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No. 42

Establishing and Improving Interventional Radiology



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ESTABLISHING AND IMPROVING
INTERVENTIONAL RADIOLOGY

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FOREWORD

Patients around the world stand to benefit from the dynamic discipline of interventional radiology, which has transformed the very paradigm and practice of medicine through a broad spectrum of image guided, minimally invasive procedures. Such image guided, often catheter based, interventions are now widely used and are generally quicker, less risky, less painful and more cost effective, and confer shorter recoveries than counterpart open surgeries. Moreover, image guided procedures can usually be conducted under local anaesthesia or intravenous sedation.

For example, in common epidemiological interventional radiology applications, the majority of masses can be biopsied under image guidance rather than open surgery, and the preferred management of post-operative abscesses requiring drainage is percutaneous, rather than open surgical drainage. Therefore, interventional radiology is indispensable to modern health care, having grown into a distinct branch of radiology with defined curricula and practice requirements in several regions.

A range of specialists worldwide provide individualized, image guided adult and paediatric patient services across the continuum of disease management and control pathways, with geographical speciality variability. Image guided patient procedures are performed primarily by interventional radiology specialists, but cross-over between specialities exists. For example, image guided cardiac interventions are generally performed by interventional cardiologists and some vascular interventions are carried out by vascular surgeons. Similarly, neurovascular procedures may be undertaken by an interventional or neuro-interventional radiologist, a neurosurgeon, or both jointly. Gastroenterologists, pulmonologists, urologists, gynaecologists–obstetricians and others also engage in some image guided interventions. Therefore, establishing and sustaining an optimal interventional radiology practice requires multidisciplinary inputs.

This publication examines the necessary elements for the establishment, safety, sustainability and updating of an interventional radiology programme. The intention is to provide an interventional radiology framework adaptable across different health care systems.

The IAEA wishes to acknowledge the many individuals who contributed to and reviewed this manuscript, in particular the late R. Kashyap. The IAEA officers responsible for this publication were M. Mikhail Lette and F. Giammarile of the Division of Human Health.

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1. INTRODUCTION

1.1. BACKGROUND

Interventional radiology (IR) is the medical speciality that uses image guided techniques to diagnose, treat, follow up and palliate a broad range of pathologies. Since 1923, when angiography was first used for the human body, the use of IR has proliferated. In 1953, Swedish radiologist S.I. Seldinger first introduced guidewire based access to vascular structures and hollow organs, which is still known as the ‘Seldinger technique’. In 1964, US radiologist C.T. Dotter performed the first percutaneous angioplasty to dilate a narrowed lower extremity artery of a woman with a non-healing ulcer, refractory foot pain and necrotic toes. These landmark events inspired innovation that has since transformed the very paradigm and practice of medicine.

The training of an interventional radiologist includes combined competencies in diagnostic imaging, image guided diagnostic and therapeutic interventions (minimally invasive), the safe application of imaging and sometimes of radioisotopes, as well as education in pre- and post-procedural clinical evaluation, informed consent and attentive patient care [1–3]. Epidemiological trends commensurate with increasing population based needs have stimulated the global growth of IR. As novel and improved IR technologies and instrumentation are developed, the role of the IR provider in patient evaluation and management is likely to expand. The Society of Interventional Radiology (SIR) clarifies the role of IR for patients and health care professionals [4–7].

1.2. OBJECTIVE

Member States are encouraged to assess their own IR provision status and to strategically implement IR clinical service enhancement strategies concordant with health management guidelines and country specific needs. Establishing and sustaining an optimal IR practice requires multidisciplinary inputs. The primary target audience of this publication includes radiologists, medical physicists, radiographers/radiological technologists, sonographers, physician assistants (PAs), nurses and other health care professionals directly involved in IR patient care. It aims to assist hospital planners and management personnel, government authorities, policy makers and other relevant parties. In summary, this publication presents an evidence based rationale for establishing, improving and maintaining an IR service, consistent with current clinical knowledge benchmarks.

Additionally, this material may aid in securing relevant authorizations, inputs, cooperation and assistance towards fulfilling pre-requisites, particularly legal and financial, considering Member State specific circumstances and feasibility. The ultimate intention is to render uniformly high quality IR services available globally to all, as part of achieving universal health coverage.

Guidance and recommendations provided here in relation to identified good practices represent expert opinion but are not made on the basis of a consensus of all Member States.

1.3. SCOPE

This publication aims to provide a general overview of IR and a summary of elements essential to the establishment, improvement and sustainability of an IR clinical service. It also outlines the challenges faced, particularly in lower resource settings, and includes a list of expert recommendations. It emphasizes safety and quality standards and discusses topics such as necessary funding, infrastructure, equipment, human resources, education, training and certification/recertification, and the involvement of key professional societies.

1.4. STRUCTURE

This publication is divided into five sections. Section 1 explains the background, objective, scope and structure of the publication. Section 2 features a synopsis of common IR imaging techniques and a list of common procedures. Section 3 describes the physical and infrastructure requirements for the interventional facility, imaging and ancillary equipment, and equipment procurement, repair and maintenance. Section 4 specifies the human resource requirements, namely the interventional radiology specialists, non-physician service providers, medical radiation technologists, PAs, anaesthesiologists, administrators or managers, administrative assistants, biomedical engineers and medical physicists, and information technology (IT) professionals. Section 5 illustrates the basic radiation protection requirements, while Section 6 outlines the needs for an efficient quality management system. Sections 7 through 12, respectively, cover IR relevant medical education and training; certification and recertification; funding; professional societies and bodies; promotion and public awareness topics; and challenges for low and middle income countries. The publication concludes with the recommendations of an expert committee convened by the IAEA on the topic ‘Needs for Interventional Radiology in

the Emerging World'. The Appendix presents a range of common procedures provided by interventional radiologists.

2. INTRODUCTION TO INTERVENTIONAL RADIOLOGY

2.1. IMAGING TECHNIQUES

The practice of IR requires the ability to perform and interpret multimodality imaging techniques, most commonly fluoroscopy, with or without the option to perform digital subtraction angiography (DSA), ultrasound imaging (also known as sonography or echography), computed tomography (CT) and magnetic resonance imaging (MRI). These can be described as follows:

- *Fluoroscopy*. A widely available dynamic imaging technique that uses the continuous application of X rays to produce a series of images in motion. The procedures are guided by differential X ray attenuation of tissues (and devices) in the images. The X ray equipment used to perform fluoroscopy varies from a conventional over-couch or under-couch system to a C-arm unit or an angiography machine, which additionally offers the capacity for DSA. The latter is an imaging technique that is used to enhance the visualization of blood vessels with carefully timed intravascular injections of radiographic contrast media by subtracting a pre-contrast image or mask from the images acquired after contrast administration [8].
- *Ultrasound imaging*. A widely available, safe and relatively low cost imaging technique that utilizes reflected sound waves (rather than ionizing radiation) to image inside the body.
- *CT*. A sophisticated, widely available technique that uses X rays to create 3-D reconstructed images of the body based on differential densities, differential attenuation and often contrast enhancement. Traditionally viewed as axial slices (transverse or horizontal), these images are very frequently reconstructed in multiple planes (sagittal, coronal and oblique).
- *MRI*. A complex technique that utilizes magnetism (rather than ionizing radiation), the differential signal characteristics of tissues and often contrast agents to acquire multiplanar and 3-D imaging [9]. Computerized 3-D image reconstruction is a key element of MRI.

2.2. CLINICAL CARE

2.2.1. Procedures

IR is characterized by an array of image guided interventions contributory to optimal clinical management of many patient conditions. All IR procedures may be subclassified as either primary or supportive, as follows:

- *Primary procedures.* In these procedures, IR is the major element of the care plan for the patient, often in a multidisciplinary context. They often involve complex imaging techniques and advanced interventional skills. In some cases, the image guided IR procedure may be the sole therapy and the interventional radiologist is the main patient care provider. The availability of such interventions strengthens the capacity of the health care system to handle, for example, common manifestations and complications arising from the management of acute conditions — such as stroke/cerebrovascular accidents or catheter guided occlusions of acute intracranial aneurysm ruptures — and manifestations of chronic diseases such as atherosclerosis, cancer and diabetes. Examples include transcatheter treatment of atherosclerotic arterial obstruction (such as angioplasty or stenting), transcatheter delivery of (chemo)therapeutic agents into benign or malignant tumours or radiofrequency tumour ablation.
- *Supportive procedures.* These are performed as part of the overall multidisciplinary treatment or management of the patient and may be either elective or emergent. This procedural group facilitates patient treatment, recovery or stabilization. In many cases, basic imaging techniques suffice for guidance in these procedures. Supportive IR often serves a critical role in the operation of a health care system. Examples include minimally invasive drainage of a post-operative abscess, paracentesis, thoracentesis, image guided needle biopsy or sampling, placement or management of dialysis catheters, and transcatheter treatment of acute gastrointestinal bleeding.

IR procedures target most organs, with the notable exception of interventional cardiology. Specifically, catheter guided cardiac interventions are most frequently performed by cardiologists specializing in coronary angiograms and, when relevant, interventions such as coronary stenting, angioplasty and intravascular administration of certain agents. Cross-over between IR and specialities other than cardiology is noted, the details of which are beyond the scope of this publication, keeping in mind that IR constitutes the main discipline implementing image guided health care procedures.

Overall, there are no patient age limits for IR, although the most common IR device sizes may be unsuitable for use in infants and small children. Some procedures are gender specific but most of them are not. Table 1 presents a partial list of common conditions treated by IR and examples of relevant IR interventions [9].

TABLE 1. EXAMPLES OF CONDITIONS AND THEIR RELEVANT IR PROCEDURES [6]

Condition	Procedure
Infectious	Image guided drainage Image guided aspiration of infected fluid (as for diagnostic tests) Central venous access devices such as PICC (peripherally inserted central catheter) lines
Malignant	Image guided biopsy Selective transarterial delivery of anti-tumoural agents Percutaneous ablation of unresectable tumours, such as radiofrequency ablation or cryoablation Central venous access devices, such as ports and PICC lines
Liver diseases	Image guided drainage and stenting of obstructed bile ducts Percutaneous portal to systemic (portosystemic) venous shunts for cirrhosis
Gastrointestinal	Image guided treatment (embolization) of gastrointestinal bleeding Image guided placement of enteral feeding tubes
Trauma	Percutaneous image guided treatment of traumatic bleeding Image guided treatment of thoracic aortic rupture
Women’s health	Image guided treatment of uterine fibroids (leiomyomata) Image guided treatment of infertility due to tubal obstruction Image guided percutaneous nephrostomy and ureteral stent placement in the setting of advanced cervical cancer encasing the distal ureters
Urinary	Image guided drainage and stenting of urinary obstruction Image guided placement of bladder drainage catheters

TABLE 1. EXAMPLES OF CONDITIONS AND THEIR RELEVANT IR PROCEDURES [6] (cont.)

Condition	Procedure
Renal failure	Image guided placement of dialysis catheters Image guided treatment of thrombosed dialysis grafts and fistulas
Arterial aneurysms	Image guided treatment of arterial aneurysms and dissections
Peripheral arterial disease	Image guided angioplasty of obstructed peripheral arteries and stent placement Image guided treatment of thrombosed arteries and grafts
Venous thrombosis	Image guided treatment of deep vein thrombosis and pulmonary embolism Image guided placement of vena cava filters
Other examples	Placement of central venous access catheters and devices Removal of intravascular foreign bodies

2.2.2. Procedural care

An IR practice may function within a multidisciplinary clinical setting or as implemented by an individual practitioner, with proper engagement in pre-procedural, intra-procedural and post-procedural care of patients, as follows:

- *Pre-procedural care.* This includes consultation on an inpatient or outpatient basis to determine the suitability of the procedure, order additional tests or consultations if warranted, order appropriate medications prior to the procedure if warranted and obtain informed consent from the patient or an appropriate authorized surrogate.
- *Intra-procedural care.* This entails haemodynamic monitoring and resultant management of any clinically significant abnormalities, ordering and administration of appropriate medications and intravenous fluids, identification of medical emergencies or procedural complications, and initiation of treatment and resuscitation.
- *Post-procedural care.* This includes pain management, assessment and management of potential complications, evaluation of response to treatment,

and determination of treatment end points or need for reintervention. In addition, the IR provider should organize any justified long term follow-up.

All or some components of the aforementioned care continuum can be delivered on an inpatient or outpatient basis, as warranted. The interventional radiologist requires hospital admitting privileges, an outpatient clinic or office, and sufficient support personnel to manage multifaceted aspects of the practice [9].

3. PHYSICAL AND INFRASTRUCTURE REQUIREMENTS

3.1. INTERVENTIONAL FACILITY

Where available, the interventional suites constitute an integral part of a radiology department. Sometimes, allied speciality departments schedule time slots in the suites, which remain managed by personnel (e.g. nurses, technologists, medical physicists) common to IR, and share many functions, such as the administration, organization and infrastructure of image guided procedures such as Picture Archiving and Communication Systems (PACS) and IT services. Running an interventional service requires integration of the following clinical patient care attributes within the radiology department [10]:

- *Procedure room.* This is the core space in the interventional suite, analogous to the operating room or theatre in surgery. This suite contains a specially designed unit capable of acquiring both dynamic fluoroscopic and static X ray images, which is centred on a moveable table upon which the patient lies. A sonography unit has to also be readily available. The room itself needs to be spacious enough to contain all primary and ancillary equipment as outlined below and allow for facile manoeuvring of personnel and equipment on all sides of the operating table. Sterile techniques and air conditioning are essential. The room has to also permit access of hospital beds transporting patients. A separate adjacent and contiguous glassed-in control area harbours further radiographic control equipment; this space may incorporate state of the art image viewing and reconstruction equipment, as well as a consultation area.
- *Facilities.* The availability of adequate space is important for the storage and use of consumables (e.g. needles, guidewires, catheters, stents, embolization

materials, contrast media, ablation probes), the preparation of operating equipment and post-procedural disposal. Some equipment may be reusable or resterilizable and may thus have an impact on the central institutional cleaning and sterilization facilities and policies. Many consumables used are unique to IR and will not be available elsewhere in the health facility. The ability to store relatively large volumes of these consumables in an easily retrievable fashion, in well designed cupboard and drawer spaces local to IR, is essential. Part of the storage space should include sufficient surface area to set up procedure specific operating trays prior to transport to individual IR suites. Equipment contaminated by body fluids or infected materials must be dealt with or disposed of safely, according to designated biohazard norms, and should be anticipated in the design of the interventional suite. Furthermore, a variety of different drugs may be used in IR, necessitating a readily available refrigerated drug storage facility, which is also protected against theft.

- *Patient and personnel safety.* Radiation protection and safety are of paramount importance and are discussed in depth in Sections 5 and 6. IR facilities should be designed to fulfil the requirements for classification of areas as controlled or supervised [11, 12]. Medical radiological equipment designed specifically for IR procedures should be used and needs to incorporate protective devices, such as ceiling suspended lead acrylic viewing screens and under-table and lateral shielding attachments to the X ray couch, mobile shielding and personal mobile shields. Devices and materials used for personal protection have to be properly stored and readily available at all times. These include lead aprons, thyroid shields and eyewear. Safeguarding the operating personnel from body fluids is also important and most procedures are undertaken using appropriate protective gowns, caps, masks and gloves. Supply channels, a storage facility and ready availability of such consumables should be included in IR planning. The ability of personnel to perform a sterile scrub is crucial for many procedures, requiring a full surgical style scrub facility to minimize the risk of post-procedural infection to the patient.
- *Pre- and post-procedure.* Additional space is necessary in the IR area for timely, patient centred pre-procedural preparation (e.g. addressing remaining questions, establishing intravenous access). Similarly, immediate post-procedure patients may require closely supervised recovery for different periods of time. The pre- and post-procedural areas may share the same physical space and have to be located near the IR suites. Some interventions will further require that the patient be admitted as an inpatient under the care of the interventional radiologist or another physician. Inpatient bed space is therefore a requirement for an interventional service. An outpatient office

should also be included in IR planning, as patients are often interviewed and examined by IR personnel well before presenting for non-emergency procedures. Moreover, post-procedural outpatient follow-up may be warranted.

- *Power and water supply.* Clearly the interventional suite is an area with multipurpose requirements, in which important patient centred operations are performed. Stable power and water supplies are crucial to the safe, effective operation of IR.

In summary, an interventional facility consists of the following:

- An interventional procedure room, often an integral part of the radiology department, with control and consultation areas, and linkages to major radiology department functions such as management of PACS and Digital Imaging and Communications in Medicine (DICOM) images;
- Facilities for the storage of consumables, pre-procedure preparation and post-procedure disposal;
- Dedicated mechanisms and expertise to look after patient and staff safety and maintain high quality care;
- Facilities for pre- and post-procedural patient preparation and recovery [10].

3.2. IMAGING EQUIPMENT

The imaging equipment utilized in IR most frequently requires the following equipment:

- *Fluoroscopy C-arm units.* The most important imaging device in IR is the X ray machine because the majority of interventional procedures require fluoroscopic image guidance at some point. The fluoroscopy unit needs to have flexibility to carry out imaging of the patient from multiple vantage points without significantly altering the patient's position. Key features that enable this flexibility include mounting the X ray tube and image detector on a structure that can rotate around at least two axes. The unit is linked to a central table (where the patient lies), which moves along the third axis. This capability differentiates fluoroscopy equipment from the more common, less mobile, general purpose fluoroscopic units used elsewhere in the radiology department.
- *Angiographic X ray equipment* with capacity for DSA. The IR X ray/fluoroscopy unit usually incorporates dual capabilities for radiography and timed angiographic injections in, for example, the arterial and venous

phases (e.g. single radiographic images, timed image series). The most advanced interventional machines additionally incorporate 3-D imaging features and/or relevant software applications.

- *Ultrasound*. Ultrasound imaging is frequently the modality of choice for IR procedures, but ultrasound units may also be used outside this area, for example in the radiology department and, more broadly, in the health care facility. An ultrasound device should be portable and able to record images in a format compatible with the software used in the radiology department and with facility wide IT. Ultrasound guidance is useful for many anatomical sites, necessitating adaptability for use with a variety of transducers, including endocavitary probes (e.g. endovaginal). An ultrasound unit also needs to be manoeuvrable around the patient, the fluoroscopy machine and the operator, with adjustable positioning of the viewing screen and the keyboard/interface.
- *CT*. This is used for image guidance in a variety of procedures (e.g. drainages, ablations, image guided biopsies). While CT capabilities are not generally needed within the main IR area, a CT scanner should be easily accessible from the interventional suite so that patient transfer to the CT suite can be made when necessary. In addition, the CT fluoroscopy mode may be used. Moreover, interventions requiring CT may necessitate use of nearby IR tools (consumables and non-consumables) and resources.
- *MRI*. This technique is utilized less in IR than the above mentioned modalities, largely because of the hazards inherent to using traditional procedural instrumentation in a highly magnetized environment. However, current and anticipated innovations in interventional MRI require progressively greater access to the MRI area for specific IR procedures and individualized patient contexts. IR technologies that are magnetic resonance safe are being developed, such as magnetic resonance guided biopsies of suspicious breast lesions, some of which are best visualized by MRI.

