interventional procedure. Measures to reduce dose should not adversely affect image quality, which should be appropriate to the particular intervention and may vary during the procedure. If the quality of fluoroscopic images is inadequate, longer periods of exposure may become necessary, resulting in an increased dose to both patients and staff. Furthermore, the efficacy of interventional procedures performed by the unit could be compromised. Although high-dose-rate fluoroscopy greatly improves image quality, it is associated with significantly increased patient exposure and should be used only when improved visualization is essential and only for limited periods.

Dose-reduction measures designed to achieve and maintain optimization of patient protection are best implemented in departments by means of a comprehensive pro-

Table 24. Methods of reducing entrance dose during high-dose-rate fluoroscopy

Method	Relative entrance dose (%)	Reference
Collimation	60	30
Remove grid	50	29, 62
Increased applied potential	60–90	32
Additional filtration	40–80	29, 32, 63, 64
Pulsed fluoroscopy	10–80	29, 32, 63, 64; A. Den Boer ^a
Combination	30–70	32

^a Personal communication.

gramme for quality assurance (61), which should be concerned with both the procedures and the equipment used, as discussed below.

Table 24 gives a broad indication of the levels of dose reduction achievable by various methods during high-dose-rate fluoroscopy.

Procedure-based techniques for reducing patient dose

It is an essential prerequisite that staff involved in interventional radiology are highly skilled, motivated, and trained in radiation protection principles.

- Diagnostic and therapeutic procedures should be performed within as short a time interval as possible, to avoid the need to repeat diagnostic procedures.
- Interventional procedures should be optimized so that doses employed are the lowest practicable consistent with clinical needs. This can be achieved by reducing both fluoroscopy time and the number of radiographic exposures, and by using all available dose-reduction features of the equipment. Moreover, interventionists should be fully aware of the considerably higher exposures associated with high-dose-rate fluoroscopy or with radiographic procedures.
- If possible, sensitive organs should be excluded from the primary beam. Collimation should be optimal, or alternative projections should be used. This is particularly important in interventional radiology since the absorbed doses are higher than those associated with general radiology.
- If possible, beam projection should be varied to keep the localized dose to skin below the threshold for deterministic effects.
- Establishment of reference dose values for general types of procedure is strongly recommended. Doses to patients should be routinely monitored to ensure that the relevant reference dose values are not exceeded. If reference values are regularly exceeded, the reasons should be investigated and remedial actions taken. Feedback

between the interventionist and the medical physicist should be established to ensure that typical doses remain within reference values.

Equipment-based techniques for reducing patient dose

- Equipment should comply with international and national standards; it should meet the specific needs of each type of interventional procedure and its performance should be appropriate for that procedure.
- Equipment should be regularly updated to incorporate cost-effective features for better dose reduction or, when required, improved image quality.
- Indication and recording of dosimetry information should be a standard feature of the equipment (see section 4).

2.4.2 Specific dose-reduction measures

Optimal filtration

The X-ray spectrum transmitted through the patient should match the energy response of the detector. The X-ray beam filtration can be changed to achieve selective removal of low-energy photons that would not otherwise reach the detector. There is some evidence that increasing the tube filtration for interventional radiology procedures reduces the dose (65); copper is a good filter material for this purpose. Optimizing filtration could result in the replacement of aluminium filters with other material. In this context it is worth remembering that “aluminium equivalent” does not mean that only aluminium may be used as a filter material. When considering the use of additional filtration, the main objective is to maintain constant the energy imparted at the energy receptor.

The use of 1-mm aluminium plus 0.1-mm copper filtration (instead of 2.5-mm aluminium filtration) produces a 10% change in contrast but results in a 40% saving in radiation dose to the skin. A combination of 2.5-mm aluminium and 0.5-mm copper filtration with the same mean energy achieved by using a lower tube potential may also be used. This results in a 50% reduction in skin dose with no loss of contrast, but requires 2–5 times as much power.

Changing the X-ray spectrum used in interventional radiology thus requires a compromise between dose reduction and loss of contrast or between dose reduction and increased tube loading/power requirements. However, an appreciable reduction in radiation dose can clearly be achieved without significantly affecting image quality or tube loading. The principal effect of novel filter combinations is to reduce skin entrance dose; there is rather less impact on the energy imparted.

In the past, manual selection of tube filtration generally led to the selection of an inappropriate filter material. Current equipment designs provide for the automatic selection of filter combinations.

Grid removal

Clearly, removing the antiscatter grid will reduce patient dose since the grid always removes primary radiation. However, it is not always appropriate to remove the grid, and there are practical limitations on removing and replacing it several times a day. It is suggested that manufacturers design interventional equipment with grids that can be easily removed. On such systems there should be a reminder to the operator to remove the grid whenever possible, possibly by the display of a prompt when patient information is entered.

Examples of procedures that do not require the use of a grid are:

- paediatric cardiology
- most interventional neuroradiology with the exception of adult spinal angiography
- paediatric general vascular studies.

Pulsed fluoroscopy

Pulsed fluoroscopy reduces patient doses since for some of the time the X-rays are switched off. The dose saving is related to the proportion of the time X-rays are not emitted by the X-ray tube compared with the exposure time, provided other factors remain constant.

The effect of changing frame rate is complicated and dependent on the temporal behaviour of the eye. There are two domains, one in which the frame rate is faster than the eye integration time. In this domain, only small dose savings are possible by changing frame rates at the same noise level. If the viewer is willing to compromise image quality (either in terms of increased image noise or loss of resolution), the dose may be reduced. At low frame rates, gap-filling techniques can lead to dose reductions. However, low frame rates lead to a loss of temporal resolution.

In any event, a facility for holding the last image taken is a desirable feature of interventional radiology equipment. The dose used to form this image can be reduced by using a suitable combination of previous images.

Automatic dose control/automatic dose rate control

All interventional radiology equipment should be provided with both automatic dose control (ADC) and automatic dose rate control (ADRC) facilities. However, optimization studies are necessary to assess the various set-up characteristics of the ADC/ADRC systems. Image-quality weighted systems increase tube current preferentially as beam attenuation increases. Dose-weighted systems characteristically operate by initially increasing tube potential as attenuation increases. However, there are numerous potential solutions between those two approaches. The optimum

approach for a given interventional imaging task is not always clear and optimization studies need to be carried out.

Manufacturers are encouraged to supply systems with some degree of flexibility in the selection of the tube potential/tube current characteristic. However, providing too many options may be unproductive and few users will use all the available features. Preference studies may be a good method of assessing the optimum settings.

Image processing

Both temporal averaging and recursive filtering in fluoroscopy may be achieved using camera persistence or computer techniques, an approach which averages frames and thereby reduces patient dose by noise averaging. The signal-to-noise ratio is thus improved. Recursive filtering using a mixing factor of 3 (i.e. 1/3 of the displayed image is new, 2/3 originating from previously acquired frames) can lead to appreciable improvements in the signal-to-noise ratio. This may in turn be used to improve image quality or to reduce dose by maintaining the same signal-to-noise ratio. Previously, plumbicon TV camera tubes, which had a small degree of persistence, were used in cardiology; vidicon cameras were used in other areas where temporal resolution was not as critical. Users of equipment should be aware of the consequences of recursive filtering since the procedure reduces the contrast of a moving catheter tip. It is critical that the image quality is not degraded to an extent that compromises the clinical objectives of the interventional procedure.

Optimization of images using temporal averaging need to be carried out in conjunction with use of clinical image quality indices. Individuals operating equipment with this facility need to be adequately trained in its use. In general, image processing may be used to enhance certain structures but often at the expense of other aspects; for example, edge enhancement improves the detection of sharp edges but results in more image noise. Conversely, noise smoothing results in a loss of sharpness. Very few image processing routines have become accepted in clinical practice although there is some inherent image processing in all images presented. It is clearly desirable for the operator to be involved in the optimization of the routines.

