Efficacy and radiation safety in interventional radiology

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Efficacy and radiation safety in interventional radiology.

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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.

Contents

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

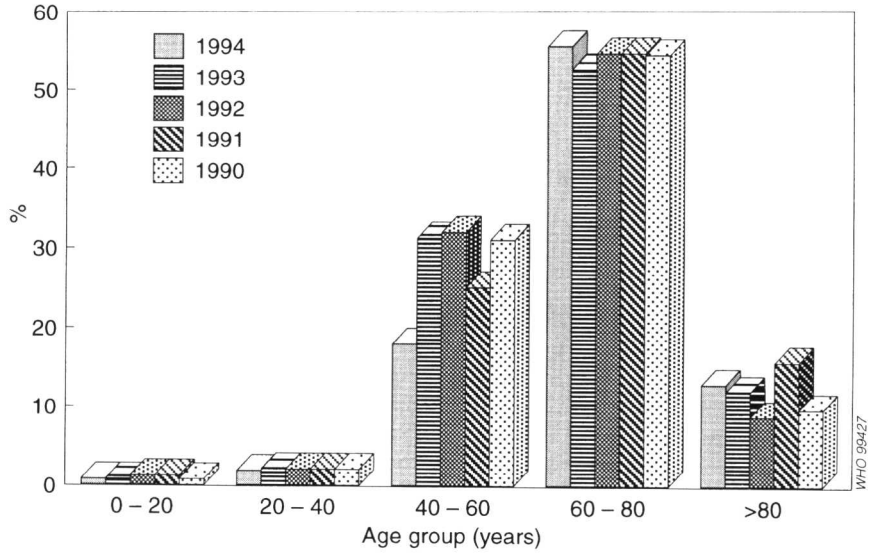
Interventional radiology comprises image-guided therapeutic interventions. Access is percutaneous and these procedures are therefore usually performed under local anaesthesia and/or sedation. Originally, guidance was provided by X-ray fluoroscopy, but more recent procedures also employ ultrasound, computerized 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 extracorporeal circulation. These advantages have made it possible to treat isolated and multiple vascular stenoses, thereby possibly extending life expectancy.

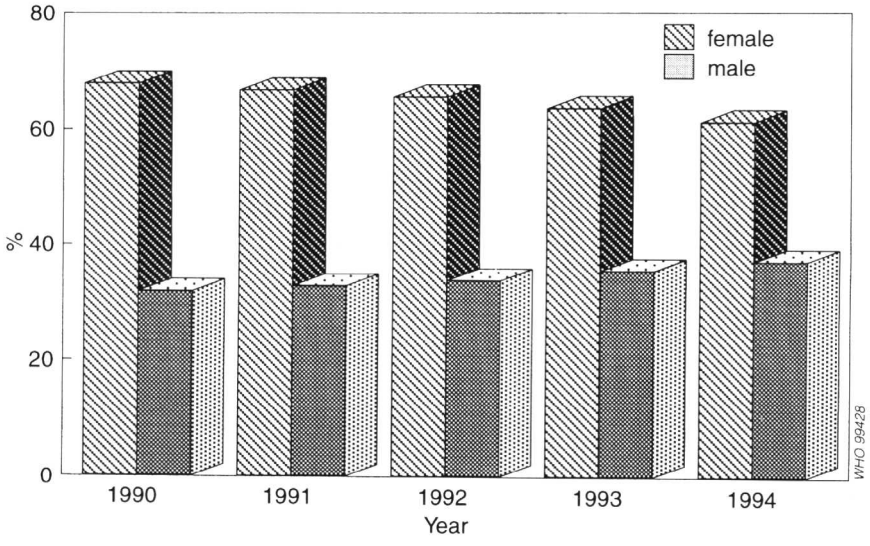
In Germany the age distribution of patients treated with angioplasty in the five years 1990–1994 showed little significant variation (Fig. 1). The sex distribution, by contrast, reveals a slowly increasing percentage of women (Fig. 2), which is attributable to changing risk factors (e.g. cigarette smoking).