In summary, the optimal interventional imaging suite needs the following:

- (a) Angiographic X ray equipment with a DSA option designed specifically for use in the interventional suite;
- (b) Ultrasound equipment with specific requirements for the interventional suite;
- (c) Easy access to the CT suite;
- (d) Access to the MRI suite [10].

For some interventions, it is advantageous to use more than one imaging modality at various points in a given procedure, often ultrasound and conventional fluoroscopy.

3.3. INTERVENTIONAL X RAY EQUIPMENT

Selection of the technical specifications for an IR X ray system should be based on the intended use of the system and type of procedures to be performed. The following lists describe the recommended technical specifications for an IR X ray system, according to Refs [12–17].

System configuration

- C-arm configuration with an X ray tube under the patient table, a fixed centre of rotation (isocentre) and the central radiation beam aligned with the centre of the image receptor. The following types are used:
 - Dedicated IR room mounted systems for complex diagnostic and therapeutic vascular and non-vascular interventional procedures;
 - Biplanar systems for sophisticated interventions, such as those in neuroradiology and paediatric cardiology, especially when the quantity of iodine contrast agent needs to be limited;
 - Mobile C-arm systems for use in surgical theatres to navigate a variety of treatment procedures, including minimally invasive procedures in orthopaedic surgery, traumatology, general surgery, vascular surgery, urology, gastroenterology and placement of certain in-dwelling devices (e.g. pacemaker, vascular access placement).
- Source to image receptor distance tracking.
- Patient table made from a low attenuation material.
- All instrumentation and switches clearly labelled.
- Automatic injector.
- Means of patient immobilization.

X ray source assembly

- X ray tube with high heat capacity to permit operation at high tube currents and short times.
- X ray tube with a minimum of two focal spots with the following dimensions:
 - Neuroradiology: 1.2/0.4 mm;
 - Peripheral vascular: 1.2/0.5 mm;
 - Paediatric: 0.4/0.6/0.9 mm.

- Tube filtration, including the following:
 - Minimum 2.5 mm Al equivalent filtration;
 - Additional heavy metal filters to shape the X ray spectrum (e.g. copper filters with thicknesses between 0.1 and 1 mm), selectable by the automatic dose rate control (ADRC) or by the user/program;
 - Semi-transparent ‘wedge’ filters to compensate for lower object attenuation in a region of interest.
- Radiation generator with at least 80 kW of power and a large dynamic range of tube current (50–1000 mA) and tube potential (40–125 kV) to minimize the pulse width necessary to accommodate differences in patient attenuation.
- Pulsed fluoroscopy with several pulse rate options (3, 7.5, 15 or 30 pulses per second, selectable by the user/program).
- An image acquisition frame rate that extends to up to 30 frames per second for some applications and for small children.
- Collimation device with the following features:
 - Automatic alignment to the input area of the image receptor or selected field of view;
 - Additional dual shape collimators incorporating both circular and elliptical shutters to modify the field for collimation around areas of interest;
 - Desirable: Virtual collimator with diaphragm position indicator on the last image hold;
 - Desirable: Automatic positioning system.
- Exposure switch device (footswitch or ‘dead man’ switch or button on the console) with clear indication of fluoroscopy and radiography modes.

Image receptor

- Digital image receptor based on a flat panel detector or image intensifier with small detector pixel size and large matrix, in different sizes:
 - 22–48 cm for radiology applications;
 - 15–32 cm for neuroradiology;
 - 15–32 cm for cardiology.
- An anti-scatter grid that is removable (for paediatric applications).

Automatic exposure control and exposure modes

- An ADRC system with selectable fluoroscopy and acquisition/cine modes for different imaging tasks:
 - Low dose, standard (normal) and high contrast (high dose) fluoroscopy;
 - Single (spot) radiography, digital acquisition, cine and DSA.

- Two to four electronic magnification modes (also referred to as ‘zoom’, ‘mag’ and ‘field of view’).
- Different ADRC programs available for different anatomical regions.
- Selectable, pre-defined study protocols and acquisition programs for common clinical conditions (e.g. cardiac, neuro, vascular, paediatric).
- Desirable: ADRC system based on fully automatic adjustment of exposure parameters.

Image display, processing and archiving

- Image display monitors with high brightness levels, preferably of large size (e.g. 60 in, 152 cm) for vascular procedures.
- Last image hold capability to capture and display the last acquired frame or last fluoroscopic frame sequence.
- Store and replay function for at least 300 frames of the most recent fluoroscopic imaging sequence.
- Image processing capabilities:
 - Spatial noise reduction (noise reduction by averaging with neighbouring pixels);
 - Recursive or temporal filtering, temporal averaging in fluoroscopy (dose reduction, improvement of the signal to noise ratio);
 - Road mapping (use of a reference image on which the current image is overlaid);
 - Automatic live motion compensation (reduction of the effect of motion in DSA imaging);
 - Edge enhancement, contrast enhancement and other vendor specific parameters.
- Minimum size of image store.
- Connectivity to radiology information systems (RIS)/PACS.

Dose display (at the control console and on monitors in the procedure room)

- Real time dose displays for the following parameters (see also Section 5.5.3):
 - Reference air kerma rate (mGy/min) and cumulative reference air kerma (Gy);
 - Air kerma–area product (KAP) rate ($\text{Gy}\cdot\text{cm}^2/\text{s}$) and cumulative KAP ($\text{Gy}\cdot\text{cm}^2$);
 - Fluoroscopy time;
 - Number of acquired images;
 - Desirable: real time, colour coded ‘skin dose mapping’ (see also Section 5.5.4).

- End of case dose report (radiation dose structured report), including export of the cumulative dose values.

Specific training in the use of the equipment or software has to be given to the staff of the medical radiation facility, including the IR physicians, medical radiation technologists, medical physicists and local maintenance engineers. The features of the equipment or software should be fully understood, including their implications for radiation protection of patients and personnel [12, 18]. To avoid any misinterpretation that could negatively impact patient and staff safety, all accompanying documents and user guides of equipment should optimally be provided both in the original and in the local language.

3.4. ANCILLARY EQUIPMENT

The requirements for ancillary equipment include the following:

- *Pressure injection pump.* During DSA, a contrast medium is injected through a catheter into a blood vessel. For a sufficiently rapid, optimally timed injection, a pressure pump is often used. This is an integral part of the fluoroscopy/DSA machine and needs to be electronically linked to it to ensure precise temporal coordination of the injection and image series acquisition.
- *Patient monitoring equipment.* Patients undergoing interventional procedures require monitoring of their vital signs, necessitating that sphygmomanometers and pulse oximeters be available at all times. Depending on the procedure and/or overall haemodynamic stability of the patient, cardiac rhythm and respiratory monitors may also be warranted.
- *General anaesthetic capability.* Some patients require general anaesthesia for their procedure or neuroleptic sedation. For this purpose, the procedure room should have anaesthetic gas supplies and suction. There should be sufficient space around the procedure table head to place an anaesthetic cart for use by the anaesthesiologist and/or nurse anaesthetist.
- *Ablation and endoscopy equipment.* Tumour ablation (thermal ablation, cryotherapy or microwave ablation) is usually performed under CT and/or ultrasound guidance and requires additional ablation units. Endoscopy is commonly used, for example, to guide the placement of biliary or intestinal stents. While endoscopy equipment may or may not remain in the interventional suite, it should be readily available for use and requires sufficient pre-planned space in the procedural room and availability of suction [10].

3.5. EQUIPMENT PROCUREMENT, REPAIR AND MAINTENANCE

The process of IR equipment procurement varies greatly from place to place. However, there are some overarching guiding principles that may prove helpful. For example, the technical specifications for choosing the equipment to be procured should be drafted by the medical physicist in cooperation with the physician end user and other relevant experts and using advice from a medical physicist qualified in diagnostic and interventional radiology, which is a requirement of the International Basic Safety Standards. Other relevant experts include radiation technologists, biomedical engineers and IT specialists [19]. The purchase process should be transparent to all involved and may or may not include contractual agreements for years of included maintenance, an extended warranty period for repairs and the inclusion of software (including the cost of regular software licence renewals and updates, such as for DICOM and PACS). It is important that tests be performed before clinical use, on-site acceptance and commissioning [20]. For the on-site acceptance tests, after delivery the system needs to be tested by the contractor and the user to demonstrate that the manufacturer's performance specifications and minimum requirements, as defined by the World Health Organization (WHO), IAEA and users, are met. The results can be documented in an acceptance test protocol signed by the end user (e.g. the hospital manager or other professional after consultation with the medical physicist) and the manufacturer. It must be emphasized that a structured plan and agreement for repair and maintenance of the relevant equipment is vital to the sustainability of the interventional service. Discrepancies in available agreements may relate to individual equipment vendors, independent repair and maintenance companies, or institutional services if available. Long term contractual details should be transparent to the end users and incorporate elements such as expected response times so that an IR service will not be halted because of non-functioning or malfunctioning equipment or applications.

In summary, equipment procurement requires the following:

- (a) A transparent purchase process;
- (b) Guidance from the end user physician and clinically qualified medical physicist (CQMP);
- (c) A contract for repair and maintenance;
- (d) A software licensing and upgrade contract (as relevant [10]).

3.5.1. Equipment maintenance and quality control

Hospital management needs to make all the necessary arrangements and coordinate with the manufacturer or the manufacturer's authorized representatives

to ensure that the IR equipment is properly configured and set up to meet the technical specifications and clinical requirements and that it retains, or improves, design specifications for image quality and radiation protection and safety throughout the useful life of the equipment. This includes complete acceptance testing and calibration according to the manufacturer's recommendations before initial operation and an ongoing maintenance programme, including necessary preventive and corrective actions, as well as appropriate hardware and software upgrades and calibrations. These actions should be included in the facility's quality assurance (QA) programme.

IAEA Safety Standards Series No. SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [12], recommends the following actions related to equipment maintenance:

“3.48. All maintenance procedures should be included in the comprehensive programme of quality assurance and should be carried out at the frequency recommended by the manufacturer of the equipment and relevant professional bodies. Servicing should include a report describing the equipment fault, the work done and the parts replaced and adjustments made, which should be filed as part of the programme of quality assurance. A record of maintenance carried out should be kept for each item of equipment. This should include information on any defects found by users (a fault log), remedial actions taken (both interim repairs and subsequent repairs) and the results of testing before equipment is reintroduced to clinical use.

“3.49. In line with the guidance provided in para. 2.113, after any modifications or maintenance, the person responsible for maintenance should immediately inform the licensee of the medical radiation facility before the equipment is returned to clinical use. The person responsible for the use of the equipment, in conjunction with the medical physicist, the medical radiation technologist and other appropriate professionals, should decide whether quality control tests are needed with regard to radiation protection, including image quality, and whether changes to protocols are needed.

“3.50. The electrical safety and mechanical safety aspects of the medical radiological equipment are an important part of the maintenance programme, as these can have direct or indirect effects on radiation protection and safety. Authorized persons who understand the specifications of the medical radiological equipment should perform this work...Electrical and mechanical maintenance should be included in the programme of quality assurance and should be performed, preferably by the manufacturer of the medical radiological equipment or an authorized agent, at a frequency

recommended by the manufacturer. Servicing should include a written report describing the findings. These reports and follow-up corrective actions should be archived as part of the programme of quality assurance.”

After installation of the IR equipment, the supplier has to go through a formal handover to the medical radiation facility’s representatives.

The facility’s QA programme needs to include the following quality control (QC) measurements on IR equipment to ensure that it performs correctly, accurately, reproducibly and predictably at all times [20, 21]:

- (a) Acceptance tests for new or significantly refurbished or repaired equipment, or after the installation of new software or modification of existing software that could affect protection and safety. Depending on the equipment purchase agreement, acceptance tests can be performed by the manufacturer in the presence of the local medical physicist and the clinical staff representing the user or, if acceptable to the manufacturer and the purchaser, by a medical physicist jointly with the manufacturer. The process has to involve verification of all specifications and features of the equipment [12]. For new equipment, the following procedure is recommended: after delivery, the system is tested by the contractor, together with the user, to demonstrate that the performance meets the manufacturer’s performance specifications and the minimum requirements specified by WHO, IAEA and users. The results of the acceptance testing have to be documented in an acceptance test protocol that is signed by the end user (after consultation with the hospital’s medical physicist) and the manufacturer [22].
- (b) Commissioning should be carried out immediately after acceptance and before clinical use on patients. It is performed by or under the supervision of the medical physicist and includes measurements of all parameters and conditions that are expected in clinical use, including setting up and validating image acquisition protocols. Protocol configuration includes proper adjustment of settings customized to the required image quality and dose saving needs for the clinical task. An important role of commissioning is to ensure that all key parameters are within the technical and regulatory limits. These include, but are not limited to, the following two important parameters:
 - (i) Maximum patient entrance surface air kerma. The United States Food and Drug Administration (FDA) [23] has set nominal limits of 88 mGy/min (10 R/min) for the normal fluoroscopy mode and of 176 mGy/min (20 R/min) for the high dose control mode. In Europe, the European Commission has set a suspension level of 100 mGy/min for the normal fluoroscopy mode, of 2 mGy per frame for the normal

digital fluorographic acquisition mode and of 0.2 mGy per frame for the cardiac mode, including backscatter and measured with a grid in place [24].

- (ii) Input air kerma rate at the image receptor in fluoroscopy and radiography modes, for different fluoroscopy dose modes, pulse rates and fields of view. Some regulations in Europe apply 1 $\mu\text{Gy/s}$ as the limit in normal fluoroscopy mode [24–26]. The setting of this parameter depends on the system's design.

During commissioning, the baseline for subsequent constancy tests is established.

- (c) QC tests include performance tests and constancy tests of all elements of the imaging chain, including the X ray source assembly, image receptor, image display, image quality and dose displays, as follows [15, 20, 24–28]:
 - (i) X ray source assembly:
 - Accuracy and reproducibility of the tube voltage;
 - Half-value layer and tube filtration;
 - Reproducibility and linearity of the tube output;
 - Tube leakage;
 - Alignment and collimation of the radiation field to the image receptor.
 - (ii) ADRC settings and performance for the most commonly used modes and programs:
 - Input air kerma rate at the image receptor and patient entrance surface air kerma rate.
 - (iii) Integrated radiation dose displays:
 - Verification of calibration of KAP meter;
 - Verification of displayed KAP and reference air kerma;
 - Correction factors for use with the radiation dose structured report when the function is available.
 - (iv) Image quality:
 - Low contrast detectability;
 - High contrast detectability;
 - Image distortion and artefacts.

The frequency of QC tests and tolerance limits should be established in the QA programme according to the guidelines and regulatory requirements. If the measured values fall outside established tolerance limits, corrective actions should be implemented, which might require maintenance or servicing of the equipment. The programme of QC measurements should be performed under the

supervision of a qualified medical physicist. Close cooperation with the service engineers is needed, as well as involvement of clinical staff operating and using the equipment. All steps of the maintenance and QC programme have to be well documented and the records maintained in the IR facility.

4. HUMAN RESOURCE REQUIREMENTS

4.1. BACKGROUND

The expanding role of IR in clinical practice, including its ability to favourably modify the management algorithms of disease states, has the potential to enhance and optimize the delivery of health care at local, regional and national levels. The implementation of such procedures on a national scale may have profound health care and socioeconomic impact implications, including reduced disease morbidity and mortality and an eventual reduction in health care costs.

High quality IR services are essential for safe and effective patient care. The range of available IR procedures varies from hospital to hospital according to local epidemiology, demand, available expertise, resources and infrastructure. Many such procedures are now performed with the intent to treat conditions that were previously untreatable or previously required open surgery. An individual IR intervention may require several hours of an IR specialist's time. Moreover, proper IR service provision requires much more than the performance of procedures. As detailed in Section 2, pre- and post-procedural patient care is often the responsibility of the treating radiologist and may entail significant additional time [29].

The rapid expansion of IR in modern health care constitutes a premise for carefully mapping IR human resource requirements. Specifically, all hospitals should have robust arrangements to provide IR services in an uninterrupted manner regardless of the geographical location, demographic issues, hospital size and time of day, among other factors. Patient safety should be the first priority in this planning. To optimize provision of the best possible IR service, it is essential to recognize the unique combination of resources, human and otherwise, required by IR, with clear and transparent planning and implementation at all levels. Staff should have core competencies appropriate to local facilities and expected requirements in order to provide optimal care in that context. There should be a safe environment for performing IR procedures, including patient monitoring, anaesthetic support and liaisons with appropriate clinical teams.

Maintenance of IR services safe to patients and staff cannot be achieved without adequate resources.

Further, the expanding or new demands of this speciality cannot be safely met simply by demanding more work from existing staff. It is therefore essential that staffing requirements in an IR facility are clearly identified. Requisite stakeholders in the practice of IR who can provide an optimal milieu for conducting IR procedures are discussed below [30–35].

4.2. INTERVENTIONAL RADIOLOGY SPECIALISTS

The IR specialist must have clinical, imaging and safety training (e.g. radiation, equipment, sterilization, consumables) and the ability to identify and treat complications of both the procedures and the underlying diseases. IR specialists should also possess adequate knowledge of the pharmacology of particular drugs and the hardware used. Minimum skill sets should be defined, along with clear training and international certification criteria, and personnel engaged in the practice of IR must be certified [36–40].

Formal IR training programmes have been developed in several Member States. For example, in the United States of America (USA), medical doctors may apply for positions in integrated general diagnostic and IR training pathways, either directly from medical school or as a direct transfer from a diagnostic radiology residency. Separate post-residency vascular and IR fellowships are also available. For example, a combined IR/diagnostic radiology speciality certificate is now available through a joint agreement of the American Board of Radiology, the American Board of Medical Specialties and the Accreditation Council for Graduate Medical Education [41].

4.3. NON-PHYSICIAN SERVICE PROVIDERS

Non-physician service providers, including nurse practitioners, PAs and radiology assistants, represent an important resource for providing patient care. The presence of these individuals in an IR department can add a great degree of competency, consistency and reliability, increasing the overall value and availability of the service. Their roles continue to match the ever-expanding demands placed upon an IR facility [42].

A dedicated nursing service is a necessity, and IR nursing staff should be trained to understand the pre-, intra- and post-procedural needs of both the operator and the patient. They function in close proximity to staff physicians and in protocol defined environments. In many instances, IR nurses should be

able to perform a variety of tasks independently under protocols mutually agreed upon and approved by the physician in charge of the IR facility, as well as by the institution where care is provided [42]. Nurses also serve actively in settings where medication, sedation or both are necessary. IR area nurses should have Master of Nursing degrees approved by the national medical council of the Member State. Their educational background needs to include intensive care, primary care and surgery care.