Roadmapping

Roadmapping generally involves the use of a reference image on which the current image is overlaid and normally applies only to non-cardiac systems. For cardiology, a reference image or loop of images linked to the ECG has been used for roadmapping purposes. Perfect overlap is not possible—roadmapping can act only as an aid to guiding catheters, as it provides the operator with an impression of the surrounding anatomy. It is a useful tool for minimizing fluoroscopy times without compromising

image quality. Static roadmaps may be created from a series of integrated images to improve the image quality. Good image quality in the reference image is important.

Viewing conditions

Optimum viewing conditions are required for interventional radiology since:

- the interventionist needs to see the microcatheters etc. to be able to manipulate them
- the anaesthetist or anaesthesiologist needs to see skin tones in natural lighting conditions to be able to monitor the patient's clinical condition
- viewing the image monitors requires low ambient light to minimize the degradation effects of light scattering on the television screen.

The use of concentrated lighting in the working areas is preferable to general lighting of the whole room. High-quality, low-reflection television monitors should be used. Optimum adjustment of the monitor's brightness and contrast settings is important, and it is desirable to reduce the level of room lighting when X-rays are being used. Viewing distance is an important consideration in being able to see the image without degradation in its quality. Attention should be paid to the monitor's image quality specification.

Quality assurance

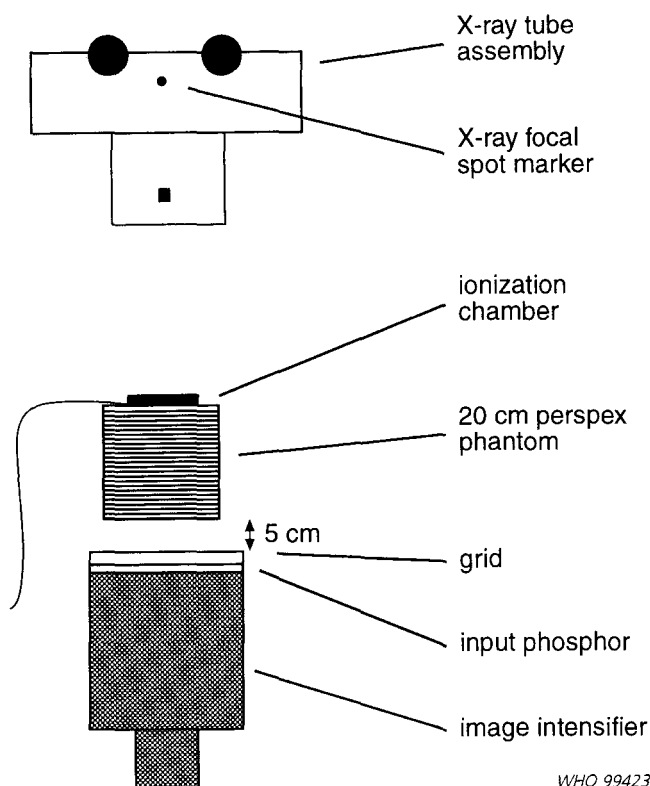
The tube and generator, fluoroscopy and digital imaging performance of interventional radiology equipment should be tested as well as other specific items. A basic list of acceptance tests is given in Table 25. Readers are referred to quality assurance

Table 25. Basic list of acceptance tests for interventional radiology equipment

Acceptance tests	Frequency^a
Reference dose/dose rate values	M
Spatial resolution	M
Field diameter	M
Collimation	M
Contrast resolution	M
Tube and generator parameters	M
Hardcopy devices	M
Processing	D
Anthropomorphic test object	3M

^a M = monthly, D = daily, 3M = 3-monthly.

Fig. 9. Experimental set-up for quality assurance measurements on interventional radiology equipment



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protocols for details of how these measurements are performed (61, 66–84). Protocols for constancy tests may be usefully applied to diagnose any problems in interventional radiology equipment that may arise.

Measurements of reference dose and dose rates during acceptance testing should be performed using a 20-cm water or tissue-equivalent phantom (30 cm may be necessary for cardiac systems)—see Fig. 9. The experimental set-up is based on IEC recommendations. For constancy tests, 1-mm copper or an equivalent material can be used, although the use of water or tissue-equivalent phantom is not precluded.

The service engineer should carry out an annual test of equipment performance in addition to undertaking the service and maintenance tasks. Independent assessment of image performance on an annual basis is highly desirable.

In the future, automated quality assurance procedures may be developed by equipment manufacturers. Such computer-based routines could be used on-line to measure physical image quality indices. Self-diagnostic computer algorithms would then be used to correct equipment performance or prevent examinations being carried out at high doses.

Image simulation

Image simulation could be one method of improving interventional radiology procedures. The impact of changes in technique factors would be displayed prospectively on the reference image. The interventionist would be able to simulate the effect of changing tube potential and tube current. When linked to a device for estimating the dose-area product, the simulator could dramatically reduce patient doses. This may need energy-selective images to be acquired on last-image hold mode.

Low-dose fluoroscopy

A low-dose fluoroscopy technique, known alternatively as region of interest fluoroscopy, has been proposed (85) in which a low-noise image in the centre of the monitor is presented to the radiologist. Surrounding the low-noise image there is a low-dose image. Fluoroscopy is performed using a semitransparent, adjustable circular diaphragm. Various methods of automatic dose-rate control are employed, and computer processing is used to display the two parts of the image at the same brightness level. The correction algorithm for the fluoroscopy images requires knowledge of the tube potential and the position of the filter. Significant reductions in dose to both staff and patients are thus possible, although the dose to the patient in the centre of the field is not reduced. Real-time display of the region of interest fluoroscopy images is achieved.

Contrast media and catheters

New contrast agents continue to be developed. There are theoretical advantages in using contrast agents based on gadolinium, which were initially developed for applications in magnetic resonance imaging. With gadolinium it may be possible to perform examinations at a potential of 90 kV with additional filtration without a loss of image quality or the need for higher output X-ray tubes. The toxicity of such contrast agents is reduced by complexing gadolinium with diethylenetriaminepentaacetic acid (DTPA).

The minimum signal-to-noise ratio necessary to detect any detail is related to the contrast of the object and the dose used to acquire the image. This may be expressed as

$$\text{signal-to-noise ratio} = \text{contrast} \times \sqrt{\text{dose}}$$

Any measure employed to increase the contrast of the object to be imaged therefore offers a possibility of reducing dose. This consideration is especially important when imaging the contrast medium in vascular structures. Methods for the optimal coordinated delivery and timing of contrast agent injection as well as initiation of exposure can thereby contribute to dose reduction.

The radiopacity of catheters is also important in determining dose. It is recommended that the X-ray attenuation be set as high as possible, and manufacturers are encouraged to supply and develop such catheters. The International Organization for Standardization is developing a standard for catheters which will permit the quantification of their radiopacity in a reproducible manner.

2.4.3 The role of reference dose values

Levels of patient dose from interventional radiology vary considerably depending on the clinical and physical characteristics of the patient, the skill of the interventionist and the equipment being used. Reference dose values have been developed for diagnostic medical exposures as a means of promoting strategies to optimize protection by allowing broad assessment of typical practices for general types of procedure within a department. Such values are intended to act as thresholds to initiate internal investigations by departments whose typical practices are likely to be far from optimum and where improvements in dose reduction are probably most urgently required.

Reference dose values are therefore essentially investigation levels and as such should be selected to provide an indication of potentially unacceptable practice. They may, for example, be based on the results of large-scale surveys that take into account the variation in performance between centres. This approach has been successfully applied to common diagnostic X-ray examinations in the United Kingdom: examination-specific reference dose values were set pragmatically at the third quartile values of the distributions of mean doses observed for representative samples of patients at each centre in a national survey (86). Accordingly, the upper dose quartiles have been taken to represent the bounds of potentially unacceptable practice, in which centres are encouraged to carry out urgent investigations with a view to taking corrective action or to provide thorough clinical justification for the use of exceptionally high doses.