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



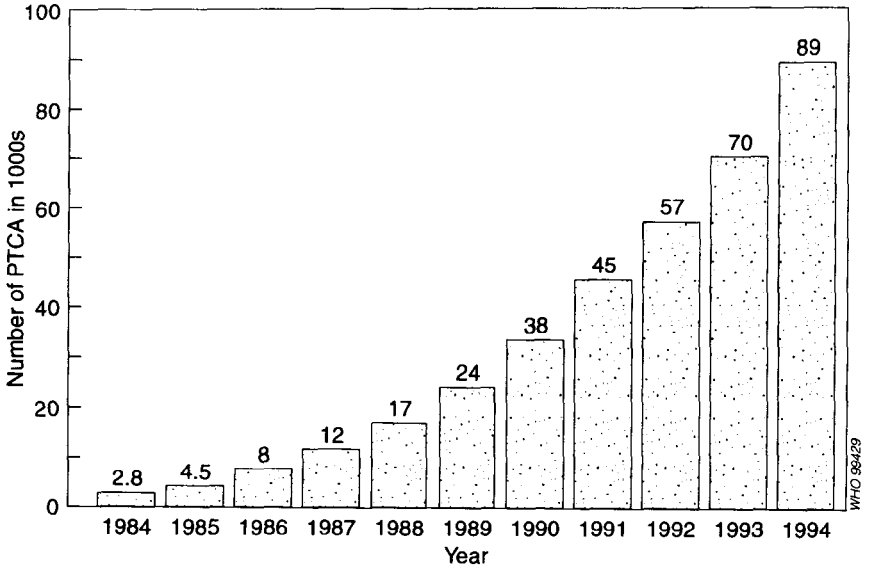
In 1983, 188 000 coronary artery bypass operations were performed in the USA; by 1986 this number had increased to 284 000. Percutaneous transluminal coronary angioplasty (PTCA) procedures increased similarly, from 32 300 in 1983 to 133 000 in 1986 (*5*, *6*). In the early years PTCA was performed mostly in patients with single-vessel coronary disease. Subsequently, however, the technique has also been applied, with increasing success, to patients with multivessel disease, multiple subtotal 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 interventionelle* (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)**
• Discrete (<14 mm length)	• Tubular (10–20 mm length)	• Diffuse (>20 mm length)
• Concentric	• Eccentric	• Excessive tortuosity of proximal segment
• Readily accessible	• Moderate tortuosity of proximal segment	• Extremely angulated segments (>90°)
• Non-angulated segment (≤45°)	• Moderately angulated segment (>45°, <90°)	• Total occlusion >3 months old
• Smooth contour	• Irregular contour	• Inability to protect major side branches
• Little or no calcification	• Moderate-to-heavy calcification	• Degenerated vein grafts with friable lesions
• Not totally occlusive	• Total occlusion <3 months old	
• Not ostial in location	• Ostial in location	
• Absence of thrombus	• Bifurcation lesions require double guide wires	
• No major branch involvement	• Some thrombus present	

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



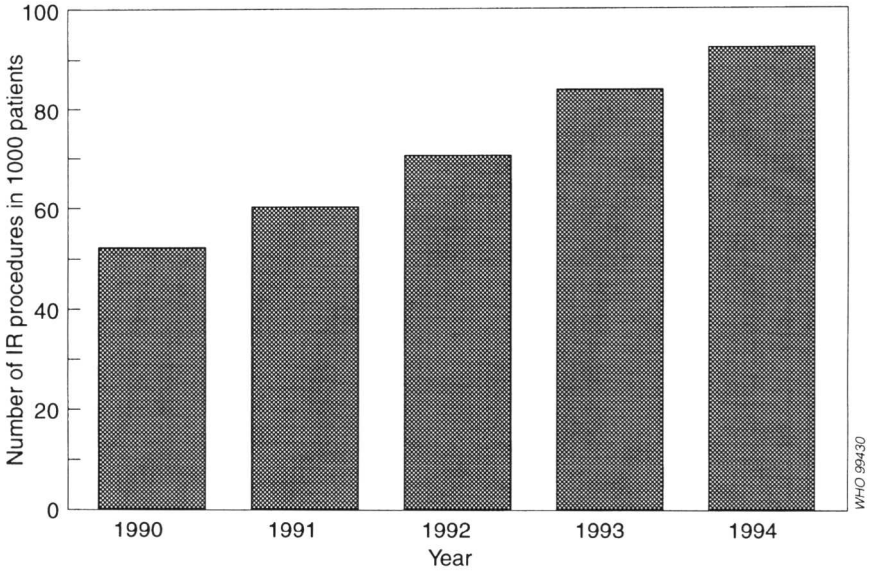
While the numbers of coronary angioplasty interventions are unlikely to increase significantly in the highly industrialized countries, catheter-guided ablations have gained in importance in recent years and continue to show an upward trend. In Germany, the number of these procedures rose from 1101 in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



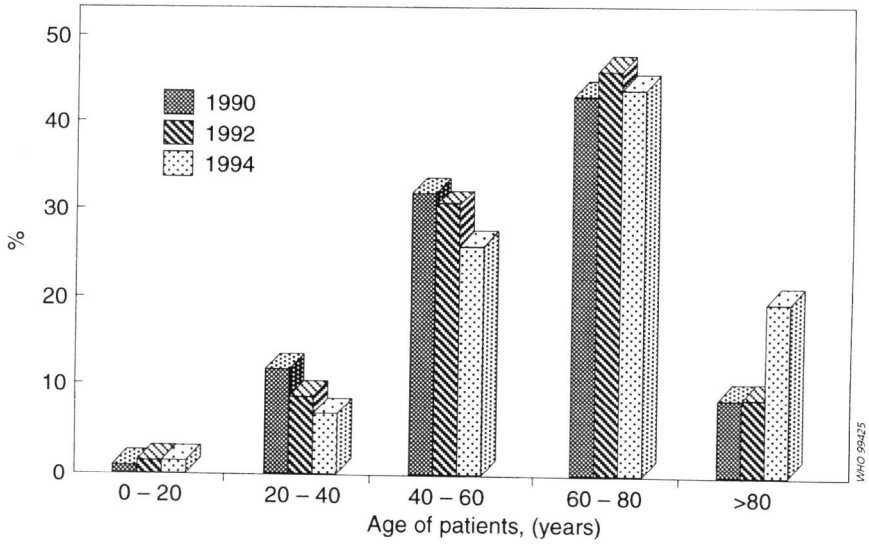
genitourinary, gastrointestinal, and musculoskeletal systems are performed not only by radiologists but also by specialists from other medical disciplines. These procedures are performed under X-ray fluoroscopy, CT, or ultrasound guidance or under endoscopic control. Registration data from Germany reveal 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] typical threshold absorbed dose (Gy)[b]	usual fluoroscopy dose rate of 0.02 Gy/min	high-level dose rate of 0.2 Gy/min	Time to onset of effect[c]
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.