In the development of a job description for non-physician providers, it is essential to define semi-independent capabilities to promote consistency of patient care. Demands may include obtaining informed consent from patients or authorized surrogates, performing targeted physical examinations, providing patient education and consultation, and performing both short and long term patient follow-up. Although the aforementioned tasks are often undertaken by residents and fellows in academic settings, these individuals routinely rotate clinically and are only transiently part of an IR service, potentially leading to inconsistency of care and sometimes confusion. Non-physician providers allow clinicians from referring services to have a ready, reliable and uniform conduit for communication to schedule examinations or troubleshoot problems and are a consistent point of facilitation of IR services. This single point of contact can enable the referring services to better understand how tasks are prioritized and accomplished.

Non-physician providers are expanding their ever-increasing contributions in a variety of primary, tertiary and critical care settings, including in IR facilities. Their presence can improve the quality of service to patients. For example, their roles in the IR team can lead to policies that encourage continuous staff education, better coordination between referring clinicians and the pathology department, better evaluation of biopsy devices and evidence based choices of new or replacement interventional equipment [42–44].

The use of non-physician providers may be divided into functionally different skill sets. Developing job descriptions, lines of reporting and appropriate credentialing entails dynamic efforts, since gradually adapting and applying these skills to benefit evolving clinical needs in an IR department requires continual consideration [42].

4.4. TECHNOLOGISTS

The radiological equipment in every IR facility needs to be handled by full time qualified and licensed radiographers (medical radiation technologists) as per the norms of each country. They should be able to perform a variety of defined radiographic special procedures at a technical level without constant supervision.

The work requires independent judgement, ingenuity and initiative and entails: planning, positioning and performance of radiographic examinations; patient handling with care, concern and support; good listening and communication skills; clear understanding of proper patient preparation procedures; and equipment operation. It also includes the ability to undertake non-technical duties, to maintain complete and accurate documentation, and implement patient safety and quality management programmes. Technologists should be able to use both pre-programmed and manual equipment settings during technique selection and imaging and to operate a variety of monitoring and nursing equipment. They should likewise be capable of assuming responsibility for designated areas or procedures as required and, depending on the practice, may be called to duty outside of daytime business hours for on-call emergency procedures. The basic qualification should include a graduate degree in radiography, certification by the national medical council, adequate experience in handling high end imaging equipment and a sound knowledge of radiation risks [1] and measures of protection [29, 33] as detailed in IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [11].

4.5. CLINICALLY QUALIFIED MEDICAL PHYSICISTS

CQMPs are responsible for developing and implementing the physical and technical aspects of the QA programmes in IR [19]. They are also responsible for patient dose assessment and for advising or assisting the IR specialist in optimizing the balance between the beneficial and deleterious effects of radiation [45].

The CQMP has a key role in the installation of new equipment and provides education and training in applied physics and radiation safety to medical practitioners, nurses, technical staff, students and other personnel. The CQMP's responsibilities are summarized below:

- (a) Installation design, technical specifications, acceptance and commissioning of equipment, including the establishment of criteria for acceptable performance.
- (b) Radiation safety and protection of patients.
- (c) Radiation dosimetry of radiation sources and patients.
- (d) Optimization of the physical aspects of diagnostic and therapeutic procedures.
- (e) Supervision of QA and QC procedures.
- (f) Risk assessment and management.

- (g) Quality management of physical and technical aspects of radiation medicine, such as:
 - (i) Clinical computing and networking;
 - (ii) Research and development;
 - (iii) Education and training.

Recommended staffing levels for clinical medical physics services in medical imaging can be found in Ref. [46]. This publication provides recommendations on the size of a service that can give patients a safe, effective and efficient diagnosis and treatment based on best practices.

Medical physicists monitor radiation doses received by the patient as well as occupational exposures. They monitor the use of badge dosimeters and advise on shielding of both patients and staff. They check the functionality of equipment using phantoms to ensure that appropriate, optimized radiation doses are being administered. The medical physicist frequently serves as the designated officer responsible for radiation safety and protection in the IR facility.

4.6. PHYSICIAN ASSISTANTS

PAs provide targeted clinical care for IR patients. They are skilled assistants who bring many skills to an IR service. As licensed health care professionals with appropriate training, PAs can perform some minor procedures under the supervision of IR physicians. Their scope of practice may vary in different Member States. Hospital credentialing of PAs is usually similar to the general process for physicians. The types of procedure performed in the IR facility define the scope of practice for a PA and the PA's ability and confidence [42].

The SIR recommendation is that “the PA performs procedures independently only after the radiologist and the PA are confident the procedures can be done safely and with high quality” [42]. In addition, “even after the PA is performing procedures independently, the radiologist remains available for immediate consultation should the PA encounter procedural difficulties or adverse situations.” [42]

Usually, a broad graduate degree in the field of medicine and surgery, as approved by the national medical council, is the minimum essential requirement for PA employment. PA graduates seeking additional training in IR usually receive it from the IR physicians who supervise them. Development of PA postgraduate programmes in IR in conjunction with interventional radiologists is desirable. This training should be standardized in terms of procedural, clinical and didactic content [42, 47].

4.7. ANAESTHESIOLOGISTS

The need for anaesthesia and procedural sedation continues to grow as the number and complexity of cases undertaken in IR increase [43]. Anaesthesiologists are well equipped to deliver anaesthesia and procedural sedation by virtue of their speciality training and broad experience. Further, unanticipated need for anaesthesia support during a procedure can compromise patient safety and affect the success of the procedure. The presence of an appropriately trained and certified anaesthesiologist will ensure delivery of the best medical care to the patient in the IR suite. This can be done on an on-call basis or as a part/full time deployment of the anaesthesia specialist during pertinent IR procedures, as deemed necessary by the IR specialist. The decision is based on the volume of work and particular needs. Responsibilities of the anaesthesiologist during IR procedures include maintenance of a physiologically stable, immobile patient who is not in pain and, when relevant, administration of an amnestic agent may be warranted. In addition, the anaesthesiologist manages changes of arterial blood pressure, as necessary, and handles the appropriate and timely management of relevant complications [44, 48].

It is incumbent upon administrators and providers of health care to ensure that all procedure rooms have adequate equipment and accessories to allow the best anaesthesia quality. Finally, practice of anaesthesiology in the IR suite and awareness of what it offers should be incorporated into the anaesthesia curricula and IR training programmes because anaesthesiology will constitute a major component [1] of all integrated practices in the future. A detailed discussion of the roles of anaesthesiologists versus those of nurse anaesthetists is beyond the scope of this publication.

4.8. ADMINISTRATORS OR MANAGERS

IR managers are front line supervisors responsible for the entire IR facility and work directly under the supervision of the director of the facility. Their supervisory duties range from planning the IR department's fiscal budget to supervising the staff and evaluating the work performance of subordinates. IR managers ensure the maintenance and QC of the department's equipment, maintain the inventory, order supplies, and can hire and fire radiology staff when required under the supervision of the director. Managers should plan and direct department goals. Other duties may include updating and improving departmental and hospital policies, and procedures and training of staff members. Knowledge and implementation of national health care policies and adherence to privacy

laws are required. The manager should also meet regularly with other department staff and supervisors to coordinate services.

Managers should possess a bachelor's degree from an accredited college, and training may include a Master's degree in business administration. They should ideally have at least five years of experience in IR or related services before becoming supervisors and need to have a thorough knowledge of human behaviour and possess interpersonal skills in order to work effectively with patients and their families. Conflicts will at times arise between the patients and the medical staff, as well as among staff members. In such cases, IR managers need to deal with conflict, seeking resolution and minimizing problems.

General computer skills are considered essential to a smooth running department. A decisive personality is also critical to a job in which lingering problems cannot go unresolved, because they may affect other departments that liaise with IR services. Managers should be capable of quickly identifying and solving problems, whether related to the equipment or to personnel.

4.9. ADMINISTRATIVE ASSISTANTS

Strong communication, organizational and multitasking skills are needed for this position, which requires cross-training in several areas, including greeting and receiving patients, answering phone calls and retrieving medical records. Functioning as the interface between patients, IR and the broader health system, administrative assistants handle appointment and procedural scheduling, apply workflow protocols and communicate with technologists and other relevant personnel regarding dynamic changes, which may include policies regarding insurance and other information pertaining to patients, as continually established by the organization. Qualifications should include at least a high school diploma or equivalent. An associate degree or medical assistant certification may be preferred. Candidates should ideally have at least two years' office experience in radiology or another relevant medical speciality. They should be familiar with medical terminology and have a strong aptitude for communication, computer skills, excellent patient handling skills and proficiency in languages, including local dialects.

4.10. BIOMEDICAL ENGINEERS

Biomedical engineering professionals are key players in developing and advancing the proper utilization and management of medical devices and clinical services in IR. A trained graduate engineer should have a certified degree from

the appropriate board as a minimum requirement for employment. In-house trained and qualified biomedical engineers often undertake warranted on-site adjustments, including revised protocolling, of certain procedures and have a central role in managing the maintenance, repairs and optimization of the available resources. Additionally, they foster local solutions to local problems and may stimulate larger scale research and innovation.

Biomedical engineers are especially useful in low and middle income countries with limited access to representatives of equipment manufacturers. In-house expertise helps in dealing with minor problems and reducing downtimes of critical equipment [49].

There is cross-over between the roles of the biomedical engineer and the medical physicist, with significant geographical variability. For example, in many centres the medical physicist regularly tailors imaging protocols side by side with the physician end users, routinely oversees or assists in the surveillance of IR radiation doses and often serves in the roles mentioned above, either independently of or alongside the biomedical engineer. Regarding calibration and dosimetry, the medical physicist has particular expertise in the medical uses of radiation and often serves a vital role in IR (see Section 4.5).

4.11. RADIATION PROTECTION OFFICER

Radiation protection officers (RPOs) are professionals designated by the registrant or licensee to supervise radiation safety in a clinical environment and to ensure that work is carried out safely in accordance with the relevant national authority requirements. RPOs provide links between the workplace, the registrant or licensee, the qualified expert and the regulatory body, and ensure that operations involving radiation are in compliance with established regulations. Furthermore, they should be familiar with operations performed in a facility (in this case primarily in the radiology department), its organizational infrastructure and working procedures, and have knowledge and understanding of the relevant regulatory requirements. They are also responsible for organizing training for personnel. Additionally, they may be assigned responsibilities concerning protection of the public in the vicinity of the facility. An RPO should be the central point of reference within an IR facility for radiation protection matters and may carry out or directly supervise contingency plans in the event of an accident or incident [11, 12].

The main roles and responsibilities of the RPO in the department include the following [50]:

- (a) Controlling occupational exposures (by constantly monitoring personal dose rate) to ensure satisfactory compliance with regulatory and licence conditions;
- (b) Ensuring safe operation of the devices on-site to promote and sustain the safety of exposed workers;
- (c) Setting up barriers around controlled areas, providing dose rate monitoring and implementing emergency response plans.

4.12. INFORMATION TECHNOLOGY PROFESSIONALS

IT forms the core IR infrastructure. The large volume of data acquired by high end IR equipment requires efficient and fast methods for distribution, storage and analysis. IR facilities utilize IT for multiple purposes, including image formatting (DICOM), image archival and retrieval (PACS), scheduling and inventory management of the IR procedures (RIS), human resource management, office management and QA/QC. Further, advanced post-processing and electronic simulation software are used for IR procedure planning, rendering the selection of particular digital medical devices important. There is great potential for customization and indigenization of these capabilities. The availability of a trained IT professional, with at least a bachelor's degree in computer science or IT from a recognized university, as per the requirements of the Member State, is essential. The roles of IT professionals include optimal IT utilization to enhance workflow, quality, cybersecurity of patient data and relevant archiving on hospital servers. The employment can be on a case by case basis, and part or full time, depending on local needs and the needs of the facility [51].

4.13. WASTE DISPOSAL UNIT

A well laid out policy for the environmentally friendly disposal of biological waste, used consumables and other wastes in IR facilities is essential to safeguard the health of the patients, the staff and others, such as facility visitors. Human resources for this disposal should be clearly identified, and the job responsibilities and procedures for disposal should be specified in the IR facility manual.

4.14. DIFFICULTIES

Human resource estimates to define the optimal size of the staff for the job descriptions detailed in Sections 4.1–4.12 are not an exact science [36–40]. Demand is difficult to determine, as it is contingent upon the interplay of the following factors:

- *Outdated workload measurement.* Human resource planning often tends to rely on outdated or incomplete measurements of workload and is frequently based on simple reports of imaging examination numbers and/or procedures performed per operator. These do not consider the complex roles and responsibilities in the IR facility.
- *Case time.* The time required to complete cases is difficult to predict in view of the inherent intricacies of the techniques, devices and individual patients.
- *Complexities of IR specialist work responsibilities.* These may include clinical, imaging, IR procedural, administrative, teaching, educational and research related responsibilities and interdisciplinary interactions, such as decision making meetings, interdisciplinary conferences and ward rounds.
- *Public and private workload balance.* Available workload data are mainly hospital based and generated by the public sector. Data from outpatient clinics are not fully available, and only limited information can be tapped from the private sector.
- *Uncertainty in population mobility.* This poses a particular challenge in many countries where IR services may be available to the population but are inaccessible to many for a host of reasons, including lack of public transport in remote areas.
- *Others.* Difficulties may arise when making certain qualitative assumptions that have a significant impact on IR employment planning, including those related to the following:
 - Dynamics of public and private sector interfaces;
 - Patient culture and expectations;
 - Health care policies in Member States;
 - Employment opportunities abroad;
 - Administrative overlay in public services;
 - Workforce outputs;
 - Unpredictable service needs;
 - Incentives and disincentives of public employment leading to rapidly changing ratios of public to private specialists.

For a more realistic appraisal, development of more population based methods to obtain projections of IR human resources is needed. This will depend

on local disease databases, infrastructure, facilities available and the clinical demands on the IR facility, among other factors. These factors make it impossible to provide arbitrary numbers in terms of IR specialists and other stakeholders required to staff a given facility. Estimates should be individualized with respect to local needs, since benchmarks do not exist.

4.15. ADDITIONAL RECOMMENDATIONS

The teaching and development of health care professionals and other staff has to address issues related to the advancement of skills and competencies relevant to human resource allocation and particular job responsibilities. Continuing professional development activities need to be documented. All personnel in the IR facility should hold an active professional licence by the designated authority and should work within the scope of practice. One health care professional in the IR facility should be the designated RPO responsible for the radiation protection programme of the facility. This programme should include, but not be limited to, the use and monitoring of personal protective devices in accordance with applicable laws and regulations in the Member State. Such implementation includes many other aspects, such as individual monitoring of staff and local rules and procedures. GSR Part 3 [11] and SSG-46 serve as references [12].

As many members of the IR staff as possible should regularly complete basic training in cardiopulmonary resuscitation and basic life support to ensure availability of a pool of informed staff in an emergency, with at least one always present until all patients have left the IR area. Moreover, every physician and nurse in an IR facility is required to maintain certification in advanced cardiac life support and in moderate sedation and analgesia, also known as ‘intravenous conscious sedation’, as per the policies of the national medical council. The dedicated training course on intravenous conscious sedation focuses on the pharmacology of agents commonly used during sedation and the antagonists for sedation reversal. IR staff should also be educated in and provided with information on waste management, radiation protection, fire safety, hazardous substances and their appropriate handling, and relevant responsibilities [52–54].

4.16. CONCLUSION

Best practices in IR should be provided to all patients on an equal access basis across any country. However, a major challenge for commissioners and providers of health care in Member States will be to ensure that good health care outcomes requiring IR are equitably available everywhere and for everyone.

A good, well resourced IR service can contribute to significant savings in both financial and non-financial terms, along care pathways for both planned and emergency care. Member States should identify all stakeholders in the practice of IR and optimize staffing requirements to ensure that the highest clinical standards are maintained in each country. They should use available resources to ensure that the practice of IR does not endanger the safety of the patient, operator, paramedical staff or others. In this regard, radiation safety as well as optimal waste disposal should figure among national health care priorities. It may be prudent to explore the possibility of developing a more flexible workforce in IR facilities.

Educational initiatives should be in place for the development and implementation of QA, QC and quality management programmes in IR. Steps should be taken to ensure that the practice of IR is conducted by qualified personnel, including structured educational programmes for initial training, as well as regular knowledge updates. Member States should move towards creating uniform certification for training programmes in IR and for radiation protection and safety at both national and regional levels.

5. RADIATION PROTECTION AND SAFETY

5.1. BACKGROUND

The use of radiation for medical purposes contributes over 95% of the total human made radiation exposure and is exceeded only by natural background radiation among sources of exposure to the world's population [55]. However, for some high income countries, the increased use of diagnostic radiology — in particular high dose X ray technology such as CT — has resulted for the first time in history in the annual collective and per capita exposure to ionizing radiation exceeding that from natural background radiation [55].

Over recent decades, IR procedures have grown more frequent and more significant in clinical management algorithms. Current trends reveal that clinical indications for IR referral should continue to grow. Of all imaging modalities employed in IR, fluoroscopy continues to be the most commonly used for guiding percutaneous procedures. It is well known that the radiation exposure to patients and staff during fluoroscopic procedures is higher than from simple static radiographic projections such as chest or abdominal X rays. Complex, fluoroscopically guided procedures that involve long fluoroscopy times and sometimes multiple runs of serial radiographic imaging surpass radiation

doses received during conventional diagnostic imaging examinations. As the popularity of these procedures increases, the potential benefits and risks of radiation exposure for both patients and staff should be realistically evaluated. The following factors need to be considered for radiation protection: first, the number of radiation induced injuries may increase unless proactive efforts are supported to identify their cause and curb their occurrence. Second, more complex procedures will continue to be developed and could lead to a greater proportion of lengthy procedures, conferring greater potential for radiation related injuries. Third, it is expected that such procedures will continue to expand not only in number but also in the number of localities where they are performed, introducing the probability that they will be attempted with equipment that is not well designed for optimized patient and staff radiation protection [56].

In view of the above concerns, it should be understood that radiation protection is a mandatory and unequivocal component of the knowledge and expertise of those who perform image guided procedures. Thus, multiple levels of safety are integrated into IR practice and training programmes.

The IR practice should be performed according to the radiation protection requirements provided in the national legislation. These requirements may vary from country to country, but in general, compliance with the requirements of GSR Part 3 would be expected [11].