Ideally, reference dose values should be expressed in terms that are easily measurable and yet provide some useful indication of patient exposure. For interventional procedures they are probably best expressed in terms of dose-area product, although fluoroscopy time, for example, could be a useful reference quantity for comparing the performance of individual interventionists within a particular department. Appropriate levels should be established nationally, based on measurements on rep-

representative groups of patients which provide indications of typical practice in different institutions. Accordingly, reference dose values should not be applied locally on an individual patient basis, but rather to the mean doses observed for representative groups of patients. Typical dose levels in excess of a reference value should be either thoroughly justified or reduced.

Measurements of patient dose and the establishment of reference dose values for interventional procedures should facilitate comparison of different practices within an X-ray unit, within hospital units, at the national level and eventually at the international level. This should be viewed as a continuing process so as to promote improvement.

2.4.4 Techniques for reducing occupational exposure

Notwithstanding statutory requirements for compliance with occupational dose limits, there is a fundamental need to keep staff doses as low as reasonably practicable (52). Dose constraints may be set prospectively and investigation levels used retrospectively as part of this process of optimizing protection. Within a comprehensive strategy for the management of staff safety, there are three important practical aspects of achieving dose reduction: time of exposure; distance from sources; and the use of shielding.

Reducing both the duration of fluoroscopic screening used during procedures and the number of radiographic exposures is likely to lower the dose received by staff. In general, measures designed to minimize patient exposures will also reduce staff exposures. The skill and training of interventionists will be particularly important in this respect.

Interventionists should also appreciate the importance of positioning themselves as far as possible from the patient couch. For example, moving 30 cm away from the couch could reduce by a factor of 2 the dose from scattered radiation to an individual, independently of the tube potential used (41). Personnel should therefore be aware of the levels of ambient radiation exposure (isodose contours) for the specific equipment in use, taking into account any increased beam filtration. They should also be aware of the higher occupational exposures associated with high-dose-rate fluoroscopy and radiographic imaging, or with particular projections such as the left anterior oblique, cranial, or caudal projection (25).

Personnel should regularly use all the protective measures available, consistent with effective treatment. Measures include use of a remotely controlled mechanical pump for the injection of contrast media (87), ceiling-mounted lead-glass screens to reduce thyroid and eye dose (30), leaded drapes around the table to reduce dose to the lower body, and the wearing of protective devices for the trunk, thyroid, and eyes/head (63). In general, staff dose can be reduced more effectively by shielding the more radiosensitive organs than by wearing thicker lead aprons. For example, when worn

with a 0.35-mm lead apron, a thyroid shield (0.35-mm lead equivalence) will typically be twice as effective in reducing effective dose as changing to a 0.55-mm lead apron (41). Similarly, wearing a lead-acrylic face mask (0.35-mm lead equivalence) in addition to a 0.35-mm lead apron will produce a 7-fold greater reduction in effective dose than wearing a 0.55-mm lead apron.

2.5 Recommendations

1. All personnel involved in interventional radiological procedures should be aware of the deterministic effects and stochastic risks of X-rays. This knowledge should be acquired through education and training programmes (see section 3), whose content should be appropriate to the type of procedure, level of exposure and staff role.
2. Patients should be counselled before undergoing procedures during which the dose is likely to approach or exceed deterministic thresholds, so that their consent is appropriately informed. The counselling should include the likely deterministic effects and the risk of stochastic effects, at the discretion of the physician.
3. Interventionists should know the average radiation doses delivered to patients for the procedures that they commonly perform. Indications of patient exposure should be available to the interventionist during the procedure.
4. Interventionists should aim to avoid deterministic effects and minimize stochastic risks, especially for paediatric patients; all practicable dose reduction methods consistent with the therapeutic purpose of the intervention should be used.
5. Patients should be asked to report any skin tissue problems occurring in the irradiated area after interventional procedures.
6. The dose-area product, estimated maximum skin entrance dose fluoroscopy time, and number of exposures should be recorded for all procedures. For any procedure during which doses approach or exceed the thresholds for deterministic effects, a record should be made in the patient's medical notes of the site of irradiation and the estimated maximum skin entrance dose. When large doses may have been absorbed by organs, organ and effective doses should also be estimated and recorded in the medical notes. Effective and organ doses should be estimated for paediatric patients at lower doses as well.
7. Hospitals should seek to optimize radiation protection for both patients and staff through the adoption of quality assurance programmes. Regular audit of these programmes is essential.
8. It should be considered the duty of all staff to ensure that doses to patients, to other staff, and to themselves are kept to the minimum levels consistent with meeting clinical objectives. All staff should promote the principles of a "safety culture" in interventional procedures.
9. Hospitals should collaborate with national authorities to develop, adopt and regularly review reference dose values for individual types of procedure with the aim of minimizing doses to patients, consistent with the therapeutic purpose of the

intervention. These doses should be used for comparisons between practices within a unit, between hospitals, at national level (through the establishment of national surveys) and eventually internationally.

10. If reference dose values are frequently exceeded, the reasons for this should be investigated formally. Remedial measures should be recommended where appropriate.
11. Occupational exposures of staff to radiation should be monitored to ensure compliance with dose limits and to improve systems of protection. The monitoring strategy should be appropriate to the pattern of exposure. Staff should have confidential access to an occupational health service.

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3.

Training requirements in interventional radiology

3.1 Introduction

Interventional radiology has expanded rapidly over the past 10 years and the procedures used are frequently performed on patient populations with multiple risk factors. The types and complexity of the procedures employed have increased immensely, and the use of X-rays as well as the radiation doses required may differ considerably from those employed in comparable diagnostic radiological procedures.

Some interventional radiological procedures can be associated with life-threatening complications and patient management has therefore become more complex. “Conventional” training of staff (physicians, nurses, radiographers, engineers) does not usually cover the specific requirements and hazards of interventional radiological procedures. In this context, a decision needs to be made on appropriate training material for personnel involved in such procedures.

3.1.1 Scope and objective

All physicians, radiographers, nurses, physicists and service engineers involved in interventional radiology should acquire attitudes and habits that produce optimal clinical results with optimum radiation protection of patients and staff. The realization of these objectives requires full knowledge and sound judgement of the benefits and potential risks associated with the procedures involved. This in turn requires continuing education, taking into account the training objectives specified in these recommendations as well as scientific and technical progress and research.

3.1.2 Training programmes

Basic training for each of the professional groups mentioned in section 3.1.1 is a prerequisite. For specific training in interventional radiology and radiation protection see references 1–3. The training process must be continued when new techniques are introduced, when new radiological systems are installed and also when new staff join the interventional radiology department. Furthermore, continuous training and refresher courses at regular intervals are recommended.

The responsibilities for training must be clearly defined and the training must be conducted by qualified personnel in accredited institutions.

3.1.3 Interventional radiology and other specialities

The practice of interventional radiology requires experience and knowledge not only of radiological procedures, but also of other nonradiological specialities. Accredited programmes for interventional radiologists should therefore be affiliated with institutions that also provide specialized training in other relevant disciplines (e.g. interventional radiology and vascular and/or abdominal surgery, interventional and clinical cardiology and cardiac surgery, interventional neuroradiology and neurology and/or neurosurgery).

3.1.4 Exchange of trainees between hospitals and countries

Requirements for accreditation in interventional radiology programmes should be based on staff experience as well as the number of procedures performed per year at an institution. Institutions with accreditation should therefore be open to members of non-accredited institutions to promote the spread of knowledge and practice. This should be realized on both national and international levels.

3.1.5 Certificate of additional qualification (CAQ) in interventional radiology

The specific training and educational guidelines discussed here should be instituted at the national level to guarantee a high quality of medical service in interventional radiology. To practise *interventional* radiology, cardiology, or neuroradiology, physicians must have certification in the speciality concerned (i.e. radiology, cardiology, or neuroradiology). Training in interventional radiology should at least, in part, be additional to that for the above-mentioned specialities, as required by national standards.

3.2 Medical training of physicians

Basic knowledge of and experience in interventional radiological procedures should be provided by national training programmes for certification in radiology, neuro-radiology or cardiology.

After certification in particular specialities, physicians require further specific training, as outlined below, to allow them to undertake interventional radiological work within those specialities.

3.2.1 Institutional requirements

Training institutions can be accredited for interventional radiology, interventional cardiology, and interventional neuroradiology.

It is suggested that institutions be accredited as teaching centres if they perform at least 300 procedures per year in interventional radiology or interventional cardiology, or at least 100 procedures per year in interventional neuroradiology.

An institution can be accredited for more than one speciality if it fulfils the above-mentioned criteria. Procedures from more than one speciality may not, however, be cumulated to obtain accreditation in only one speciality.

3.2.2 Physicians' requirements

Typically, physicians can be accredited for interventional radiology, cardiology, or neuroradiology if they present proof of at least one year dedicated to full-time interventional radiology in an accredited institution, and at least 200 (interventional radiology and interventional cardiology) or at least 70 (interventional neuroradiology) procedures performed both under supervision and during continuing education.

3.2.3 Specific training

Training for physicians in interventional radiology should include the topics listed below. Apart from thorough procedural training, teaching should emphasize the clinical implications of interventional radiology.

• ***Indications for interventional procedures***

- patient selection
- selection of procedure
- clinical and technical success rates
- benefit–risk assessment
- concurrent therapeutic options.

• ***Procedure performance***

- preparation of the patient
- hygiene
- selection and application of appropriate instruments and materials including contrast media
- medication

- state-of-the-art procedural technique
- patient monitoring (psychological and physiological).

- ***Complications***

- types and incidence
- implications and consequences
- treatment
- emergency management.

- ***Clinical follow-up***

- documentation of procedure
- information and cooperation with referring physicians
- additional therapy
- feedback and clinical outcome.

- ***Medical quality assurance and quality control***

3.3 Medical training of radiographers and nurses

Radiographers and nurses directly involved in interventional radiology should be trained in the topics listed below. The amount of training they need depends on their background and on the tasks they are performing in relation to the patient.

- ***Procedure performance***

- preparation of the patient (pre-procedure)
- information provided to the patient in order to obtain consent for the procedure
- hygiene
- selection and application of instruments and materials including contrast media
- medication
- patient monitoring (psychological and physiological).

- ***Complications***

- types and incidence
- implications and consequences
- treatment
- emergency management.

3.4 Training in radiation protection

3.4.1 Basic topics

It is assumed that personnel involved in interventional radiological procedures will have completed certified training as physicians (board certification, e.g. as radiologists, cardiologists), radiographers, or nurses. A basic understanding of radiation protection, including at least the following aspects, is therefore assumed before training in the specific topics described in section 3.4.2 is undertaken:

- atomic structure
- interaction of electrons and photons with matter
- radiological quantities and units
- physical characteristics of X-ray machines
- physical characteristics of X-ray spectra
- fundamentals of radiation detection
- radiobiology
- fundamentals of quality assurance and quality control
- general radiation protection
- regulations and recommendations concerning radiation.

In addition, adequate knowledge of the safe and correct operation of the specific X-ray systems used for interventional radiology is required.

3.4.2 Specific topics

Education and training in specific aspects of radiation protection in interventional radiology, which should be adapted to the particular tasks and responsibilities of the personnel concerned, should cover the following areas:

- X-ray systems for interventional radiology (Table 26)
- dose quantities in interventional radiology (Table 27)
- radiobiological risks in interventional radiology (Table 28)
- radiation protection of patients and staff during interventional radiological procedures (Tables 29 and 30)
- quality assurance (Table 31)
- local regulations and international recommendations applying to interventional radiology (Table 32)
- optimization of procedures (Table 33).

Table 26. Training requirements for personnel involved in interventional radiology: X-ray systems

Training topic	Personnel ^a			
	P	R	N	S
Continuous and pulsed-beam operation modes	xx	x	0	xxx
High filtration of beam	xx	x	0	xxx
Image intensifier size and image magnification	xx	x	0	xxx
Automatic brightness control	xx	x	0	xxx
High- and low-dose operation modes	xx	xx	0	xxx
Noise level versus suitable image quality and diagnostic information versus cine frame frequency	xxx	xx	0	xxx
Image-storing modes (including last-image hold)	xxx	xx	0	xxx
Use and position of auxiliary items (television terminals, contrast injectors, etc.)	xxx	xxx	0	x
Other capabilities (different operation modes, C-arm settings, grids, etc.)	xx	xx	0	xxx
Effective reception area	xx	xx	0	xxx
Image processing and software programs	xx	x	0	xxx

^a P = physicians, R = radiographers, N = nurses, S = service engineers.

Training requirements: xxx = advanced, xx = intermediate, x = basic, 0 = none.

Table 27. Training requirements for personnel involved in interventional radiology: dose quantities

Training topic	Personnel ^a			
	P	R	N	S
Dose-area product	xxx	xx	0	xxx
Surface dose	xxx	xx	0	xx
Organ dose	xx	x	0	x
Differences between air, surface and depth doses	xx	x	0	x
Backscatter	xxx	xx	x	x
Practical dosimetry (ion chambers, thermoluminescence, personal dosimeters)	xx	xx	x	xx

^a P = physicians, R = radiographers, N = nurses, S = service engineers.

Training requirements: xxx = advanced, xx = intermediate, x = basic, 0 = none.

3.5 Conclusions and recommendations

1. Education and training of physicians, radiographers, nurses, physicists, service engineers and other allied health personnel involved in interventional radiology are necessary and are basic aspects of the overall optimization process.

Table 28. Training requirements for personnel involved in interventional radiology: radiobiology

Training topic	Personnel ^a			
	P	R	N	S
Stochastic effects (somatic and genetic)	xxx	xx	x	x
Deterministic effects	xxx	xx	x	x
Risk estimation during pregnancy (staff and patients)	xxx	xx	x	x
Risk factors for paediatric patients	xxx	xx	x	x

^a P = physicians, R = radiographers, N = nurses, S = service engineers.
 Training requirements: xxx = advanced, xx = intermediate, x = basic.

Table 29. Training requirements for personnel involved in interventional radiology: radiation protection of patients

Training topic	Personnel ^a			
	P	R	N	S
Number of images and frame frequency	xxx	xx	0	xx
Interruption of series	xxx	xx	0	x
Use of different projections to avoid deterministic effects	xxx	xx	0	x
Zooming on image-intensifier	xxx	xx	0	xx
Low-dose and high-dose modes	xxx	xx	0	xx
Coping with questions from patients regarding doses	xxx	xx	xx	0
Patient records on dose-relevant parameters	xxx	xx	0	x
Patient follow-up on possible deterministic effects in high-dose situations and cooperation with other hospital departments	xxx	x	x	0

^a P = physicians, R = radiographers, N = nurses, S = service engineers.
 Training requirements: xxx = advanced, xx = intermediate, x = basic, 0 = none.

2. Education and training in the medical aspects of interventional radiology and in radiation protection must be organized at two levels—basic and specific—as indicated in these recommendations.
3. Radiation protection training must consider patient as well as staff exposure.
4. Installation of new systems, induction of new staff and the introduction of new techniques must be preceded by specific training.
5. Continuous training (updating) including radiation protection aspects must be considered.
6. The level of training in the various topics should be tailored to the professional group concerned.