According to the International Commission on Radiological Protection (ICRP), the medical uses of ionizing radiation are a planned exposure situation involving three categories of exposure [57]:

- (a) Medical exposure. This primarily relates to patients undergoing radiological procedures, but also to carers and comforters and to volunteers subject to exposure as part of a programme of medical research.
- (b) Occupational exposure. This concerns medical staff involved in the performance of IR procedures.
- (c) Public exposure. This applies to members of the public, such as hospital staff and patients not involved in radiological procedures.

The ICRP defines three general principles of radiation protection, which form the basis of the IAEA safety standards [11, 12, 57]:

- (a) Justification of practice. Facilities and activities that give rise to radiation risks must yield an overall benefit. This principle applies to occupational, medical and public exposure.
- (b) Optimization of protection and safety. Protection must be optimized to provide the highest level of safety that can reasonably be achieved. This principle is applicable to occupational, medical and public exposure.

- (c) Limitation of doses. Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm. Dose limits apply only to occupational and public exposure; they do not apply to medical exposure.

This section covers general requirements for radiation protection and safety with respect to these three categories of exposure related to fluoroscopy guided procedures in IR. It is based on ICRP recommendations [57], requirements set out in GSR Part 3 [11], as well as guidance provided in SSG-46 [12], among other relevant publications.

5.2. MANAGEMENT SYSTEM FOR RADIATION PROTECTION

Every IR facility should have an appropriate management system in place to ensure complementarity between the requirements for radiation protection and safety and other health care delivery requirements. A licensee (and employer where appropriate) should develop, implement and document a radiation protection and safety programme commensurate with the nature and extent of the risks of the practice to ensure compliance with radiation protection standards. This programme needs to cover all relevant aspects of the protection of workers, patients and the general public. In addition, a QA programme for medical exposures needs to be established, according to the requirements of GSR Part 3 [11].

Depending on the size of the IR facility, committees might be formed to help the implementation of those aspects of the management system pertaining to the radiation protection and safety programme. One such committee might be a radiation safety committee and another a QA committee. The function of the radiation safety committee is to advise on safe operation and compliance with radiation protection and safety regulatory requirements. The QA committee oversees the QA programme for medical exposures, determines policy and gives direction to the programme, ensures that proper documentation is being maintained and reviews the effectiveness of the programme [12]. The radiation safety committee and the QA committee have some functions in common, especially regarding medical exposure, and harmonization of their work is required to avoid the duplication or the inadvertent omission of some functions.

The members of the radiation safety and QA committees should be at the senior level and typically include an administrator representing the management, an IR physician, a medical radiation technologist, a CQMP and the RPO. The RPO should have day to day oversight of the radiation protection programme and report to the radiation safety committee. The RPO has no direct responsibilities or roles with respect to the QA programme for medical exposure, which requires

involvement of a medical physicist qualified in IR [11, 12]. In facilities with fewer personnel, the role of the RPO is often assumed by a medical physicist or other clinical staff member. The licensee should ensure that the committees are provided with the resources required to oversee the programmes, as well as the authority to communicate with the management on a periodic basis.

Every individual involved in IR activities has to regard the rules and regulations as necessary and needs to know their responsibilities for radiation protection through the formal assignment of duties. The following parties have responsibilities regarding radiation protection: the licensee and employer, IR physicians, IR medical radiation technologists, RPOs, CQMPs, nurses and other medical staff involved in IR procedures, and maintenance engineers. Provision needs to be made to ensure that all personnel with responsibilities for radiation protection and safety are appropriately trained and qualified so they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures.

The management system should also provide for record keeping and access to records. Available digital information systems in medical facilities should be utilized to have a positive effect on the practice of radiation protection and safety. For example, use of these systems can help to avoid unnecessary, inappropriate or repeat studies by making patient information available to multiple users. These systems can also help in monitoring doses to patients, optimizing procedures, setting alert levels and planning patient follow-up. The management system should include a review cycle.

5.3. SAFETY ASSESSMENT ANALYSIS

Safety assessment is required before an IR facility is operational or when a major change in operation is contemplated. It needs to be performed according to the requirements of the national regulatory body and to be well documented, and the report should be submitted to the regulatory body if required.

Safety assessments in IR include consideration of all the steps in the use of X ray imaging; occupational, public and medical exposure; and the possibility of unintended or accidental exposures. Assessment should be systematic and contain information on the identification of possible events leading to accidental exposure and on how it can be prevented and mitigated [12].

The typical causes and contributing factors to accidental exposures in IR that must be considered in the safety assessment analysis are presented below, adapted from SSG-46 [12]:

- (a) Problems leading to accidental exposures that have been identified from reported events include the following:
 - (i) Equipment not meeting the requirements of the International Electrotechnical Commission (IEC) or equivalent national standards.
 - (ii) Maintenance errors.
 - (iii) Errors in the identification of patients and examination sites.
 - (iv) Inappropriate examination protocols or a lack of such protocols.
- (b) Factors that may influence the frequency and severity of accidental exposures include the following:
 - (i) Insufficient training and expertise of the IR physician, medical physicists or medical radiation technologists in the following areas:
 - Equipment being used and its features and options;
 - Optimization of protection for patients;
 - Optimization of protection for staff.
 - (ii) No reassessment of staffing requirements after the purchase of new equipment or an increase in workload.
 - (iii) Lack of a programme for acceptance tests and commissioning of equipment.
 - (iv) Inadequate QA and lack of defence in depth. Examples include:
 - Dose rates for IR equipment set too high;
 - Malfunction of the ADRC system or the automatic brightness control.
 - (v) Lack of a maintenance programme.
 - (vi) Poor, misunderstood or violated procedures.
 - (vii) Lack of operating documents in a language understandable to users.
 - (viii) Dose display or dose rate display not used during a procedure.
 - (ix) Lack of dose alerts if the selected factors seem inappropriate.
 - (x) Lack of radiation protection tools and devices in the examination room.
 - (xi) Misunderstanding of displays or software messages.
 - (xii) Inattention of staff to the task at hand.
 - (xiii) Inconsistent use of different quantities and units.
- (c) A combination of several contributing factors (as in most accidental exposures), such as the following:
 - (i) Lack of commitment of the licensee (administrators and managers of the medical facility and/or the IR facility).
 - (ii) Insufficient training of staff.
 - (iii) Insufficient QA.

5.4. DESIGN OF AN INTERVENTIONAL RADIOLOGY FACILITY AND EQUIPMENT

5.4.1. Facility design

Provisions for the incorporation of radiation safety features are best made at the facility design stage, including the design of X ray rooms and other related rooms. The siting and layout need to take into account the types of IR procedure, workload and patient flow, both within the IR facility and, in cases where it is part of a larger hospital or medical centre, with other departments of the wider facility.

Larger rooms are preferable to allow easy access for patients on bed trolleys. They also allow easier patient positioning and facilitate both equipment and staff movement during the procedure, which, in the case of IR procedures, helps to reduce time and exposure. Larger rooms also reduce the levels of secondary radiation (owing to scattering and leakage) potentially reaching areas occupied by staff and public areas, typically reducing the level of shielding required.

At the design stage, both structural and ancillary protective barriers should be considered for shielding. Considering that in angiography rooms IR staff members work close to the patients, ceiling mounted protective screens and table mounted leaded curtains should be installed. Such ancillary protective barriers for image guided interventional procedures have to be part of the initial facility plan and should be designed so as to not interfere with the sterility requirements and other aspects of the medical procedure. Shielding of walls needs to be at least two metres high, and any doors and viewing windows in walls or doors should have at least the same lead equivalence as the minimum shielding specifications for the shielded wall or barrier in which they are located. Due consideration needs to be given to the provision of floor and ceiling shielding when rooms immediately below and above the X ray installation, respectively, are occupied. All penetrations and joints in shielding need to be arranged so that they are equally as effective in shielding radiation. Further guidelines for planning IR facilities and relevant references are given in paras 3.9–3.16 of SSG-46 [12].

5.4.2. Safety features of fluoroscopy equipment

The requirements for medical radiological equipment and its software are established in paras 3.49 and 3.162 of GSR Part 3 [11]. Hospital managers, who act as licensees and take responsibility for the radiation safety of medical radiological equipment used in the hospital, need to impose purchasing specifications that include conditions to meet relevant international standards developed by the IEC and the International Organization for Standardization (ISO) and/or equivalent national standards adopted by the regulatory body. In

some Member States, there may be an agency with responsibilities for medical devices or a similar organization that gives type approval to particular models and manufacturers of medical radiological equipment [12]. Technical specifications for X ray equipment are provided in Section 3.4.

Additionally, the following radiation protection tools need to be provided:

- In-room protective devices:
 - Protective lead curtains or drapes mounted on the patient table.
 - Ceiling suspended protective screens for protecting eyes and the thyroid while keeping visual contact with the patient. Technical advances with such screens include systems that move with the operator.
 - Mobile shields either attached to the table (lateral shields) or mounted on coasters (full body).
 - Disposable protective drapes for the patient.
- Personal protective equipment for all staff members (see also Section 5.6.1):
 - Wraparound aprons, preferably consisting of vests and skirts.
 - Thyroid shields.
 - Protective eyewear.

IR equipment should be supplied with all appropriate radiation protection tools as a default, rather than as optional extras. This applies to both patient radiation protection and occupational radiation protection.

5.5. RADIATION PROTECTION OF PATIENTS

5.5.1. Justification of medical exposure

With respect to justification of medical exposure of patients, SSG-46 [12] states:

“The diagnostic or therapeutic benefits of exposure are weighed against the radiation detriment they might cause, with account taken of the benefits and risks of available alternative techniques that do not involve medical exposure.”

This includes generic justification of a given radiological procedure and individual justification of every exposure of a given patient. The health authority, in conjunction with the appropriate IR professional society, needs to carefully review and justify existing and new techniques and technologies as they

evolve, considering their effectiveness and risks, including — but not limited to — radiation risk.

The responsibility for individual justification of every particular IR procedure for a given patient is shared between the physician who refers the patient for a procedure and the IR specialists who will perform the procedure. In taking the decision, the specific objectives of the exposure, the clinical circumstances and the characteristics of an individual involved need to be taken into account, as well as the risk of not performing the procedure and the effectiveness and risks associated with any available alternative diagnostic or therapeutic methods [11, 12]. Useful tools to support the decision making process are national or international imaging referral guidelines developed by professional societies.

The risks associated with the use of ionizing radiation to treat patients with urgent medical needs require a different type of consideration from the risks associated with exposure to a population of healthy individuals. For example, when a patient is likely to die because of a condition, the long term risks associated with IR radiation exposure are outweighed by the immediate benefit of the potentially life saving procedure. This is true, for example, in a 65 year old patient with severe obstructive arteriosclerotic disease or in the setting of acute gastrointestinal bleeding.

On the other hand, healthy patients undergoing embolization of uterine leiomyomata (fibroids) or of a scrotal varicocele require a different type of consideration because of the anticipated life expectancy ahead of them. In other words, when appraising the anticipated benefit of a procedure during which ionizing radiation is used, it is necessary to assess the radiation risk in relation to the overall health status of the individual undergoing the procedure. This assessment includes age, sex, health status and life expectancy considering the medical condition and treatment. Often omitted when discussing the benefits versus risks of medical ionizing radiation are the following three aspects [56]:

- (a) Assessing the risk of ionizing radiation in relation to the specific medical status of an individual patient;
- (b) Assessing the prognosis of the patient in the absence of its use;
- (c) Placing all risks in perspective against the anticipated benefits of the medical procedure.

As many fluoroscopy guided interventional procedures are associated with a relatively high radiation exposure, special attention in the justification process is required for two groups of patients: pregnant patients and paediatric patients. In the case of the former group, attention is needed because of the higher radiation sensitivity of the embryo and foetus [58, 59]. With regard to the

latter, greater attention is needed because children are at higher risk of incurring long term radiation induced stochastic effects. In paras 3.254 and 3.255, SSG-46 recommends the following approaches for ensuring that the pregnancy status of patients is known [12]:

“3.254. The first approach is through the posting of clear signs (possibly including a pictorial representation of pregnancy) in languages easily understood by the people using the radiology facility, posing the question ‘Are you pregnant or possibly pregnant?’ and ‘If so, please tell the staff’. Such signs should be posted widely in the facility, including in waiting rooms and cubicles. The second approach is to ask patients directly whether they are or might be pregnant. This might not always be so easy given social and cultural sensitivities, but it should be done when necessary.

“3.255. Neither of the approaches described in para. 3.254 will work if the patient does not know whether she is pregnant. For this reason, para. 3.176 of GSR Part 3...has an additional requirement on facilities to ‘ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus’. Such radiological procedures would include those that involve primary beam irradiation of the abdomen or pelvis area delivering relatively high patient doses directly to the embryo or fetus, or to volumes near the uterus such that significant scatter radiation reaches the embryo or fetus. Cooperation with the referring medical practitioner, through standard requests for pregnancy status for specified procedures, is one approach. The referral form should include a ‘tick box’ for pregnancy status. In case of doubt, a pregnancy test or a determination of hormone levels to assess menopausal status can be carried out.”

The importance of radiation protection is greater in the paediatric setting owing to multiple factors, including that children are more sensitive to radiation than adults and have a longer life expectancy. Information to support health care discussions about the benefits and risks of the increasing use of ionizing radiation in paediatric imaging and health care has been published by WHO [60].

5.5.2. Optimization of protection and safety

Following justification, the IR procedure is required to be performed in a way that optimizes patient protection by keeping the exposure of patients to the minimum necessary while obtaining images of sufficient quality to guide the

intervention in achieving the procedure’s objective [11, 12]. Optimization does not mean minimization of dose. GSR Part 3 [11] states the following:

“Too low a radiation dose could be as bad as too high a radiation dose, in that the consequence could be that...the images obtained are not of suitable diagnostic quality. It is of paramount importance that the medical exposure leads to the required outcome.”

The core team members in the optimization process are the IR physicians, the medical radiation technologist and the medical physicist qualified in IR, all with sufficient knowledge and understanding of the factors affecting image quality and patient dose [45]. Other members of the IR team — such as other clinicians, anaesthetists and nurses — need to also understand the principle of optimization and to undergo both initial education and ongoing training [61].

Optimization includes the following equally important components:

- (a) Design considerations. These involve optimal selection of design features of a fluoroscopy system consistent with the intended clinical uses, and their optimal setting at the time of commissioning of the system, tailored to the clinical tasks and required image quality (see Section 6.3.2).
- (b) Comprehensive QA programme. This includes equipment maintenance and QC tests to verify the performance of equipment (Section 5.4.3), as well as clinical audit reviews (Section 5.1.1).
- (c) Dose audits and diagnostic reference levels (Section 6.4.3). These include monitoring of skin doses (Section 6.6.4).
- (d) Operational considerations. These involve proper use of the available equipment features and settings by the operators in order to perform the intended clinical task with minimum possible exposure to the patient and the clinical team members (Section 6.4.5).

5.5.3. Dose audits and diagnostic reference levels

Different radiation dose quantities are introduced to quantify the radiation exposure and related risk. Table 2 and Fig. 1 present a summary of the basic dose quantities, their definitions, units and their application, as recommended by the ICRP [58]. These quantities can be used for different applications and exposure categories, including patients, staff and the public.

The dose to tissues and organs provides the best estimate of radiation effects, but it is not easily measurable in patients. In most situations, it is calculated or estimated using mathematical models and simulations [62].

TABLE 2. RADIATION DOSE QUANTITIES

Quantity	Symbol	Unit	Definition	Application
Absorbed dose	D	Gy (gray)	Mean energy (joule) per unit mass (kilogram) imparted by ionizing radiation to matter	Measurable for any type of radiation and any type of matter
Air kerma	K	Gy (gray)	Sum of the initial kinetic energies of all charged particles liberated by X ray photons per unit mass	Measurable for photons in air For X rays, air kerma and absorbed dose in air are equal
Equivalent dose	H	Sv (sievert)	Absorbed dose averaged over a tissue or organ, multiplied by the radiation weighting factor, which depends on the type of radiation	Assessed by calculation For X rays, 1 Gy = 1 Sv
Effective dose	E	Sv (sievert)	Weighted sum of the equivalent dose in a number of tissues/organs, using tissue specific weighting factors that approximately reflect their relative sensitivity to radiation induced stochastic effects	Assessed by calculation Used to assess the probability of health detriment from stochastic effects at population level Not to be used for individual risk assessment [57]

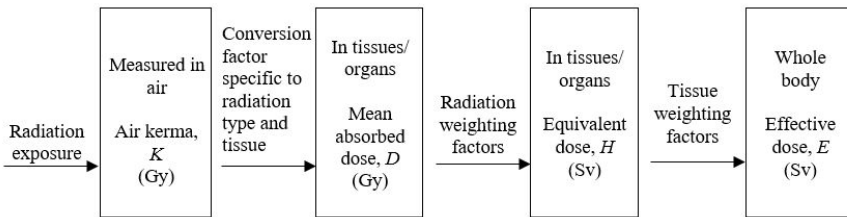


FIG. 1. Relationship between air kerma (K), absorbed dose (D), equivalent dose (H) and effective dose (E).

For practical dosimetry in fluoroscopy, two specific dose quantities describing exposure to the patient are used. These dose indexes are displayed, recorded and archived in modern IR fluoroscopy systems:

- (a) Kerma–area product (KAP) or air kerma–area product (P_{KA}), reported also as dose–area product (DAP), is widely used as an estimate of patient dose in X ray planar imaging (radiography and fluoroscopy). It is defined as the integral of the air kerma over the area of the X ray beam in a plane perpendicular to the beam axis. The unit is $Gy \cdot cm^2$, but the unit for the reading from integrated dosimetry systems may vary with manufacturer and software version. It is approximately invariant with distance from the X ray tube focus and is measured with a transmission ionization chamber integrated into the X ray equipment (known as a KAP meter or DAP meter). In modern fluoroscopy equipment, it can be also calculated using the available data of the X ray exposure.
- (b) Incident air kerma at the patient entrance reference point, $K_{a,r}$ (unit Gy), is the air kerma at a point in space located at a fixed distance from the focal spot (patient entrance reference point). For isocentric fluoroscopy systems (C-arms) the patient entrance reference point is defined as lying on the central axis of the X ray beam, 15 cm from the isocentre in the direction of the focal spot [15]. The IEC refers to this quantity as ‘reference air kerma’. Other common terms for this quantity are ‘cumulative air kerma’ and ‘cumulative dose’. It is a useful predictor of maximum skin dose, and therefore of the risk of tissue effects, such as radiation induced skin injury [62].

Fluoroscopy systems for IR display cumulative values of KAP and reference air kerma during and after the procedure, as well as their rates during the procedure. Further guidance on the measurement of these two quantities and the calibration of dosimeters and dose displays is provided in Ref. [62]. Calibrations of dosimeters and displays should be verified by a CQMP, preferably at intervals of no more than 1–2 years.

Information about dose values (P_{KA} and $K_{a,r}$) for each patient needs to be recorded in the departmental records, along with important procedure details. These include fluoroscopy time and number of recorded images, pulse rate for fluoroscopy, frame rate for DSA and exposure programme options [63, 64].