Table 30. Training requirements for personnel involved in interventional radiology: radiation protection of staff

Training topic	Personnel ^a			
	P	R	N	S
Factors affecting staff doses	xxx	xxx	xx	xx
Use and effectiveness of radiation-shielding equipment	xxx	xxx	xxx	x
Isodose curves by relation to role of staff	xx	xx	xx	0
Rotation of staff in high-dose procedures	xxx	xx	xx	0
Possible interactions between radiation protection of staff and radiation protection of patients	xxx	xx	x	0

^a P = physicians, R = radiographers, N = nurses, S = service engineers.

Training requirements: xxx = advanced, xx = intermediate, x = basic, 0 = none.

Table 31. Training requirements for personnel involved in interventional radiology: quality assurance

Training topic	Personnel ^a			
	P	R	N	S
Concept of quality assurance and quality assurance programmes	xx	xx	0	xxx
Quality control:				
Acceptance tests	x	xx	0	xxx
Status tests	x	xx	0	xxx
Constancy tests	x	xxx	0	xxx

^a P = physicians, R = radiographers, N = nurses, S = service engineers.

Training requirements: xxx = advanced, xx = intermediate, x = basic, 0 = none.

Table 32. Training requirements for personnel involved in interventional radiology: local regulations and international recommendations

Training topic	Personnel ^a			
	P	R	N	S
National regulations	xxx	xxx	0	xxx
International recommendations	x	x	0	x

^a P = physicians, R = radiographers, N = nurses, S = service engineers.

Training requirements: xxx = advanced, xx = intermediate, x = basic, 0 = none.

Table 33. Training requirements for personnel involved in interventional radiology: optimization of procedures

Training topic	Personnel ^a			
	P	R	N	S
Use of reference dose-related parameters	xxx	xx	0	x
Regular review of own reference parameters	xxx	xx	0	0
Reasons for non-agreement with reference parameters	xxx	xx	0	x
Remedial actions to improve compliance with reference parameters	xxx	xx	0	x

^a P = physicians, R = radiographers, N = nurses, S = service engineers.
Training requirements: xxx = advanced, xx = intermediate, x = basic, 0 = none.

- 7. Training should be offered by qualified persons in accredited institutions.
- 8. Training should be evaluated and accredited on an individual basis.
- 9. Training should cover theoretical as well as practical aspects.
- 10. Elaboration of teaching material for specific training in interventional radiology should be promoted.

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4.

Equipment, technical aspects, improving performance

4.1 Introduction

The aspirations of interventionists to perform more complex procedures have been matched by the desire of manufacturers to design and market systems that meet these perceived requirements. Complex, time-consuming procedures often result in high dose levels of radiation to staff and patients (1–4, and A. Den Boer, personal communication 1994). Dose levels may be such that significant deterministic effects are reported in patients undergoing interventional procedures.

The equipment used for interventional procedures is based on equipment intended for specific diagnostic investigations rather than for interventional techniques. The different nature of interventional procedures demands that the basic design criteria be re-evaluated and that optimization strategies be employed. In other words, the imaging requirements for embolization of the gastrointestinal tract are different from those for a barium enema: in the former there is a need, *inter alia*, for dedicated interventional radiology equipment with a high-quality image intensifier and a high-specification tube and generator.

4.2 Equipment specification

Specifications for equipment should facilitate the selection and procurement of radiological imaging units for interventional radiology (5). When the purchase of interventional equipment is being considered, there is likely to be budgetary pressure to buy the least expensive unit. However, the purchase of an inappropriate unit as a result of this pressure could:

- compromise the efficacy of interventional procedures performed by the unit
- affect the radiation dose to both patients and staff
- result in litigation if complications occur.

In an attempt to prevent outcomes of this nature, a series of purchase specifications is presented here to provide guidance to prospective purchasers. The specifications have been categorized according to the various aspects of the interventional radiology imaging chain. They should be regarded as a minimum and should not preclude the purchase of higher performance equipment. Currently, manufacturers tend to

offer units for interventional radiology that are specifically designed for a particular group of procedures (e.g. interventional neuroradiology). However, in some hospitals the purchase of a single unit for a relatively limited number of procedures may not be justified and a compromise between different imaging requirements then needs to be made.

Guidance on purchase specifications for interventional radiology equipment is given in Tables 34–38. This information is based upon a critical analysis of recommendations made by the following organizations:

Bundesamt für Strahlenschutz [German Central Agency for Radiation Protection]
 Bundesärztekammer [Federal General Medical Council]
 Bundesministerium für Arbeit und Sozialordnung [Federal Ministry for Employment and Social Affairs]
 Deutsche Gesellschaft für Herz- und Kreislaufrorschung [German Society of Cardiovascular Research]
Kassenärztliche Bundesvereinigung (association of physicians under contract to a health insurance fund)
 United States Food and Drug Administration
 Zentralverband des Elektroindustrie [German Central Association for the Electrical Industry]

Some explanation for the underlying considerations associated with the information given in Tables 34–38 is needed. Equipment with an undercouch X-ray tube and an overcouch image intensifier is recommended for interventional radiology because of the scattered dose levels at the couchside. Equipment with an overcouch X-ray tube and undercouch image intensifier is designed to be used remotely, and in this mode the operator's exposure to radiation is low. Such equipment is primarily designed for uses other than interventional radiology. If equipment operators stand by the couch during interventional radiology, they will receive unacceptably high radiation exposure unless protective shielding is always used. Such shielding may of course interfere with the clinical objectives of the procedure.

Source intensifier distance tracking (see Table 34) refers to a feedback mechanism in the generator control circuitry which limits the patient's maximum dose rate at the entrance surface (see section 2). This mechanism ensures that the equipment does not automatically adjust the tube current to a level at which the maximum dose rate recommended by the regulatory authorities is exceeded (6).

A computer interface for dosimetry information (see Table 34) facilitates the automated collection of dosimetry data. This is useful for comparing with reference dose levels typical doses for a group of patients undergoing a particular procedure, as part of a strategy for patient dose reduction.

Table 34. Equipment purchase: general specifications

Purchased equipment should conform to all relevant standards published by the International Electrotechnical Commission (7), national regulations, and recommendations contained in the International Basic Safety Standards (6) applicable to interventional radiology

-
- Overcouch image intensifier, undercouch X-ray tube geometry (recommended)
 - Source intensifier distance tracking (desirable)
 - Low attenuation table
 - Table and image intensifier designed for ease of handling
 - Concave couch top for patient comfort (desirable)
 - Means of assessing dose–area product
 - Staff protective shielding
 - Display of fluoroscopy time, number of exposures, maximum skin entrance dose, and total dose–area product. Separate display of fluoroscopy dose–area product and radiographic dose–area product (recommended)^a
 - Computer interface for dosimetry information
 - Iso-scatter distribution diagrams for normal and boost-mode operation
 - Minimum size of image store
 - Roadmapping facility
 - Automatic injector (desirable)
 - Means of patient immobilization
 - Clear labelling of all instrumentation and switches
 - Minimum focus skin distance 30 cm
-

^a See also Table 40.

Roadmapping (see Table 34) refers to a computer program used as a guide for the operator when manipulating catheters. The exact mechanism associated with image formation varies according to equipment and has been described in section 2.4.2. This facility is recognized as a useful means of reducing dose to staff and patients.

With pulsed fluoroscopy (see Table 35), the pulse rise time is important. In paediatric cardiology pulse rise times of 1–5 ms are desirable; otherwise 40-ms pulse rise times are required.

There is debate about the design and operational characteristics of automatic dose and dose-rate control systems for equipment for interventional radiology (8, 9) and there is no clear strategy for optimizing these systems. In the meantime it is suggested that the operating characteristics of the automatic dose and dose-rate control systems should be determined and be adjustable.