The QA programme should include periodic local reviews of patient dose quantities. Following the requirements of GSR Part 3 [11], each IR facility should establish ‘typical doses’ to patients as a basis for applying methods of dose reduction [11, 12, 45]. Typical doses are then compared to diagnostic reference levels (DRLs) for the same procedure, established as a result of consultation

between the health authority, relevant professional bodies and the regulatory body and following well established international guidelines [12, 45, 62, 63, 65].

In GSR Part 3 [11], the DRL is defined as:

“A level used in medical imaging to indicate whether, in routine conditions, the dose to the patient...in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure.

“Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.”

For establishing DRLs, the most frequently performed procedures and those associated with higher doses are selected, and for each procedure, dose data are collected from a representative number of IR facilities in the region/country. The ICRP recommends that for IR, data from at least 30 patients are collected for diagnostic fluoroscopy procedures and from a larger group for IR procedures, preferably including all patients, to compensate for the larger variability of dose values [63]. Considering that patient dose depends strongly on the complexity of each individual procedure, in addition to the analysis of large samples, the ICRP recommends setting DRL values based on the complexity of the procedure. For example, for percutaneous coronary interventions, complexity is determined according to the number of vessels treated [66–68]. The national DRLs in Spain for common IR procedures (i.e. transjugular hepatic biopsies, biliary drainage, uterine fibroid embolization, colon endoprosthesis placement, femoropopliteal revascularization, iliac stent placement and hepatic chemoembolization) have been set for three levels of complexity [69]. Recently, the European EUCLID project conducted a survey to collect data to establish DRLs on the basis of clinical indication for the most important — from a radiation protection perspective — IR procedures in Europe [70].

Once DRLs are established, they need to be used for benchmarking local practice and identifying potential for optimization [71, 72]. Each IR facility has to establish its own typical dose values for the same procedures for which DRLs are provided. This is done by collecting dose values from a representative sample of patients for the same age, size and weight group for which DRLs have been established. A typical dose value is then set at the median of the dose distribution in the patient sample. If the comparison shows that the typical dose value for the IR facility exceeds the DRL, or that it is substantially below the DRL (e.g. if it is below the tenth percentile [68] of the dose distribution used to set DRLs), this should trigger investigation, review and, if appropriate, corrective actions to optimize patient protection [11, 12, 63, 73]. Higher radiation doses may be due

to the equipment (poorly functioning equipment or incorrect equipment settings), suboptimal procedure performance or operator inexperience. Values below DRLs may need optimization if the image quality is inadequate for clinical purposes. It is important to note that a dose audit should always be performed in parallel with image quality evaluation and should obtain enough information for diagnosis. In such a review, the complexity of procedures performed in the facility needs to also be considered, since higher doses might be also due to more complex procedures. If national or local DRLs are not available, a facility's typical dose values can be compared with values published in the literature, with careful consideration of the specificity of IR procedures. It is important to stress that DRLs should not be used as dose limits and no individual patient's dose should be compared with a DRL.

Typical dose values and DRLs are an important and objective optimization tool. They do not constitute a delimitation between good and bad medicine and will continue to warrant revision as technologies and techniques improve and as medical knowledge overall progresses. The adaptable nature of DRLs should be understood by relevant IR personnel. DRLs should be updated periodically to reflect any change in the equipment, its settings and operation. SSG-46 recommends a review cycle of three to five years for DRLs and more frequently for local dose audits [57]. Availability of electronic dose monitoring tools can facilitate the process and enable deeper and more efficient dose analyses, as they allow the collection of not only dose values but also all equipment and procedural factors that might explain dose variations and identify where improvement is possible.

For a successful patient dose optimization process, the following five step process at the hospital level is recommended [74]:

- (a) Establishment of a QA programme.
- (b) Establishment of a dose optimization team consisting of an IR specialist, a medical physicist and a medical radiation technologist.
- (c) Determination of baseline patient radiation dose levels and image quality, as well as comparisons with benchmarks to prioritize the clinical IR protocols to be optimized.
- (d) Modification of protocols by the dose optimization team. The reassessment of examination technical parameters is a complex task that needs to be performed by the medical physicist in collaboration with the other members of the team once steps (a)–(c) are finalized. Medical technology today offers numerous tools to achieve this goal, but this should be attempted only when in-depth knowledge of machine performance has been acquired and the influence of each technical parameter, post-processing algorithm or other feature on image quality and radiation dose has been considered. Therefore,

the medical physicist needs to study all the technical documentation to understand each machine's features and optimization tools. The manufacturer's application specialists can provide advanced knowledge, best practice, and tips and tricks for the specific modality in question.

- (e) Evaluation of optimization process and its effect on patient dose and image quality.

5.5.4. Skin dose monitoring and prevention of tissue overexposure

In addition to the stochastic risk, which is considered as a primary risk in X ray imaging methods, some complex IR procedures under fluoroscopy guidance might involve the risk of tissue reactions (deterministic effects) [75, 76]. Tissue reactions are different from stochastic in that they have a practical threshold under which the effect does not occur. The threshold dose is not an absolute number and varies somewhat by individual. The dose threshold for tissue response is defined as the dose estimated to result in only 1% incidence of defined tissue reactions [75]. Both the onset and severity of deterministic effects vary according to the dose of radiation absorbed by the tissues. Usually, there is a period of latency (several weeks) before the effect becomes clinically apparent. Therefore, the physician who performed the procedure may not observe or be aware of the symptoms and/or signs when they occur. Examples of deterministic effects include skin injury, hair loss and cataract.

The primary tissue reaction from fluoroscopically guided interventional procedures is skin injury that might involve not only skin but also the underlying tissues at several centimetres below the skin surface [77, 78]. The first known case of radiation induced dermal necrosis from a transcatheter intervention occurred in 1990 but did not appear in the literature until 1996 [79]. In 1992, a conference jointly sponsored by the American College of Radiology (ACR) and the FDA was held in Reston, VA, USA, to address changing uses of fluoroscopy [80]. In 1994, the first published report on the potential for injury to patients undergoing high X ray dose IR procedures appeared in the medical literature and, subsequently, more cases were reported [56, 59, 76, 81].

If the radiation dose is high enough to kill or sterilize a critical number of cells, a skin injury will develop. The severity of the reaction increases as the local dose increases. The injury threshold, the nature and severity of the injury and its time course vary from patient to patient. Most radiation induced skin injuries are self-limited and can be managed with conservative medical care, but some are major, require extensive surgical repair and may cause pain and disfigurement. Such cutaneous injuries typically involve the patient's back, but injuries to the scalp (especially hair loss) and to the skin of the arm or breast may also occur, depending on the location where the X ray beam enters the patient's body [78].

The expression of skin injury varies and depends on several factors that affect the dose–response relationship and the kinetics of healing. Total dose, the interval between radiation exposures (dose fractionation) and the size of the irradiated area can affect the expression and severity of radiation injury. Physical and patient related factors that affect the expression of the injury include smoking, poor nutritional status, compromised skin integrity, obesity, overlapping skin folds and the location of irradiated skin [78]. The anterior aspect of the neck is the most sensitive site. The flexor surfaces of the extremities, the trunk, the back, the extensor surfaces of the extremities, the nape of the neck, the scalp, the palms of the hands and the soles of the feet are less sensitive, in that order. The scalp is relatively resistant to the development of skin damage, but scalp hair epilation occurs at lower doses in comparison with hair elsewhere on the body. Ethnic differences in skin colouration are also associated with discrepant radiation sensitivity; individuals with light coloured hair and skin are most sensitive [78]. Skin injury includes the following:

- Erythema (redness, dry desquamation, peeling) and temporary epilation that may be apparent after a latent period of three weeks. Epilation from higher doses can be permanent.
- Moist desquamation (blistering) and tissue necrosis are effects that may be seen after three weeks of latency following a very high level dose.
- Telangiectasia becomes apparent after a longer latency period, usually more than 50 weeks.

The onset of skin reactions and injuries depends on the dose received by the skin. Effects are classified into prompt (less than two weeks), early (2–8 weeks), midterm (6–52 weeks) and long term (more than 40 weeks). The National Cancer Institute of the USA has established a skin reaction grading system that classifies skin reactions according to severity, ranging from grades 1 to 4, with 1 being the least severe and 4 the most severe (Table 3) [82, 83].

The radiation dose delivered to skin in many IR procedures is significant. In a multicounty study by the IAEA, it was found that about 20% of patients receive a skin radiation dose greater than 2 Gy, a threshold for early transient erythema [84]. In another IAEA sponsored multicounty project to measure patient skin dose in interventional cardiology, about 9% of patients received more than 2 Gy [85]. Moreover, medical specialists other than radiologists and cardiologists are using fluoroscopy in patient care. Examples of these procedures, which may or may not be performed using IR, include endovascular aneurysm repair, renal artery angioplasty, iliac angioplasty, ureteric stent placement, therapeutic endoscopic retrograde cholangio-pancreatography (ERCP) or bile duct stenting

TABLE 3. OVERALL DOSE–TIME RELATIONSHIPS FOR RADIATION EFFECTS ON THE SKIN AND HAIR FROM A SINGLE DELIVERY OF RADIATION DURING A FLUOROSCOPICALLY GUIDED PROCEDURE, CLASSIFIED IN FIVE BANDS [82, 83]

Band	Single site acute skin dose ^a (Gy)	NCI skin reaction grade	Approximate time of onset of effects			
			Prompt (<2 weeks)	Early (2–8 weeks)	Midterm (6–52 weeks)	Long term (>40 weeks)
A1	0–2	n.a.	No observable effects expected			
A2	2–5	1	Transient erythema	Epilation	Recovery from hair loss	None expected
B	5–10	1	Transient erythema	Erythema, epilation	Recovery At higher doses, prolonged erythema, permanent partial epilation	Recovery At higher doses, dermal atrophy and/or induration
C	10–15	1–2	Transient erythema After very high doses, oedema and acute ulceration; long term surgical intervention likely to be required	Possible dry or moist desquamation Recovery from desquamation	Prolonged erythema Permanent epilation	Telangiectasia ^b Dermal atrophy and/or induration Skin likely to be weak

TABLE 3. OVERALL DOSE–TIME RELATIONSHIPS FOR RADIATION EFFECTS ON THE SKIN AND HAIR FROM A SINGLE DELIVERY OF RADIATION DURING A FLUOROSCOPICALLY GUIDED PROCEDURE, CLASSIFIED IN FIVE BANDS [82, 83] (cont.)

Band	Single site acute skin dose ^a (Gy)	NCI skin reaction grade	Approximate time of onset of effects			
			Prompt (<2 weeks)	Early (2–8 weeks)	Midterm (6–52 weeks)	Long term (>40 weeks)
D	>15	3–4		Erythema, epilation Moist desquamation	Dermal atrophy Secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required At higher doses, dermal necrosis; surgical intervention likely to be required	Possible late skin breakdown Wound might be persistent and progress into a deeper lesion Surgical intervention likely to be required

^a Single site acute skin dose. Note that this is the actual skin dose, including backscatter, and should not be confused with the reference point air kerma (kinetic energy released per unit mass, $K_{a,r}$). Skin dosimetry is unlikely to be more accurate than $\pm 50\%$.

^b Radiation induced telangiectasia. This condition is associated with an area of initial moist desquamation or the healing of ulceration, which may be present earlier.

n.a.: Not applicable.

Note: The data shown do not apply to the skin of the scalp; rather, they are applicable to the normal range of patient radiation sensitivities of skin and hair in the absence of mitigating or aggravating physical or clinical factors. The dose and time bands are not rigid boundaries; signs and symptoms are expected to appear earlier as the skin dose increases. Abrasion or infection of the irradiated area would be expected to exacerbate radiation effects. NCI: National Cancer Institute of the USA.

and drainage. These interventions can potentially impart skin doses above threshold to patients [86].

Recent guidelines of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) [87] identified the following as potential high dose procedures requiring additional attention: transjugular intrahepatic portosystemic shunt (TIPS); percutaneous biliary drainage/stenting with or without biopsy, stone removal or rendezvous manoeuvre; hepatic chemoembolization/abdominal arterial embolization; pelvic arterial embolization; thoracic and/or abdominal endovascular aneurysm repair; neuroembolization/head (arteriovenous malformation (AVM), aneurysm, tumour); neuroembolization/spine (AVM, aneurysm, tumour); mechanical thrombectomy (stroke); selective internal radiation therapy (SIRT; ⁹⁰Y radioembolization); transcatheter aortic valve implantation; percutaneous coronary interventions (e.g. coronary stenting, ablation); and percutaneous vertebroplasty and kyphoplasty.

While severe skin injury is rare, the near term impact on the patient and the patient's family, as well as on the medical profession, can be quite severe. For the patient, consequences can include a relatively acute onset of long term pain and suffering with loss of mobility and income, leading to severe depression in some cases [56]. Prevention of skin injuries is possible in most cases and IR physicians should be aware that significant radiation induced skin injury can result from long duration fluoroscopy and extended and inappropriate use of fluoroscopy [77].

Minimizing the likelihood and severity of skin injuries requires attention before, during and after the procedure [76, 88–91].

Special attention might be required in the following cases [87]:

- Where patient weight is greater than 120 kg;
- In interventions in paediatric and young adult patients involving substantial absorbed dose to radiosensitive organs (e.g. lens of the eye, breasts, gonads, thyroid);
- During pregnancy;
- In procedures anticipated to be technically difficult or unusually prolonged;
- In fluoroscopically guided interventions performed in the same region within the previous three months;
- In patients with increased radiosensitivity (especially due to younger age or genetic predisposition);
- Where radiation therapy has been used or is planned for the same anatomical region.

IR departments should develop a standard checklist to identify patients at higher risk and should provide a form to educate the patient and obtain

written consent before the procedure. Monitoring of radiation dose to skin is essential. Ideally, peak skin dose needs to be assessed and displayed, but direct measurements using different types of dosimeter (e.g. thermoluminescence detectors, slow X ray films, radiochromic films, MOSFET radiation sensors) attached to the patient's entrance surface could be possible only in limited situations and cannot be used routinely [92–94]. A limited number of modern IR systems provide skin dose estimation in real time during the procedure using a calculation algorithm, while others, including some radiation dose monitoring electronic systems, provide post-procedure estimation of skin dose distribution represented as 2-D and 3-D colour coded maps [95–97]. Real time feedback has been demonstrated to have a significant positive effect on operator awareness and it is expected that such information will be integrated into IR fluoroscopy systems in the future [98, 99].

If there is no means to estimate skin dose, the quantities to be monitored during and after the procedure are the incident air kerma at the patient entrance reference point (cumulative air kerma), KAP and fluoroscopy time, displayed on the console and saved in the procedure records. The cumulative air kerma is a better predictor of peak skin dose, although they do not always correlate well, especially for procedures involving frequent change during projection, exposure mode, magnification, etc. KAP is a weaker predictor but is still useful for some procedures [100]. The fluoroscopy time and number of acquired images are poor predictors of skin injuries [93, 94]. A CQMP, with the help of the clinical staff, needs to assess the correlation between peak skin dose and dose indicators for each equipment and procedure type. A good practice is to establish a QA procedure for monitoring available dose indicators throughout the procedure and setting alert/notification levels that help operators to avoid reaching high doses to the extent possible without compromising procedure outcome. Such alerts, or notification levels, are proposed by the SIR Safety and Health Committee and the CIRSE Standards of Practice Committee [82, 101] and include the following:

- When peak skin dose is displayed: First notification at 2000 mGy (2 Gy) and subsequently every 500 mGy.
- For cumulative air kerma: First notification at 3000 mGy (3 Gy) and subsequently at every 1000 mGy.
- For KAP: First notification at 300 Gy/cm² and then at every 100 Gy/cm² (assuming a 100 cm² field at the patient's skin; the value should be adjusted to the actual field size).
- If these dose values are unavailable, first notification is at 30 min fluoroscopy time, and subsequently every 15 min.

If no automatic alerts are possible, a staff member might be appointed to monitor values and notify the operator.

The IR department should establish a procedure to record all dose indicators related to skin dose and a follow-up programme for cases with a risk of skin injury. The criteria for patient follow-up need to be set up following the guidelines of professional organizations [82, 87]. Such trigger values for patient follow-up are suggested by the IAEA to be used in an international web based voluntary and anonymous reporting system for fluoroscopy guided interventional procedures [102] and are shown in Table 4. The trigger values have been chosen so that not many patients have to be recalled. Depending on the effects discovered after following up patients who have exceeded these trigger levels, these values might be adjusted.

The dose indicators in Table 4 are listed in order of value for determining the likelihood of tissue reactions, with the most useful indicator at the top. The indicators with lower importance (KAP and fluoroscopy time) should be used to trigger follow-up only when neither of the top two (peak skin dose and incident air kerma) is available. In addition to the trigger values, the SAFRAD (Safety in Radiological Procedures) voluntary reporting system proposes that multiple fluoroscopy guided interventional procedures performed on the patient within one month might also lead to follow-up.

After the procedure, if dose indicators reach the trigger level, the patient or their carer should be advised of the possibility of a skin injury due to a tissue reaction and should be advised in writing to examine the X ray beam entrance site two to four weeks after the procedure and to notify the operator if any skin changes are observed. Some facilities place a follow-up call to the patient during this time to ask about skin irritation, and this is found to be effective in ensuring

TABLE 4. POST-PROCEDURE TRIGGER VALUES FOR PATIENT FOLLOW-UP [102]

Dose parameter	Trigger level for patient follow-up
Peak skin dose	3 Gy
Total incident air kerma at the interventional reference point	5 Gy
Total air kerma–area product	500 Gy/cm ²
Fluoroscopy time	60 min

that a patient who develops skin irritation does not seek medical help at a place where there may be a chance of missing the correct diagnosis [88].

5.5.5. Operational considerations

Following the selection and proper set-up of the fluoroscopy system for an IR procedure, optimization of the radiation protection of patients depends strongly on the proper use of the equipment's features and program modes by the operators so that clinical tasks can be carried out with minimum possible exposure to the patient and team members. The IR specialist performing the IR procedure has the main responsibility for patient protection, but other team members might also have a role. For example, the fluoroscopy system might be operated by a dedicated medical radiation technologist who is responsible for selection of the exposure modes and adjustment of the exposure settings to the clinical task, keeping in mind exposure to the patient. When the equipment is operated by physicians who perform the procedure, they should be well trained to perform this multitask role, including in the optimal use of imaging. A nurse can be responsible for briefing the patient before the procedure to ensure proper immobilization and cooperation, positioning the protection screens, monitoring the dose indicators and notifying the operator when indicators reach alert values.