Table 35. Equipment purchase: specifications for X-ray tube/generator

<ul style="list-style-type: none">• Focal spot size as defined in IEC 336• Typical focal spot sizes:<ul style="list-style-type: none">cardiology 1.2/0.5 mmneuroradiology 1.2/0.4 mmperipheral vascular 1.2/0.5 mm• Minimum focus skin distance 30 cm• Heat capacity of X-ray tube adequate for all anticipated procedures without time delay• 80-kW generator• Constant potential generator (multipulse frequency convertor or 3-phase 12-pulse)• Tube voltage waveform ripple <10%• Automatic collimation to size of image-intensifier input surface• Pulsed fluoroscopy facility in addition to continuous fluoroscopy• Pulse rise times:<ul style="list-style-type: none">paediatric cardiology 1–5 msother procedures 40 ms		
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Table 36. Equipment purchase: specifications for image-intensifier television chain and dose control systems

	<i>Diameter</i>	<i>Maximum dose rate^a</i>
Cardiology	25 cm	0.6 μGys^{-1}
Neuroradiology	25–30 cm	0.6 μGys^{-1}
Peripheral vascular	35–40 cm	0.2 μGys^{-1}

<ul style="list-style-type: none">• $\times 2$ magnification• Low dose-rate and boost modes in fluoroscopy• Manual selection of operation level of the automatic dose-rate control setting (desirable)• Operation design characteristic of the automatic dose-rate control should be specified• Clear and unambiguous indication of automatic dose-rate control characteristic or dose output selected• User-selectable tube potential/tube current characteristic of the automatic dose-rate control• Less than 1 second delay between depression of foot-switch and display of image• Last-image hold• Diaphragm position indicator on last-image hold (desirable)		
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^a Normal-mode operation; measured at the entrance surface of the image intensifier.

Table 37. Equipment purchase: specifications for acquisition and display mode

• High-level or boost mode (desirable)
Cardiology:
12.5–60 frames/s
625-line display (minimum)
x2 zoom
512 × 512 digital image matrix (minimum)
temporal resolution 10–20 ms in fluoroscopy mode
Neuroradiology:
3–30 frames/s
625-line display (minimum)
x2 zoom
512 × 512 digital image matrix (minimum)
temporal resolution 30–40 ms in fluoroscopy mode
General vascular:
up to 12 frames/s
625-line display (minimum)
x2 zoom
512 × 512 digital image matrix (minimum)
temporal resolution 100 ms in fluoroscopy mode

**Table 38. Performance specifications:
23–25 cm image intensifier**

<i>Acquisition mode</i>	Dose/frame (μGy)
Digital spot imaging	1–5
DSA	3–20
DCA	0.1–0.15
Cinefluorography	0.15–0.3
100-mm camera	1
	Resolution ^a (line-pairs/mm)
Fluoroscopy	1.2
Digital	1.0
100-mm camera	2.5–4
Cinefluorography	2.8
Hard-copy film	1

^a Depending on television standard.

4.3 Patient dose control

Interventional radiology differs from almost all other aspects of diagnostic radiology in that deterministic effects as well as stochastic effects may occur. It is therefore important to consider ways to minimize the occurrence of both types of effect. It is clearly important to provide equipment fitted with a means of assessing the maximum skin entrance dose.

A number of means are available for indicating to the operator the skin entrance dose. Studies indicate that the proportion of the total dose to patients from fluoroscopy varies widely. As a consequence, the total fluoroscopy time elapsed is not necessarily a good indicator of deterministic effects. It is suggested that the estimated maximum skin entrance dose be displayed at the operator's console. There are no currently available technical solutions for assessing skin entrance exposure. However, the following approaches are currently being developed:

- calculation of skin entrance dose from the generator settings, assuming a given focus skin distance
- direct measurement of the X-ray tube output, also assuming a given focus skin distance
- use of a large area, field-size-sensing ionization chamber which measures dose–area product and field size, together with a means of directly assessing focus skin distance

Equipment that uses the last-mentioned approach is currently at the development stage and is not yet commercially available (10). The first two approaches assume a given focus skin distance; methods of assessing this may be developed by equipment manufacturers in the future. All approaches make a general assumption about the back scatter factor (usually taken to be 1.2). Rather than estimate skin entrance dose by assuming a particular focus skin distance, it is permissible to specify it at a reference plane, obviating the need to assess the patient's position. This approach yields an estimated maximum skin entrance dose to an accuracy better than that for the onset of deterministic injuries. This is considered to be an acceptable *ad interim* solution.

If skin entrance dose can be assessed more accurately through technical innovations, the above-mentioned approaches should be encouraged, since they will provide more precise information about the onset of deterministic injuries. All approaches assume that the same area of the patient is irradiated all the time. This is clearly a worst-case estimate, but it may be possible to improve on this through position sensing or observational studies (2, 11) on interventional procedures.

Measurement of the total dose–area product is essential for estimating the stochastic effects associated with interventional procedures and is also useful for comparing techniques and procedures. In addition, separate determination of radiographic and fluoroscopic dose–area products is desirable for:

- research
- teaching/training
- optimization studies.

Use of a dose limitation approach has been suggested (12) but, since its application to interventional radiology could imply that a procedure would be halted if the dose

Table 39. Summary of dosimetry information for interventional radiology

Fluoroscopy time	Required
Number of exposures	Required
Estimated maximum skin entrance dose	Required
Total dose–area product	Required
Fluoroscopy dose–area product	Recommended
Radiographic dose–area product	Recommended

were too high, it was concluded that under no circumstances should dose limits in any form be introduced. Reference doses that apply to a group of typical patients are a different concept, however, since they are a useful means of optimizing patient protection. The critical issue here is that if the examination is clinically justified at the outset, the physician must be able to complete the interventional procedure without any interference or hindrance. In this context it was felt that the display of dose information would be of assistance in providing the physician with information about the impending onset of deterministic effects.

Many display options for dose information are available. However, display of the cumulative maximum estimated entrance skin dose relative to the onset of deterministic effects has the merit of providing the physician with a suitable warning. Display of the instantaneous dose–area product rate, on or by the physician's monitor, would also emphasize the need to avoid high-dose-rate techniques in combination with large field sizes.

Although other dosimetry information could be displayed, it might well be overlooked among the multitude of other patient-monitoring displays. It is especially important that physicians receive instruction on the significance of the displayed data. The use of audible dose or dose-rate alarms is not appropriate since such alarms could be confused with those emitted by physiological measuring equipment.

Comprehensive dosimetry information should be available at the operator's control and is summarized in Table 39. These data should be entered on the patient's record at the end of the examination.

4.4 Approaches to the reduction of patient dose

In dose optimization, the fundamental issue is the extent to which radiation dose can be reduced without undue degradation of image quality. It is essential to determine what constitutes clinical image quality for specific interventional procedures. Unfortunately, there are no widely recognized clinical image quality indices for interventional radiology. It is surprising that so few studies have been carried out in this

area, particularly since dose is a user-selectable variable on current digital imaging equipment.

Interventional radiology equipment that employs digital imaging technology offers the operator the opportunity of reducing radiation doses without necessarily impairing clinical image quality. Dose, and hence image quality, are user-selectable variables (13). At a low dose per frame, increasing the dose improves image quality because quantum noise (caused by the small numbers of photons used to form the image) is reduced. Beyond a particular level, increasing the dose does not improve clinical image quality since other noise sources (e.g. electronic) begin to predominate. Flexibility in the selection of technique factors may be used to reduce dose. However, it is important to ensure that the clinical objectives of the interventional procedure are not compromised.

Many approaches to dose reduction in interventional radiology involve making a compromise between image quality and radiation dose; it is therefore important to determine image quality criteria for interventional procedures and patient dose reference levels. Since interventionists have to be satisfied with the image quality, it is difficult to recommend specific methods for dose reduction, although generic approaches may be suggested.

Image quality criteria for interventional radiology have not been studied. Visualization of the reflux of embolization material in interventional neuroradiology has been proposed as a candidate criterion for image quality. Existing criteria, based on radiographic positioning, are inappropriate for interventional radiology.

Different clinical approaches and protocols exist in individual institutions, but no peer-reviewed studies have been published on their efficacy, dose, and image quality criteria. This is a clear indication for multicentre studies to examine this general problem.

The absence of accepted indices for image quality poses an ethical dilemma for equipment manufacturers. There is a need to minimize radiation dose levels because of the risk of deterministic effects. While some physicians may worry about stochastic effects, many do not. For the former group, guidance on approaches to dose reduction is needed. For interventional radiologists who are relatively unaware of radiation protection matters, the dominant criterion when selecting equipment is image quality.

The lack of image quality criteria has meant that no accepted approaches to the optimization of interventional radiology procedures have been developed. One method proposed was to image microcatheters under conditions approximating those that occur clinically, so that the assessment would need to be performed in the presence of a scattering medium. Such an approach would also have to be linked to the forth-

coming standard on the opacity of catheters currently being developed by the International Organization for Standardization.

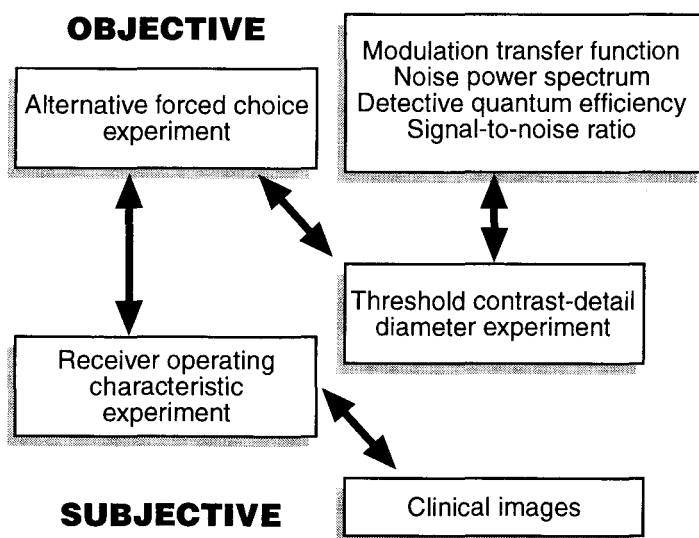
A general approach to the optimization strategy was proposed. There is a need to define image quality criteria and link them to measurable physical indices of performance. Such indices should be studied in order to develop optimized interventional procedures. There is a hierarchy of image quality assessment methods, and these are summarized in Fig. 10.

4.5 Reduction of occupational exposures

4.5.1 Introduction

Most occupationally exposed individuals working in hospital diagnostic radiology departments receive radiation doses that are considerably lower than doses received from natural background radiation. However, since occupational doses are additional to natural background doses it is important that the former be minimized. Analysis of personal monitoring results reveals that a typical radiologist in the United Kingdom receives an annual radiation dose of 0.18 mSv, which is approximately 14 times lower than that normally received by an average member of the general population (14). The situation is similar in other European countries. Over the years there

Fig. 10. Hierarchy of image quality assessment methods



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has been a gradual decline in occupational exposure levels to staff working in diagnostic radiology departments, reflecting a good safety culture and improvements in X-ray equipment.

During radiographic examinations, staff stand at the operator's console during X-ray exposures. When these examinations are performed using fixed X-ray equipment, a protective barrier constructed from materials that substantially attenuate radiation will be interposed between the patient and the operator. In consequence, the operator's dose is relatively low and may be regarded as insignificant.

During fluoroscopy, higher radiation doses to staff occur because some individuals stand adjacent to the patient's couch. Scattered radiation levels are highest close to the scattering source—the patient. Staff wear protective aprons but these are less effective at attenuating radiation than the fixed protective barrier discussed above.

Interventional radiology has a number of implications for staff monitoring and minimization of doses to staff. Radiation doses received by staff tend to be higher than those received during other types of examination because interventional radiology procedures usually involve extended fluoroscopy times and a large number of exposures. As interventional radiology procedures become more prevalent, the declining trend in average occupational exposures for staff working in diagnostic radiology departments may be reversed. If their workload is sufficiently high, staff could potentially receive doses approaching one of the limits suggested by the Interventional Commission on Radiological Protection (12, 15). In addition, patients undergoing interventional radiology procedures usually require physiological monitoring or perhaps even anaesthesia. Thus more staff will be present during many interventional radiology procedures than during diagnostic procedures.

The individual performing interventional radiology procedures needs to be able to manipulate catheters and other devices close to the patient. It is therefore impractical to use lead curtains suspended from the image intensifier as a means of limiting staff doses, as is common practice on undercouch X-ray tube equipment designed primarily for barium studies. As a consequence, scattered radiation levels at the side of the couch are higher in interventional procedures.

Because of the above-mentioned factors it is important to develop adequate monitoring arrangements for staff working in interventional radiology. Moreover, since doses to staff may increase, methods of minimizing radiation exposures need to be investigated.

4.5.2 Monitoring

Staff working in interventional radiology who may be exposed to radiation should be adequately monitored for the radiation dose they receive; monitoring results

Table 40. Suggested action levels for staff dosimetry results

Monitor position	Period worn (weeks)	Action level (mSv)
Body	4	0.5
Eyes	4	5
Hands/extremities	4	15

should be interpreted by a qualified medical physicist. Individuals should be provided with one or more dosimeters to wear at prescribed positions. Usually one dosimeter is issued to monitor whole body dose; this is worn either below the lead apron at waist or chest level or above the apron at collar level. However, practices vary according to centre and country.

The fundamental problem with the use of a single dosimeter worn in conjunction with a lead apron is that it does not usually provide a good estimate of effective dose (16). Staff may also be asked to wear dosimeters in addition to those used to assess whole body or effective dose. Under certain circumstances an individual's eye, hand or thyroid dose may approach a dose-limit (17, 18) and additional dosimeters may be issued to monitor these particular areas.

One method of limiting occupational exposures in interventional radiology is to use local action levels. When a dosimeter reading exceeds the appropriate action level given in Table 40, an investigation is undertaken to assess why this occurred and how the dose can be minimized. These action levels are set below the dose levels at which an individual would need to be classified as a radiation worker and are intended to act as a constraint on staff doses.

4.5.3 Minimization of staff exposure

In interventional radiology, the lead-equivalent aprons worn by staff to shield them from radiation are available in a range of lead equivalences. Clearly it is desirable for staff to minimize the dose they receive by wearing appropriate protective clothing. However, it is impractical to recommend that staff wear thick lead aprons; these may be heavy and uncomfortable to wear, and a situation could develop in which patient and staff doses increase because the radiologist takes longer to perform a procedure due to fatigue. This illustrates the need to optimize personal shielding in interventional radiology (11).

The objective when optimizing personal shielding is to minimize the effective dose to the individual. Techniques for reducing occupational exposure are outlined in section 2.4.4 (11). Increasing the lead equivalence of a protective apron above

0.35 mm has only a marginal effect in reducing effective dose. In contrast, wearing additional shielding in the form of a thyroid shield or lead-acrylic face mask will substantially reduce effective dose, by an amount that is always greater than can be achieved by increasing the lead equivalence of the protective apron. Installation and use of articulated, ceiling-suspended, lead-glass viewing screens can also reduce staff doses.

As discussed in section 2.4.4, exposure in interventional radiology can also be minimized by having staff stand at locations in the room where scattered dose rates are reduced. This implies that the individual has a knowledge of the measured isodose curves around the X-ray unit (19). Measured isodose curves are also useful in the predication of staff doses. Provided that it is possible, taking one step back away from the couch will reduce the effective dose by a factor of 2. This reduction is greater than that achieved by exchanging a 0.25-mm lead equivalence apron for one which is 0.55-mm equivalent (11).

Staff training is an essential component of a strategy for the minimization of occupational exposures in interventional radiology. All staff should be provided with practical training in how to reduce the dose they receive.

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5.