Many factors influence patient exposure and image quality, including technical exposure and geometrical factors. These must be well known and used in practice by the operator. The following advice summarizes the main approaches to reducing patient dose [86–90]:

- Use a low dose rate fluoroscopy mode when possible;
- Use a low pulse rate fluoroscopy mode when possible;
- Remove the grid when performing procedures on small children;
- Use the lowest dose mode for image (cine) acquisition that is compatible with the required image quality;
- Minimize fluoroscopy time; use fluoroscopy only to guide devices and observe motion;
- Use the image on the last image hold for review instead of fluoroscopy, when possible;
- When possible, store a fluoroscopy loop instead of performing a cine run;
- If available, use a stored fluoroscopy loop for review instead of fluoroscopy;
- Minimize the number of cine series;
- Minimize the number of images per cine series;
- Never use cine as a substitute for fluoroscopy;
- Collimate the radiation beam to the area of interest;
- Use virtual collimation if it is available;

- Use wedge filters when they are appropriate;
- Keep the image detector (image intensifier or flat detector) as close as possible to the patient;
- Keep the patient as far as possible from the X ray tube;
- Try to avoid steeply angulated projections (especially left anterior oblique cranial);
- Try to vary the C-arm angulation slightly to avoid concentrating the radiation dose at a single site on the patient's skin;
- Use magnification only when necessary;
- Remember that for large patients and for steeply angulated projections, the dose to the patient increases substantially;
- Pay attention to the patient radiation dose display in the procedure room;
- If the patient has had previous similar procedures, try to obtain information about the previous radiation doses to optimize subsequent procedures.

These approaches are summarized in Ref. [103].

5.6. RADIATION PROTECTION OF STAFF

5.6.1. Practical aspects of staff protection

Scattered radiation, produced when the primary X ray beam interacts with the patient body, represents the main source of radiation for the staff in a fluoroscopy room. The scatter dose rate around the patient is a complex function of several factors and ranges from 1/100th to 1/1000th of the dose rate from the primary beam on the patient's skin. Reduction of patient exposure reduces scattered radiation in a similar proportion, thus reducing exposure to staff members. Therefore, the actions described in Section 5.5.5 that reduce the dose to patients will also reduce staff dose.

Only staff members who have functions during the procedure should be in the procedure room during the exposure. All other staff should stay in the control room, where the radiation intensity is typically tens of thousands of times less than that at the operator's position [88]. No staff member should enter the control room without personal protective equipment. All staff members should know and use the three basic approaches of radiation protection: reducing time, increasing distance and adding shielding.

The time during which radiation is on can be reduced by reducing fluoroscopy time and the number of acquired images, thus contributing to patient dose reduction. Distance must be reduced as much as clinically possible. Radiation dose decreases as the square of the distance between the radiation

source and the staff member. Considering that the patient is the source of scatter radiation exposing staff, stepping back from the patient's body reduces exposure. Staff members who are not involved in the entire procedure should wait to be called at the largest possible distance from the radiation source or/and behind a protective barrier. The use of automatic injectors of the contrast medium allows the operator to step away from the patient when a contrast is injected for angiographic runs [72, 88].

Shielding includes architectural shielding, equipment mounted shields and personal protective devices [88, 104]. Architecture shielding is designed during the construction of the facility and has the role of protecting all rooms and areas adjacent to the procedure room, including the control room of the fluoroscopy system. Equipment mounted shielding includes shields suspended from the table, lateral shields and shields suspended from the ceiling. These provide more than 90% protection from scatter in fluoroscopy and should be always used. The ceiling suspended screen needs to be properly positioned between the patient's body and the operator or other staff members. Mobile floor shields are useful to protect both the operator and other staff, such as nurses and anaesthetists. Operators can step behind such a mobile shield during cine acquisition.

All staff in the procedure room must wear personal protective equipment, including leaded aprons, thyroid shields and eyeglasses. For IR, the ICRP recommends using wraparound aprons of 0.25 mm lead equivalence, with a thickness of 0.25 mm at the back and 0.5 mm at the front. Two piece, skirt type aprons help to distribute the weight and prevent back injuries. Leaded glass eyewear should fit the face well and have side shields to reduce the radiation coming from the sides [72].

In addition to the time–distance–shielding principle, operators and other staff members should be aware and make full use of factors influencing staff dose (in addition to those that can reduce patient dose). This includes keeping the X ray tube under the patient table, positioning the X ray tube farther and the image detector closer to the patient, standing in the area with lower scatter radiation that is on the image receptor side when using lateral projections, and limiting the field size to the area of clinical interest. When the procedure requires manipulation closer to the primary beam, efforts should be made to keep hands outside the beam. A C-arm with an X ray tube under the table is preferred, as both primary and scatter radiation are much less on the image receptor side of the beam.

The following advice summarizes the main approaches to minimize the dose to staff [72, 86, 88]:

- The distance from the patient should be increased.

- Staff members should try to position themselves in a low scatter area. Scattered radiation is higher on the X ray tube side and much lower on the side of the image receptor.
- A ceiling suspended shield, a table suspended screen and other protective shielding — such as a lead apron, thyroid collar and leaded eyeglasses with side shields — should be used whenever possible.
- The ceiling suspended shield should be placed as close to the patient as possible.
- If biplane systems are used, the proper use of lateral shields is very important for eye protection.
- When appropriate, a dose reduction pad or drape should be used at the catheter entrance site to reduce hand dose.
- The use of fluoroscopy needs to be minimized and low dose fluoroscopy modes used instead (e.g. low dose rate pulsed fluoroscopy) when possible.
- The number of cine series and images in each cine series have to be minimized.
- Electronic magnification should be used sparingly.
- The X ray beam needs to be collimated as tightly as possible.
- Virtual collimators should be used whenever available.
- Direct exposure of the hands to primary radiation should be avoided.
- Appropriate training in radiation management and radiation protection is needed.
- Dosimeters must be worn and the dose received must be monitored.
- Generally, the patient's radiation dose must be reduced, which will also reduce the dose of medical personnel.

These approaches are summarized in Ref. [105].

5.6.2. Occupational dose limits and individual dose monitoring

According to GSR Part 3 and SSG-46 [11, 12], the following dose limits apply to occupational exposure of workers over the age of 18 years:

- An effective dose of 20 mSv per year averaged over five consecutive years (100 mSv in five years) and of 50 mSv in any single year;
- An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in five years) and of 50 mSv in a year;
- An equivalent dose to the extremities (hands and feet) or the skin of 500 mSv in a year.

Additional restrictions apply to occupational exposure for a female worker who is pregnant [11]. Female workers are strongly encouraged to notify their employer as soon as possible if they suspect they are pregnant, so the employer can promptly adapt the working conditions in terms of occupational exposure to ensure that the embryo or foetus receives the same level of protection as is required for members of the public (1 mSv for the duration of pregnancy).

GSR Part 3 [11] establishes the requirement of individual monitoring for “any worker who usually works in a controlled area, or who occasionally works in a controlled area and may receive a significant dose from occupational exposure”. In IR, this includes all staff involved in IR procedures. Individual monitoring includes measurements, interpretation, assessment, investigation and reporting, which may lead to corrective measures, if necessary [12].

For IR, the ICRP and IAEA strongly recommend using at least two dosimeters — one under the protective apron at chest level and the other outside the apron at neck or eye level [12, 72]. The readings of both dosimeters are used to estimate body dose, which is compared with the dose limit of effective dose, and the dosimeter outside the apron is used for the assessment of dose to the lens of the eye. The need to control eye lens dose is motivated by the recent new evidence that eye lens opacities that might cause cataracts have a much lower threshold for occurrence than previously thought and that can be even stochastic in nature [75]. For the lens of the eye, the threshold in absorbed dose was delineated as 0.5 Gy, lower by a factor of 10 than had been deduced and included in previous ICRP reports through 2007 [57, 75, 106]. As a result, for occupational exposure the ICRP recommended an equivalent dose limit for the lens of the eye of 20 mSv a year averaged over defined periods of five years, with no single year exceeding 50 mSv [75]. The reduction in the annual occupational eye dose limit from 150 mSv per year to 20 mSv per year constituted one of the most striking changes from earlier ICRP recommendations [57] and was reflected in GSR Part 3 [11]. This recommendation has significant implications for IR personnel because a cumulative ocular dose of 0.5 Gy falls within the range of exposure expected during a working life if proper radiation protection measures — such as ceiling suspended shields or protective eyewear — are not routinely employed [107]. Therefore, the impact for IR planning and improvement is significant, and it is hoped that a culture of radiation safety and awareness will be further promoted to reduce the prevalence of lens opacities among IR practitioners, as noted in Ref. [106]. Additionally, improved eye lens dosimetry is needed for all staff at risk of exceeding the prescribed dose limit. Advice on proper eye lens dose monitoring is provided in Refs [72, 108].

For pregnant workers who perform or assist in fluoroscopic procedures, the dose to the conceptus is usually estimated using an additional dosimeter placed on the mother’s abdomen at waist level, under her radiation protective garments,

and evaluated on a monthly basis [12, 62, 72, 104]. An additional direct reading dosimeter, such as an appropriately calibrated electronic dosimeter, can also be used to give an instant indication of both the cumulative dose and the current dose rate and is a useful tool for the optimization of occupational radiation protection [12, 72].

5.7. EDUCATION, TRAINING AND CERTIFICATION

Increasing numbers of medical professionals engaging in fluoroscopically guided procedures, particularly in IR, give rise to the need for continuing education and training programmes on radiation protection and safety. This is reinforced by the well known fact that many of these professionals have been inadequately trained in radiation protection. Demand for these interventions continues to gain greater acceptance by the global health care community and the general public alike, necessitating promotion of awareness regarding the potential health risks of excessive radiation while mandating implementation of relevant standards by medical professionals and health facilities.

The most optimal training method should be chosen on the basis of course objectives that coincide with the radiation protection job responsibilities of the participant. Upon completion of a training module, measurable and achievable performance goal mastery should be assessed and could include targeted objectives such as the following [109]:

- Understand the fundamentals of radiation protection;
- Understand the principles of radiation detection, namely measurement, quantities, units and dosimetry calculations;
- Recognize the biological effects of radiation;
- Understand the scope and responsibilities for radiation protection in IR;
- Understand the concept of justification of medical exposures;
- Recognize common actions for optimization of protection for medical exposures;
- Understand the operation of X ray systems commonly used for IR and its safety requirements;
- Be aware of relevant regulatory systems;
- Contribute to developing QA programmes.

An outline of specific training in radiation protection and learning objectives for IR is presented in Table 5 [88, 110].

GSR Part 3 [11] places great emphasis on education and training for everyone engaged in activities relevant to protection and safety, with the

TABLE 5. TRAINING TOPICS AND LEARNING OBJECTIVES IN RADIATION PROTECTION FOR INTERVENTIONAL RADIOLOGY [88, 110]

Topic	Objectives
X ray systems	<p>Explain the effect of high additional filtration (e.g. copper filters) on conventional X ray beams</p> <p>Explain virtual collimation and the importance of wedge filters</p> <p>Explain the operation of continuous and pulsed X ray emission modes</p> <p>Explain the benefits of the grid controlled X ray tube when using pulsed beams</p> <p>Explain road mapping</p> <p>Explain temporal integration and its benefits in terms of image quality</p> <p>Analyse the changes in dose rate when varying the distance from the image receptor to the patient</p>
Dosimetry quantities	<p>Define KAP and its units</p> <p>Define entrance dose and entrance dose rate in fluoroscopy</p> <p>Explain virtual collimation and the importance of wedge filters</p> <p>Discuss the correlation between entrance surface dose and KAP</p> <p>Discuss the relationship between KAP and effective dose</p> <p>Correlate the dose upon entry into the patient with the dose at the exit surface and the dose at the intensifier input surface</p>
Radiological risks	<p>Describe deterministic effects that may be observed in IR</p> <p>Analyse the risks of deterministic effect induction as a function of the surface doses received by patients</p> <p>Raise awareness of the probability of these effects in interventional practice</p> <p>Analyse the relationship between received doses and deterministic effects in the lens of the eye</p> <p>Raise awareness of the likely time intervals between irradiation and occurrence of different deterministic effects, the required follow-up and control of patients</p> <p>Analyse the stochastic risks in interventional procedures and their age dependence</p>

TABLE 5. TRAINING TOPICS AND LEARNING OBJECTIVES IN RADIATION PROTECTION FOR INTERVENTIONAL RADIOLOGY [88, 110] (cont.)

Topic	Objectives
Radiological protection of staff	<p>Comment on the most important factors that influence staff doses in IR laboratories</p> <p>Analyse the influence of X ray C-arm positioning on occupational doses</p> <p>Analyse the effects of using different fluoroscopy modes on occupational doses</p> <p>Analyse the effects of using personal protection (e.g. leaded aprons, gloves, eyeglasses, thyroid protectors)</p> <p>Analyse the benefits and drawbacks of using articulated screens suspended from the ceiling</p> <p>Explain the benefit of protecting the legs using lead rubber drapes</p> <p>Explain the importance of the appropriate positioning of personal dosimeters</p>
Radiological protection of patients	<p>Analyse the correlation of fluoroscopy time and the number of images taken in a procedure with the dose received by patients</p> <p>Analyse the effects of using different fluoroscopy modes on patient dose</p> <p>Discuss the effects of the focus to skin distance and patient image receptor input distance</p> <p>Analyse the dose reductions attainable by modifying the image rate in cine or in digital acquisition</p> <p>Give typical examples of patient entrance dose value per image in different procedures</p> <p>Analyse the effect of using different magnifications on patient dose</p> <p>Discuss the parameters that should be recorded in the patient history regarding (or with reference to data on) the dose received</p>
Quality assurance	<p>Discuss the difference between equipment performance parameters that do not usually downgrade with time and those that could require periodic control</p> <p>Understand how image quality can be assessed</p> <p>Discuss the importance of establishing simple criteria to compare doses at the patient or image receptor entrance in different situations</p> <p>Note the importance in quality assurance programmes of the periodic control of patient dose and its comparison with diagnostic reference levels that take into account the complexity of the interventional procedure (in this case, 'diagnostic reference levels' refer to the patient dose from the imaging part of the interventional procedure)</p>

TABLE 5. TRAINING TOPICS AND LEARNING OBJECTIVES IN RADIATION PROTECTION FOR INTERVENTIONAL RADIOLOGY [88, 110] (cont.)

Topic	Objectives
Optimization of procedures for radiation dose	Understand the influence of tube voltage and tube current on image contrast and patient dose when using contrast media Understand the different features available on radiology equipment Note the importance of optimization of radiation protection in IR procedures Discuss the importance of diagnostic reference levels that take into consideration the complexity of the interventional procedure in relation to the patient dose at local, national and international levels Analyse the importance of periodic patient dose control in each room Discuss the possibility of using different C-arm orientations during long procedures in which the threshold for deterministic effects may be attained Analyse the importance of recording the dose imparted to every patient
Local and international rules	Discuss local and international rules for IR Discuss the different national regulations that apply to IR installations Describe the international recommendations for IR (e.g. from WHO, IAEA, ICRP, EC) Provide information on the international recommendations concerning the limitation of high dose modes

Note: KAP: air kerma–area product; IR: interventional radiology; WHO: World Health Organisation; ICRP: International Commission on Radiological Protection; EC: European Commission.

responsibility placed on government to ensure that requirements for education, training, qualification and competence are established and arrangements are in place for the provision of the necessary education and training. The registrant or licensee of the IR facility has the responsibility to ensure that all of the health professionals in that facility with responsibilities for protection and safety have appropriate education, training, qualifications and competence.

Practitioners and individuals involved with IR procedures should have their competence in radiation protection certified by well known, independent, local or international organizations, scientific societies or specific regulatory agencies. Member States should be encouraged to implement an appropriate curriculum and recognize the corresponding diplomas, certificates or formal qualifications [11, 12, 61, 111, 112].

Hospitals and administrators need to support human resource training by requiring documentation of credentials in radiation management as a prerequisite for obtaining fluoroscopy privileges [113]. A concerted effort on the part of professional medical organizations and regulatory agencies is required to train fluoroscopy users to prevent physicians from unwittingly causing serious radiation injuries to their patients [113]. The Joint Commission in the USA, a standards setting and accrediting body in health care, requires that practitioners be ‘privileged’ for all activities that they perform and that each organization defines its criteria for receiving each privilege [114]. The following recommendations address these issues [113]:

- (a) All physicians who use or operate fluoroscopic X ray systems need to have this clinical privilege specifically delineated on the basis of evidence of completion of specific training in radiation safety, management of fluoroscopic radiation and operation of the specific fluoroscopic X ray system(s) used in the facility.
- (b) Such training in radiation safety and fluoroscopic radiation management should be in addition to any clinical training or qualifications to perform the specific clinical diagnostic or therapeutic procedure(s) for which the fluoroscopic systems are used.
- (c) The facility requires specific documentation of appropriate training prior to granting fluoroscopic privileges and evidence of appropriate training with respect to the operation of the specific fluoroscopic systems utilized in the facility. Such training is described and documented in the records of the facility prior to the granting of such privilege.
- (d) The facility requires annual in-service training or evidence of continuing education in radiation safety and management for all providers granted privileges to use fluoroscopic X ray equipment.

Thus, all practitioners who use fluoroscopic equipment should be required to complete focused training in radiation physics, radiation biology and radiation safety. Audits from independent organizations and/or agencies have to ensure that the programme goals have been achieved to grant the specific certificate/licence for practicing these procedures.

5.8. CONCLUSION

IR is a safe medical speciality from the radiation protection point of view and highly beneficial to patients. However, awareness is needed that levels of radiation delivered in IR are among the highest used in medical imaging. The

physicians involved need to be trained and certified in radiation protection for this practice. Such training should be maintained and updated over the years. X ray systems used for IR have to undergo a strict acceptance and commissioning process in order to optimize initial settings in agreement with the users. The industry has to continue to implement dose reduction options for interventional systems and standardize the patient dose reports, as well as archiving and processing them automatically using existing RIS and PACS. Real time and post-procedure skin dose distribution maps need to be integrated into the IR systems and dose monitoring tools, as such data facilitate the selection of patients in need of clinical follow-up. Occupational dosimetry needs to be improved and those practicing IR have to be convinced of the benefits of good personal dose records. Medical radiation doses are increasingly being incorporated into patient records. Patient dose surveys and the use of DRLs needs to be extended and considered as indicators of good practice. Member States have to be encouraged to establish local regulations and policies for the safe development of this valuable medical speciality.

6. QUALITY MANAGEMENT

6.1. BACKGROUND

In the health care industry, quality care has become essential for patient dose assessment and optimization, patient well-being, accuracy in treatment and diagnosis, and proper utilization of medical devices. The IAEA audit tool Quality Improvement Quality Assurance Audit for Diagnostic Radiology Improvement and Learning (QUAADRIL) was geared towards providing advice on standards and processes used for comprehensive clinical audits of DR services. To improve the quality of such services, QUAADRIL focuses on clinical management, infrastructure, patient focused technical procedures, education and research [21].