Summary and conclusions

There has been a rapid increase in interventional radiology over the past 25 years. Over the period 1984–94, it has been estimated that the frequency of interventional radiology procedures rose 30-fold. Technological developments in X-ray equipment, guide wires, and microcatheters have inevitably led to the rapid evolution of new and improved clinical approaches to interventional radiology. Demand for interventional radiology in many countries (both developed and developing) is likely to increase because of health care economic issues and a general rise in the levels of heart disease and other clinical conditions. The advantages of interventional radiology to the patient are that it is less invasive than a surgical operation and may be performed on an outpatient basis. The age distribution of patients undergoing interventional radiology is biased towards the 40–80-year age group. However, significant numbers of children also undergo these procedures.

Interventional radiology is characterized by patient radiation doses that are relatively high compared with diagnostic X-ray examinations. These high doses arise due to a combination of extended fluoroscopy times, elevated fluoroscopy currents, and the number of radiographic images acquired. In some instances dose levels may exceed the threshold for deterministic effects. Stochastic effects may be an important consideration in justifying use of interventional procedures for certain groups such as children.

In view of the potential for high patient and staff doses, it is recommended that all individuals involved with interventional radiology procedures be aware of the potential for both stochastic and deterministic effects. It is therefore essential that all such individuals receive adequate training in radiation protection principles.

The rapid expansion in interventional radiology has inevitably led to difficulties in the training and education of individuals in the technique. These difficulties involve both radiology training and other clinical specialities that employ interventional radiology. Training non-radiologists from other clinical specialities is particularly important since they may have received little or no formal training in either radiology or radiation protection. Such training should not be limited only to physicians, but should include also radiographers, nurses, engineers, and medical physicists.

Adequate education and training of personnel is fundamental to optimization of interventional procedures. It is recommended that:

1. Education and training in interventional radiology and radiation protection be provided at two levels—basic and specific.
2. Education and training programmes should consider the protection of both patients and staff.
3. The installation of new or modified equipment as well as the induction of new staff must be accompanied by specific training.
4. Training and education programmes should be documented and accredited by professional bodies, should be performed by suitably qualified individuals accredited by professional bodies, and should take place in accredited institutes. Each course should be individually appraised and accredited. A continuing medical education scheme to ensure that individuals regularly attend training courses throughout their career is recommended.
5. The training should be tailored to meet the requirements of the various professional groups involved. Both practical and theoretical tuition should be offered.
6. Since there is a dearth of good teaching material on interventional radiology, there is a need to evaluate the material that does exist and develop more, including computer-aided learning techniques.

Because interventional radiology procedures may result in patient doses that approach or exceed the threshold for deterministic effects, appropriate patient consent should be obtained beforehand. Counselling should include information on the likely deterministic effects and the risk of stochastic somatic effects, at the discretion of the physician. As part of this process, patients should be encouraged to report problems with skin tissue that arise after the interventional procedure.

The costs of purchasing, installing, maintaining, and running interventional radiology equipment have significant budgetary implications. With the increasing demands that are placed on health care budgets, it is vital that appropriate equipment be specified and purchased. In this respect, careful consideration of the technical specification of interventional radiology equipment is necessary. Close attention to the planning and project management aspects of the equipment procurement process is desirable. Ideally, interventional radiology should be performed in large specialized institutions, in radiology departments that are close to emergency and surgical departments.

Although some patient dose study results have been reported here, there are serious shortcomings in the peer-reviewed literature in this area. It is essential that the dose that may be delivered is known, so that the interventionist can counsel the patient. Patient dose information is needed in order to check that the interventional procedure is justified. Such justification may also involve a consideration of the doses

received by staff. In any event, deterministic effects should be avoided and stochastic risks minimized through use of patient dose reduction techniques, consistent with the overall clinical objective of the procedure.

Given that there are significant differences in practice between different interventionists, doses received by patients and staff will vary widely between centres. Multi-centre studies are needed to establish the effect of clinical procedures on patient and staff dose levels. There is also a need to estimate the collective effective dose to the population from interventional radiology procedures.

Patient dosimetry in interventional radiology is required to assess stochastic effects and to determine whether the dose approaches the level at which the onset of deterministic effects occurs. It is recommended that interventional radiology equipment be required to provide an indication of the following:

- total fluoroscopy time
- number of radiographic exposures
- estimated maximum skin entrance dose
- total dose–area product.

Separate displays of fluoroscopic and radiographic dose–area products should be provided on interventional radiology equipment. Novel approaches to patient dosimetry will need to be developed, such as on-line dosimetry systems. In the future, such systems should be capable of indicating when the entrance surface dose approaches the level for the onset of deterministic effects, e.g. erythema.

The development and use of reference dose levels is recommended since such doses can be used for comparative purposes and to identify good practices. If reference dose levels are exceeded, the reasons should be investigated. An action plan and timetable for remedying the situation should be considered.

Radiation dose levels to staff should be monitored and regularly reviewed to ensure that doses are less than the limits set. Staff should have confidential access to an occupational health service.

Interventional radiology is performed using fluoroscopy equipment comprising an image intensifier television system, possibly with digital imaging capabilities. These systems usually operate under automatic dose-rate control, keeping the dose rate constant at the input surface of the image intensifier. The performance of these systems can drift over a period of time; for example, any change in the response of the image intensifier, coupling optics, or television camera would be compensated by the automatic dose-rate control. Any decrease in the conversion gain of the image intensifier would lead to a commensurate increase in dose rate at the image intensifier input surface. This could result in an increase in patient dose without the operator's knowl-

edge. It is therefore essential to implement a routine quality assurance programme, including measurement of the dose rate at the image intensifier input surface. Regular audit of the quality assurance programme is essential and facilitates establishment of a good safety culture.

Some approaches to the optimization of interventional radiology procedures involve accepting a lower image quality in order to reduce the patient dose. Critical to the implementation of this strategy is the development of suitable indices for image quality criteria and patient dose reference values. In the optimization process, it is clearly inappropriate to reduce image quality to a level that compromises the clinical objective of the interventional procedure. Image quality criteria for interventional radiology have not been developed; however, criteria based on radiographic positioning are appropriate for this purpose.

Interventional radiologists in different centres use a variety of clinical approaches and protocols. For some interventional procedures it is unclear which of the procedures is optimal. Moreover, there have been no published studies in the peer-reviewed literature on efficacy, dose, and image quality criteria.

The lack of accepted indices for image quality poses problems for X-ray equipment manufacturers. Many physicians purchase equipment on the basis of image quality, and want equipment that operates in a high-dose, high-image quality mode. A considerable effort is therefore needed to ensure that the equipment available on the market is optimized for image quality/dose rather than the dose and image being maximized. Unfortunately, there are no accepted approaches to the optimization of interventional radiology procedures.

Annex

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Interventional radiology procedures are becoming ever more important in the effective diagnosis and treatment of both cardiovascular and non-vascular diseases. Their use facilitates – and often replaces – surgery, thus reducing hospitalization time; in fact, many interventions can now be undertaken on an outpatient basis. However, interventional radiology typically involves more prolonged exposure to radiation than conventional X-ray examination, and the benefits of the procedure must therefore be carefully weighed against safety considerations, both for patients and for clinical staff.

This publication reflects continuing efforts by WHO to improve the quality and safety of radiological services. It describes the principal interventional procedures and their applications, and examines the associated risks. Measures for reducing exposure of patients and staff are considered – and, indeed, emphasized – throughout the book. The importance of adequate and continued training of medical staff of all levels is stressed. Guidance on equipment specifications is also provided, underlining again the need to achieve a rational balance between clinical efficacy and reduction of radiation exposure.

Clinicians and public health administrators alike will find much valuable information in this book, whether their interests lie principally in the purchase of new equipment for a single medical facility or in the establishment of interventional radiology services at the national level.

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ISBN 92 4 154529 1