The quality of health is of interest to health managers, planners, providers and users as efforts continue to maintain and improve the performance of health services. The benefit to the patient of having an IR service has been demonstrated in the literature. Appropriate, timely radiology intervention has been shown to enhance patient safety, experience and outcomes, with proven efficiencies for the provision of health care. However, improving patient safety and quality will always be a continuous process that revolves around two fundamental questions:

- (1) How might a particular procedure fail to provide the predicted benefit?
- (2) How can the current process be changed to increase the probability of future

success [115]? An additional issue is that many procedures developed in IR have gained considerable attention from physicians without formal training in IR techniques.

Additionally, the growing use and increasing complexity of these procedures have been accompanied by public health concerns about complications and increasing radiation exposure to patients and health care personnel [91]. It is also well known that excessive variation in the way that health care is delivered may diminish IR quality and patient safety. Thus, it is important in the current economic climate of quality, innovation, productivity and preventive medicine to look rationally at the role of IR in improving the efficiency and cost effectiveness of medical services [116, 117].

All efforts to improve health care should be centred on the patient. Patient centred care is the cutting edge of precision, individualized medicine, and the current focus on quality and safety are steps on the path to excellence. IR is a dynamic, technology driven speciality in which high quality patient care should be the norm and ensured by all stakeholders, including members of governments, the health regulatory body, scientific societies, health organizations and providers, as well as medical practitioners. This section presents some of the concepts and definitions of quality that are related to IR and evaluates why introducing or enhancing a quality programme is an important component in health care delivery.

6.2. QUALITY PROGRAMME

The development of a QA and quality improvement (QI) programme for IR is essential to ensure high quality images while keeping radiation doses as low as reasonably achievable. As part of the QA programme, the imaging facility should have documented policies and procedures for monitoring and evaluating the effective management, safety and operation of equipment involved in the use of ionizing radiation. The programme should be designed to minimize patient, personnel and public radiation risks while optimizing the quality of diagnostic information or therapeutic benefit obtained from imaging.

Equipment performance should be monitored and estimates of typical patient dose should be made by a CQMP, as described in accepted standards for equipment performance monitoring. QC testing should be conducted by trained individuals with reviews performed at least annually by the supervising CQMP. As vascular and non-vascular percutaneous interventions constitute the cornerstone of IR, the facility should have policies and procedures in place to control the spread of infection. These should include adherence to universal precautions and the use of clean or aseptic techniques as warranted by the

procedure or intervention being performed. As recommended by QUAADRIL, guidelines for interventional procedures should address the following:

- Accident and incident reporting in compliance with their corresponding corrective actions;
- Instrumentation and calibration;
- Sterile techniques for interventional procedures;
- Training of personnel to use equipment;
- Patient, pregnancy and equipment based dosimetry;
- Performance of automatic exposure control;
- Dose audits and DRLs;
- Radiation protection and safety.

It is also proposed to follow the recommendations of the US Joint Commission for labelling medications [118] and preventing mistakes in surgery in terms of the site, procedure and patient during the time-out process [119, 120] for all procedures, if applicable.¹

Interventional procedures need to be systematically reviewed and evaluated as part of the overall QA programme to identify and correct problems and improve the clinical practice. Quality parameters should be set for the clinical aspects of interventional practice, as well as the technical outcomes of the procedures. The clinical practice of radiology includes the assessment of the patient's signs and symptoms to set forth a diagnostic and/or treatment plan. The assessment may lead to the determination that no treatment is necessary. Constant evaluation of the overarching treatment plan is necessary to ensure that the interventional radiologist follows up, as warranted, the clinical, laboratory and treatment recommendations that result from the clinical evaluation of the patient.

Individual physician outcome data are also necessary for the granting and maintenance of physician privileges. Outcome data also inform referring physicians of the benefits of patient referral to IR. Complications and adverse events or activities that are potential sentinel events need to be monitored, analysed and reported as required and periodically reviewed to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer review procedures to confirm confidentiality of the peer review process. Office practices are encouraged to

¹ The US Joint Commission is: "An independent, not-for-profit organization, The Joint Commission is the nation's oldest and largest standards-setting and accrediting body in health care. To earn and maintain *The Gold Seal of Approval*® from The Joint Commission, an organization undergoes an on-site survey by a Joint Commission survey team at least every three years (Laboratories are surveyed every two years)" [119].

monitor relevant aspects of both their clinical and business operations, such as the following:

- Procedures and aspects of clinical decision making to be tracked;
- Appropriateness of the clinical diagnosis and laboratory and radiological tests ordered;
- Assessment of the clinical effect of the treatment provided;
- Appropriate mechanisms to ensure adequate follow-up of patients;
- Thoroughness of medical record keeping;
- Adherence to the appointment schedule;
- Thresholds for any criteria for which QA will be performed;
- In the hospital setting, quality outcome analysis in a regular forum.

If a problem is identified, actions need to be designed to improve quality and monitored and documented to ensure improvement. Given that outcomes of the procedural and clinical decisions made by the interventional radiologist will often manifest themselves over time, the clinical practice's dedication to long term follow-up will become the critical component in any quality programme.

Measurements of the process have grown more commonplace and are easily achievable, in part because the metrics do not depend on long term changes in clinical patient status. Quality indicators are a significant part of hospital and physician assessment. Quality measures are reportable to the public in the form of core measures. These indicators have had a tremendous impact and are directly related to effective quality care.

6.3. QUALITY PROGRAMME GUIDELINES

Guidelines published by SIR for a QI programme in IR [121] are given below. Implementing continued QI practices in a functioning IR department can pose challenges. In general, a good framework for a thorough quality management programme is one that includes: (i) QA; (ii) ongoing focused plan–do–study–act model (PDSA) cycles; and (iii) a global continued QI programme. QA focuses on individual events and providers, PDSA focuses on specific processes and continued QI deals with the entire system or department and the complete cycle of patient care before, during and after the procedure. An example from the USA is presented in the following.

6.3.1. Quality assurance

QA includes the following:

- (a) Ongoing peer review to evaluate individual events or providers;
- (b) User friendly voluntary reporting system for adverse events;
- (c) Internal and external benchmarks against which outcomes of specific procedures are compared;
- (d) Participation in continuing medical education (CME) programmes and the American Board of Radiology maintenance of certification (MOC);
- (e) Establishment of a process to communicate critical results.

6.3.2. Ongoing PDSA projects

These involve the use of rapid cycle improvement (PDSA cycles) focused on individual departmental processes (e.g. transport, procedural pause, timing of pre-procedure antibiotics).

6.3.3. Continued quality improvement

Continued QI involves the following processes:

- (a) Pre-procedure:
 - (i) Ensure patient participation in the development of a treatment plan, assess the patient's pain and obtain informed consent.
 - (ii) Prepare the patient for the procedure as follows:
 - Follow established laboratory guidelines;
 - Use medication reconciliation;
 - Ensure correct timing of administration of pre-procedure antibiotics;
 - Ensure correct patient identification using two patient identifiers;
 - Ensure correct procedure and location using the universal protocol and procedural pause;
 - Confirm that the most appropriate procedure has been chosen, referencing SIR QI guidelines and ACR clinical practice guidelines;
 - Use a simple method for reporting issues and events across the continuum of patient care.

- (b) Procedure:
 - (i) Ensure technical expertise by initiating programmes to compare the outcomes of procedures. Examples of such outcomes include the following:
 - Lung biopsy: diagnostic yield;
 - Lung biopsy: pneumothorax and chest tube placement rate;
 - Deep organ biopsy: diagnostic yield.
 - (ii) Monitor patient safety within the IR suite by keeping track of and investigating the time between ‘code blue’ events, medication errors, falls and other adverse events.
 - (iii) Implement a radiation safety programme with regular monitoring of badges and number of patient exposures, exposure time or total dose.
 - (iv) Use a simple method for reporting complications, issues and events across the continuum of patient care.
- (c) Post-procedure:
 - (i) Monitor the following clinical outcomes:
 - Catheter infection rate;
 - Vertebroplasty (kyphoplasty): rate of successful pain relief;
 - Uterine artery embolization: symptom improvement;
 - Creation of TIPS: patency, decreased recurrent bleeding rate and improvement in symptomatic ascites;
 - Varicocele embolization: symptom improvement and fertility improvement.
 - (ii) Correctly and promptly document findings and orders within the medical records (consider checking dictation turnaround times).
 - (iii) Communicate findings with physicians managing care.
 - (iv) Schedule necessary follow-up (consider telephone follow-up to identify any delayed complications that might not otherwise be identified).
 - (v) Administer patient satisfaction surveys and encourage feedback (consider a dedicated ‘comment line’).
 - (vi) Use a simple method for reporting issues and events across the continuum of patient care.

6.4. ACCREDITATION

The term ‘accreditation’ (applied to organizations rather than speciality clinical training) reflects the origins of the systematic assessment of hospitals against explicit standards [74, 122]. Accreditation is the most used external mechanism for standards based QI in health care. Fundamentally, accreditation

of health care facilities and hospitals focuses on improvements in how care is delivered, including the quality of that care. Accreditation has been defined as follows:

“A self-assessment and external peer assessment process used by healthcare organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve” [123].

Accreditation is an important component in patient safety. ACR offers multiple accreditation programmes in the imaging field, including stratified by subspeciality and/or by imaging modality [122]. Where evidence based guidelines do not exist, best practices should be sought.

However, accreditation for IR services remains largely elusive, despite an array of evidence based documents, including QI guidelines and safety standards available through scientific societies such as ACR, SIR and CIRSE. Thus, Member States may encourage local medical societies to fill this void by developing accreditation quality programmes specific to IR [21].

6.5. CONCLUSION

Improving population based health care is a means to achieve national development, rather than a mere by-product of development. Providing excellent patient care by making IR techniques available constitutes a major step towards strengthening the health systems of countries and in promoting the best population based, minimally invasive health management. Moreover, the establishment or improvement of IR services in a country promotes sustainable business models for universal health coverage, and extends the benefits of modern medical management to everyone while prioritizing quality driven, patient centred and safe image guided procedures. In the era of precision medicine, IR is individually tailored to the patient undergoing an image guided procedure.

Many exciting changes are occurring in the industry. Some of these changes may be short lived, but others stand to revolutionize health care delivery. Quality and safety are fundamental factors that shape this dynamic industry, impacting hospitals and medical care providers alike [122].

To successfully practice quality driven health care, physicians have to understand and thrive in an environment of process improvement and outcome metrics. They should be encouraged to make continuous improvements and track their impact and to share individual, group, departmental and hospital data to demonstrate increased value for patients. This requires robust and flexible

systems to collect, analyse and process data. The era of quality driven health care provides tremendous opportunities for health organizations to showcase the value of the IR field, build credibility and ensure the growth and improvement of the speciality.

7. MEDICAL EDUCATION AND TRAINING

7.1. BACKGROUND

To fulfil the requirements for high quality patient care in IR, expertise in the following areas is required:

- (a) Diagnostic imaging;
- (b) Radiation protection and safety, as well as other aspects of patient safety;
- (c) Image guided, minimally invasive procedures and techniques applicable to multiple organ systems and a broad spectrum of pathology;
- (d) Evaluation and management of patients presenting with clinical indications for image guided interventions included in the scope of IR practice;
- (e) Longitudinal clinical follow-up of patients as warranted after IR procedures.

7.2. MEDICAL SCHOOL GRADUATION

Image guided invasive procedures are medical interventions based on in-depth medical knowledge. Therefore, formal medical training grounded in evidence based science is required, incorporating the interrelated disciplines of anatomy, physiology, pathology and pharmacology, as well as a thorough understanding of the continuum of health care (screening, diagnosis and treatment — both curative and palliative) for the management of human diseases.

7.3. CLINICAL INTERNSHIP TRAINING

Following medical school, the next educational step towards becoming an IR practitioner entails hands-on clinical training during a hospital based internship. Knowledge gained during such internships strengthens the ‘front line’ clinical acumen of the anticipated interventional radiologist, who ultimately bears responsibility for confirming the correct clinical indication and preparation

for the image guided procedure at hand. Moreover, as warranted, the practitioner cares for the patient in the post-procedural period. In collaboration with multidisciplinary colleagues, the interventional radiologist may also recommend further follow-up and/or additional treatment. Some dedicated diagnostic and/or integrated IR residencies may incorporate the experience attained during internships.

7.4. RADIATION PROTECTION

Radiation protection training is of utmost importance for both diagnostic and therapeutic procedures in IR. The European Directive 97/43/EURATOM on medical exposures, Article 9, collectively addresses interventional techniques as an example of procedures that can deliver high doses of radiation to patients and establishes certain requirements for IR practice [124]. Most IR societies include aspects of radiation protection as part of their quality programmes.

With respect to radiation protection, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the ICRP and the IAEA have contributed to improved radiation safety over years of collaborative and interdependent work [55–57].

It has been reported that the estimated effective dose per case per operator was 1.7–56 μSv for percutaneous nephrostomy, 0.1–101 μSv for vertebroplasty, 2.5–88 μSv for orthopaedic extremity nailing, 2.0–46 μSv for biliary tract procedures, 2.5–74 μSv for TIPS, 1.8–53 μSv for head/neck endovascular therapeutic procedures and 0.2–49 μSv for ERCP. Overall, mean operator radiation dose per case measured over personal protective devices at different anatomical sites on the head and body was 19–800 μSv (median 113 μSv) at eye level, 6–1180 μSv (median 75 μSv) at the neck and 2–1600 μSv (median 302 μSv) at the trunk. For patients, the largest contributors to collective effective dose equivalent were angiography (768 person-Sv) and related IR procedures [125–129].

7.5. DIAGNOSTIC IMAGING

Image guidance is the cornerstone of percutaneous and intravascular interventional procedures and facilitates targeted, minimally invasive treatment approaches. Therefore, image interpretation and guidance are prerequisites for interventional diagnostic procedures and IR treatment. Image guidance constitutes a fundamental part of residency training. It is incorporated into radiology curricula and includes (a) fluoroscopy guided techniques, (b) ultrasound guidance, (c) CT

guidance and (d) MRI guidance. Furthermore, training focuses on optimization of imaging parameters, tissue contrast maximization, minimization of radiation to the patient and personnel, choice of the optimal imaging modality for guidance tailored to the organ and other factors, type of procedure and the nature of the lesion [3].

7.6. RADIATION PHYSICS AND SAFETY

If non-radiological specialities are incorporating radiological techniques such as image guided procedures into their training curricula, or are planning postgraduate education involving imaging techniques, it should be done within the context of existing national and international requirements for education in radiation protection and patient safety, collaborating with the national radiological society to maintain high quality standards. Radiologists should also be involved in these training programmes to ensure that the procedures are clinically indicated, optimally performed and appropriately monitored. The following features need to be included:

- Formal training and certification in image guided, minimally invasive and related procedures and techniques, including radiation protection and safety;
- Formal training and testing in longitudinal outpatient and inpatient care relevant to patients undergoing IR procedures;
- Training in research.

7.7. CERTIFICATION

Certification should primarily include the following:

- Completion of standardized IR and imaging training programmes;
- Examination by a generally accepted and recognized medical certifying body;
- Maintenance of certification as required by national and local medical certifying bodies;
- Formal acknowledgement by board certifying organizations (or their equivalent) of IR as a unique speciality or subspeciality of radiology.

7.8. CONCLUSION

Owing to the progressively increasing significance of image guided procedures, formal training and tailored professional certification is needed, as outlined in Section 7.7. The components of IR education, such as radiation protection, need to be integral to the curriculum of any discipline that uses image guidance.

8. CERTIFICATION AND RECERTIFICATION

8.1. BACKGROUND

This section presents an overview of certification and recertification in IR to help Member States to develop such programmes to support optimal patient care [130–133].

8.2. CERTIFICATION LEVEL

Certification can encompass a range of knowledge and skills and varies depending on the baseline certification structure in the Member State for different medical professional groups. For physicians, certification in IR is either in addition to primary certification in diagnostic radiology or a primary certification on its own. When additional, this may be a subspecialty certification (post-fellowship) as an added qualification. When primary, the IR certificate can be either independent of, or linked to, diagnostic radiology certification. The path to certification may change over time. This occurred in the USA, where IR was initially recognized as a subspecialty of diagnostic radiology in 1991, requiring an IR fellowship after radiology residency. However, in 2012, IR also became a primary speciality. For radiographers, nurses and advanced practitioners, the IR certification is most often supplemental to the respective primary certifications.

8.3. CERTIFICATION OF PERSONNEL

All medical professionals engaged in IR patient care have to receive the highest level of training that is reasonable and feasible. In many instances, a general certification is appropriate, such as for nurses caring for IR patients

admitted to the hospital. Specialized certification in the unique IR skill set is recommended for physicians (interventional radiologists), radiographers supporting IR procedures, nurses supporting patients during IR procedures and advanced practitioners, such as the PAs and nurse practitioners, who work in IR departments or units. If specialized certification is not feasible, particularly for physicians, then IR skills have to be incorporated into general diagnostic radiology certification.

Certification in IR is distinct from certification for one or a few image guided intervention(s). The former encompasses formal training and competency in image generation and interpretation, imaging physics and safety, a very broad spectrum of image guided interventions and techniques, and focused care of patients eligible for image guided interventions. The latter concerns non-radiology specialists who employ imaging for specific interventions as part of overall care of a particular patient group, disease or organ system. For non-radiology related specialities, training in specific image guided interventions is usually conducted by other non-radiology specialists in their own discipline. These individuals are usually not certified by either diagnostic radiology or IR speciality boards. Certification, recertification or eligibility therein should be independent of gender, race, religion, political belief, social or economic status, or sexual orientation.

8.4. CERTIFICATION ELEMENTS

Certifying organizations should produce clear, consistent, succinct and readily accessible criteria for certification and maintenance or recertification. An organization susceptible to influence by private, commercial or political forces will neither possess the legitimacy nor meet the goal of protecting the patient. Detailed requirements for certification and the certification processes will vary among the Member States and by medical speciality [134, 135].

8.5. CERTIFICATION IN INTERVENTIONAL RADIOLOGY

This section provides a brief overview of select current certification practices in IR. Member States are encouraged to develop locally appropriate certification processes but need to ensure a minimum level of uniform competence.

8.5.1. Interventional radiology physicians

In the USA, in 2012, the American Board of Medical Specialties recognized IR as a subspecialty of diagnostic radiology. Certification in IR required accreditation in diagnostic radiology (four years of diagnostic radiology residency and one year of internship), achieved by a one year accredited fellowship. The Accreditation Council of Graduate Medical Education has established criteria for training programmes and certification processes with a minimum of 500 cases, and one year of practice with a minimum of 200 cases (700 cases in total) [135].

An alternative training option, the DIRECT (diagnostic and interventional radiology enhanced clinical training) pathway, entails two years of non-radiology clinical training, three years of diagnostic radiology and one year of IR fellowship. The initial examination for all vascular and interventional radiology subspecialty certificates is an oral case based examination in three sections: vascular diagnosis, vascular interventions and non-vascular interventions. Each section is 30 minutes long. To maintain certification, the following are required: current medical licence, 75 American Medical Association category one CME credits per three year cycle (including at least 70% radiology related credits and a specified number of self-assessment continuing education credits), successful completion of a computer based examination and completion of a practice QI project.

Union Européenne des Médecins-Spécialistes (UEMS) recognized IR as a distinct speciality in Europe in 2009. Criteria for certification were established by the European Board of Interventional Radiology, organized by CIRSE, the European Society of Radiology (ESR) and the UEMS IR division. To qualify, an applicant should document completion of diagnostic radiology training, and either one year of dedicated IR training or at least seven years of IR practice, with at least 150 cases in the two years preceding the examination (at least 25 cases as first operator; 100 cases have to be vascular and 50 non-vascular).

8.5.2. Interventional radiology radiographers and nurses

Radiological technologists complete formalized education of up to four years after secondary education, resulting in an associate's or bachelor's degree. In the USA, certification is received by passing an examination administered by the American Registry of Radiologic Technologists (ARRT). This examination in vascular and interventional radiography is additionally open to individuals with significant clinical experience in IR. The certification renewal is annual, based on documented CME. The ARRT constitutes one of many national member organizations of the global umbrella organization for radiographers, the International Society of Radiographers and Radiologic Technologists (ISRRT), a professional society officially affiliated with WHO.

Nurses are also essential team members during IR procedures, providing skilled assistance to the radiologist, as well as supportive care, analgesia and sedation for the patients. In the USA, nurses can be specifically certified as radiology nurses, covering all radiological procedures without particular emphasis on IR. Nursing certification in the care of IR patients does not exist at this time.

8.5.3. Medical physicists

A CQMP specializing in diagnostic radiology physics should have the following:

- (a) A university degree in physics, engineering or equivalent physical science;
- (b) Appropriate academic qualifications in medical physics (or equivalent) at the postgraduate level;
- (c) At least two years (full time equivalent) structured and supervised clinical training in a hospital.

Postgraduate courses in medical physics at the Master's level are offered by many universities. To enrol in these courses, students are normally required to have completed an undergraduate (bachelor level) degree in physics or an acceptable alternative. These Master's courses are typically of 18–24 months duration. Then, clinical training for at least 24 months full time in a hospital with access to full diagnostic radiology services under the supervision of a medical physicist qualified in diagnostic radiology is needed. The total time required for education and clinical training of a medical physicist is at least four years (two years postgraduate university education plus at least two years of clinical training) following completion of a bachelor's degree in physics or acceptable alternative. The holder of a university degree in medical physics without the required hospital training cannot be considered clinically qualified. The above standard for the education and training of medical physicists has to be recognized by a nationally responsible authority. Continuing professional development through short courses, conference attendance and access to the scientific literature needs to follow [136].

8.6. CONCLUSION

Certification and documented lifelong learning of all members of an IR team are recommended for Member States to ensure global uniformity in quality standards of IR patient care. When feasible, certification specific to IR is highly encouraged. Early establishment of these processes will greatly benefit

patients as IR becomes more widely available and may eventually lead to beneficial reciprocity of licensure in multiple Member States.

9. FUNDING

9.1. BACKGROUND

IR requires significant capital investment in high cost equipment and technology and integration with complex IT systems. Funding arrangements for IR should ensure that the right amount of money is paid in the right way to support access for patients to quality services. Areas of funding in IR may include the establishment of new IR centres, maintenance and improvement of existing centres, purchase of consumables, human resource development and IR research and education. Other relevant important areas include billing and health insurance schemes [29, 137].

9.2. ESTABLISHMENT OF NEW INTERVENTIONAL RADIOLOGY CENTRES

Establishing an IR centre requires many resources in terms of physical infrastructure, equipment, consumables and staffing, among others. The equipment is usually of advanced technology and expensive. As mentioned, the main equipment components in IR are the angiography and fluoroscopy units, which are used for most of the procedures. Other equipment includes ultrasound, CT and MRI devices, ablation generators and various devices used for recanalization, endovascular repair, thrombectomy, clot lysis and biopsies, among others. Funding usually comes from governments, the private sector, public–private partnerships, international bodies and donor agencies.

There is a need for increased funding to establish new IR centres. Given the backdrop of current epidemiology and the potential socioeconomic benefit of making IR widely available, governments and health care providers need to spend more on establishing or improving IR services. Population based health care needs justify increased spending for IR services, if currently unavailable or inadequate in a region. For example, countries without availability of image guided biopsies cannot optimally handle their epidemiological burden of cancer and cannot triage patients for appropriate treatment or, in the case of advanced disease, for palliative care rather than futile, potentially morbid or risky

treatments. Governments should work with IR experts to determine how federal funding for new equipment will be distributed. Interventional radiologists and other imaging specialists should play an important role in appropriate equipment selection [29, 137].

9.3. MAINTENANCE AND IMPROVEMENT OF EXISTING CENTRES

In planning the establishment of IR centres, appropriate funds need to be secured for maintenance of the equipment. This is one of the major causes of failure of service delivery, especially in lower income countries. Competency needs to be the key point when selecting a maintenance service provider. Replacement of outdated equipment with more efficient, modern equipment has to be considered to improve the service. Establishment of a maintenance service and strengthening of quality standards are vital to ensuring an IR service that reflects the best clinical practice. Budget consideration over change of equipment and maintenance prices with time or new technology should be part of the strategic planning. There is a need to have a mechanism that takes into account the impact of advances in technology on service delivery time and professional input time [29, 137]. Moreover, service maintenance contracts can often be negotiated as part of the initial contract at the time of procurement. The prices of related software installation, updates and anticipated licence renewals also need to be clarified from the outset, including PACS, DICOM and RIS.

9.4. PURCHASE OF CONSUMABLES

The availability of consumables is essential to the practice of IR. Proper planning with fund allocation for the purchase of consumables is needed, and purchasing quality products from reputable manufacturers is cost effective. There is great variation in the cost of consumables from country to country, making prices prohibitively high in some countries. The rationalization of pricing policies for consumables used in IR will assist in this regard. The establishment of revolving funds in IR units and departments will greatly enhance the purchase of consumables and participatory management by stakeholders [29].

9.5. HUMAN RESOURCE DEVELOPMENT

In applied economics, investigations into costs for diagnostic imaging equipment have found that capital is not the largest component. The workforce

constitutes the largest investment component cost, and this cost will continue to grow. This includes payments to medical specialists, as well as to technical and other support staff. Quality standards are ensured when an IR service is performed by an appropriately qualified practitioner. As IR involves sophisticated and advanced technology, employment of qualified, highly trained staff in new centres and retraining in existing departments are essential components of its success. Interventional radiologists, radiographers, nurses, medical physicists, IT specialists and biomedical engineers are the core staff to be considered for training; therefore, appropriate training funds should be allocated by governments and health care providers. International agencies such as the IAEA, WHO and other non-governmental organizations and professional societies should also assist in human resources development, especially in low and middle income countries. The creation of a centralized national referral centre for IR will be cost effective in meeting training needs for a Member State [33, 34].

9.6. HEALTH INSURANCE OR FEE FOR SERVICE

In many countries, IR procedures have not yet been incorporated into national health insurance schemes; this holds true even in places where such procedures are already available. For the success of IR and effective health care provision, IR procedures have to be recognized as part of national and private health insurance programmes. A uniform billing and coding system needs to be instituted for all IR procedures to facilitate reimbursement. Moreover, the scope of an IR procedure often changes once the patient is ‘on the table’, although this is not always reflected in either the clinical notes or in the RIS. Despite significant progress, in many situations the tariff does not adequately reflect the actual cost of service delivery. When patients have to pay for a service, appropriate fees should be discussed and fairly ascribed by involving all relevant stakeholders. This process will also promote better communication between referrers and IR providers and will ensure that they encourage practices that direct patients to the most appropriate IR service for optimal patient care [29, 137].

9.7. RESEARCH AND EDUCATION

Member States should be encouraged to support education and research in IR, since it is one of the fastest growing fields of medicine (being minimally invasive and cosmetically acceptable), with potential for further growth. Currently, various national and regional professional societies such as SIR, CIRSE and the British Society of Interventional Radiology are providing grants

to assist with research in IR. Global and local organizations and societies can promote IR development by funding print, electronic, radio, TV, telephone or web based awareness campaigns and screening programmes. In addition, funding educational programmes and materials in the form of lectures, CDs and handouts, among others, to faculties will enhance the broad development of IR.

9.8. EXTERNAL FUNDING

External funding sources may be available to a given organization for the purchase of radiology equipment, yet they often remain untapped because organizations are not convinced that the proposed recipients are eligible. Basic terminology, the three major sources for funding and some examples of foundation awards are described in Ref. [138].

9.9. CHARITIES

Charities are another way that IR departments can obtain funds from society directly. Charitable gifts to IR departments will provide critical support for innovative research as well as new and advanced patient care and services. The support may advance promising new research and treatment programmes, train future generations of physicians and scientists, expand vital support services and enhance community outreach. Individuals and donor agencies should be encouraged to donate towards this cause and departments should also establish funds. Stanford Interventional Radiology's Fund is a good example of such an innovation.

9.10. PUBLIC-PRIVATE PARTNERSHIPS

Public-private partnerships involve the provision of IR services in government run health care facilities in partnership with private health care companies. In this scenario, the private health care company will build new, or refurbish existing, facilities, install new equipment and provide services to the public at a predetermined cost agreeable to both parties. The selection of the private company to render this service should be determined on the basis of competitive bidding. This form of service provision is gaining popularity globally. It will assist in the improvement of health care services in low resource settings, particularly in low and middle income countries [139].

10. PROFESSIONAL SOCIETIES AND BODIES

Professional societies form an essential part of the identity of a profession. In the case of IR, over 40 such societies exist worldwide, and the number is growing as IR continues to grow in more countries. The purpose and actions of each professional society will be shaped in part by the regulatory requirements of individual Member States. These include some governmental jurisdictions, administrative tasks and negotiations conducted by general medical bodies, while the promotion and support of individual specialities in medicine are undertaken by speciality societies. This section refers to speciality societies for IR. To facilitate progress in health care, Member States are encouraged to find a relevant IR speciality society.

There are several areas of professional interest where speciality societies perform important work, ultimately benefitting patient care. Setting standards of work and care is the function of the speciality, is vital to the health of the speciality and is very important for patient care. Collaborating on treatment guidelines is similar but usually involves multidisciplinary working groups, with individuals supplied by the speciality interests particular to each guideline. Certification of individuals for certain types of work is often part of the role of speciality societies, which usually handle the accreditation of individuals and facilities. Speciality societies also run educational programmes, often in conjunction with clinical facilities, and regular meetings of the professional members cover clinical and administrative issues. Promotion of relevant research is an important function of the speciality society, and a facet of this may be the establishment of treatment registries, which can prove important in multiple improvement initiatives, including quality management. All of the above functions may additionally enhance continuing professional development of the individual society member.

In addition, the society also maintains close relations with other radiological, medical and surgical professional societies, as that image guided interventions are part of a multidisciplinary approach to the management of patients. IR societies may play a fundamental role as a source of information for the public and in publicity and advocacy for the profession. Furthermore, international intersociety collaboration is critical to establishing a high quality professional body, harmonized with evidence based standards. In summary, the establishment of an IR society is important for the following [140, 141]:

- (a) Setting standards and collaborating on guidelines;
- (b) Certification and accreditation;
- (c) Educational and clinical programmes;
- (d) Research and registries;

- (e) Meetings, publicity and advocacy;
- (f) International cooperation.

11. PROMOTION AND PUBLIC AWARENESS

11.1. BACKGROUND

The promotion of IR entails any activity that encourages people to believe in the value or importance of IR or that helps IR to succeed. Public awareness is the dissemination of knowledge on IR activities, including its importance in the management of diseases using image guided, minimally invasive techniques. The goal is to share information through effective public awareness campaigns and outreach efforts and to identify optimal locations for the integration of IR in sustaining effective clinical care.

Recognizing that countries, international and regional organizations, and institutions need to develop policies and programmes for creating public awareness to promote IR will help to expand IR practice to improve health care delivery. Increasing public awareness constitutes a core element of any successful IR practice. Efforts should focus on effective media coverage and influencing the decisions of policy makers. Establishing and maintaining a good reputation in the eyes of stakeholders such as the government, donors, partners, clients and the public are extremely important.

11.2. PUBLIC AWARENESS

The incorporation of IR in clinical care in low and middle income countries, or in low resource settings in high income countries, needs government support and funding. Public awareness is important for fundraising and for support from the government, the community and other important groups. Public awareness campaigns inform existing and potential partners about the IR work of an organization, which strengthens networking and collaboration. Effective public awareness creates a positive view of the benefits of IR.

11.3. GOOD IMAGE

A strong public image of IR will improve the working relationship between IR staff and with other health care workers, as well as with outsiders, creating sound financial prospects and partnerships. Improving understanding is important because the general public does not understand the tasks of IR practitioners. Much IR work is technical or scientific, and larger public awareness campaigns can describe the nature and relevance of IR work, ensuring that it is easy to understand for the public.

11.4. HEALTH PROMOTION

Health promotion is an approach to health development that has been adopted in many countries and is supported by many international bodies. It provides leadership, guidance and technical support in the formulation, implementation, monitoring and evaluation of health promotion policies, plans, strategies and programmes. It represents a comprehensive social and political process that embraces actions directed at strengthening the skills of individuals and changing social, environmental and economic conditions to influence their impact on public and individual health. All countries have programmes and/or activities with health promotion elements. Incorporation of IR into health promotion will assist in promoting IR practice [142].

11.5. INTERNATIONAL ORGANIZATIONS

International bodies such as the IAEA and WHO can raise awareness about IR by optimizing the use of publications, web sites, electronic media and online teaching, including tutorials and webinars. They can also create opportunities for improving awareness of and education on established radiation safety norms and strategies for dose reduction in IR procedures. International bodies can also promote local research on the role of IR in regional diseases and identify regional centres of excellence for coordination. They may also identify stakeholders of IR practice and ensure the highest standards of their education. This can be achieved by convening a committee to develop strategies to address human resource requirements for IR in low and middle income countries [141].

11.6. PROFESSIONAL SOCIETIES

Local, regional and international professional societies of radiology and IR have an essential role in promoting IR and in supporting education and research in this field. Promoting IR will improve the level of clinical practice and research. Professional societies organize annual scientific meetings that help to promote educational activities. Organizations such as the Radiological Society of North America (RSNA), SIR, ESR, CIRSE, Pan Arab Interventional Radiology Society (PAIRS), Pan African Congress of Radiology and Imaging (PACORI), Asia Pacific Society of Cardiovascular and Interventional Radiology (APSCVIR) and various national IR societies contribute towards the growth and development of IR at national, regional and global levels [139].

11.7. EQUIPMENT AND CONSUMABLE MANUFACTURERS

IR equipment and consumable manufacturers can collaborate with IR practitioners to promote educational programmes, research and outreach programmes and to donate IR equipment to developing countries.

11.8. RESEARCH

The promotion of research in IR will improve the current provision of services and the acceptability of IR procedures and will ensure evidence based practice of this speciality. The support for clinical trial outcomes in IR will help to bring more IR trials to fruition. IR research will enable the development of new procedures and therapies that will maintain IR at the forefront of beneficial health care innovation well into the future.

11.9. TARGETS

Promotion and public awareness should be targeted towards the following stakeholders:

- Governments;
- Health managers;
- Hospital administrators;
- Medical professionals;
- Students;

- Insurance companies;
- The general public;
- Philanthropic organizations;
- Patient interest groups;
- Humanitarian organizations, including international agencies;
- Industries.

11.10. MECHANISMS

Mechanisms of public awareness include the following:

- (a) Print publications;
- (b) Electronic media, radio, TV, telephones, etc.;
- (c) Web based educational materials, for example provided by existing institutional or international organizations;
- (d) Awareness campaigns and screening programmes.

11.11. EDUCATIONAL PROGRAMMES AND MATERIALS

Educational programmes and materials include the following:

- Lectures. The delivery of lectures by renowned interventional radiologists to many disadvantaged faculties, especially in lower or middle income settings.
- CDs. The production of CDs on various topical subjects or procedures in IR as educational materials.
- Handouts. The production of handouts with IR educational information targeted to the public, radiologists, physicians and patients.
- Advocacy. Encourage governments to change or institute laws to favour growth of IR. This can be achieved by first influencing public opinion [142].

12. CHALLENGES FACING LOW AND MIDDLE INCOME COUNTRIES

12.1. BACKGROUND

IR has improved health care delivery to communities, reducing both morbidity and mortality and decreasing overall health care and societal costs. Guidelines established using evidence based IR literature are rapidly changing the way that clinical medicine is practised today. IR is gaining recognition as a core element of modern health care in many Member States. The impact of IR on health care systems can be especially great in low income areas of the world, in view of the vast spectrum of IR applications in the management of pathology involving all organ systems, its ability to shorten the duration and cost of treatment in otherwise overcrowded and overburdened hospital environments, and its overall positive influence on health economics. It may be fair to say that the lack of an IR service within a hospital is a true disservice to the patients. Health represents human capital, the central thrust of sustainable economic growth and development in any given community and country.

Therefore, efforts should be directed towards integrating IR into existing health care systems in lower resource settings of the world. Addressing a variety of factors pertinent to local issues, infrastructures and practices may favourably influence this integration. Steps to identify these factors and devise strategies to optimize their incorporation into the existing policies at local, regional and national levels will help to build a credible health care system in Member States. Such initiatives are elaborated in the following sections.

12.2. INCORPORATION INTO CLINICAL PRACTICE

The incorporation of IR into clinical practice as a national agenda poses challenges to emerging economies. Evolving health care challenges include the dynamically changing epidemiology, a well informed and demanding public, rising costs, new medical technologies and rapid globalization. Access to health care and its efficacy in meeting the needs of the population are contingent upon how health care is organized and delivered and what type of medical technology is used to render the delivery more efficient. On both these counts, a comprehensive and integrated IR service built on appropriate imaging technologies will play a pivotal role in addressing such challenges. Most countries in the developing world lack a distinct national framework for the development of IR. The administrative authority in Member States should have a national

policy for the development of IR based on the country's needs. This should be accorded a high priority by Member States, who are also encouraged to create a relevant position statement, such as a white paper for health administrators, medical personnel and other stakeholders. A coherent national programme is essential for the development and judicious utilization of IR services in the health sector [143].

12.3. DEFINITION AND IMPROVEMENT OF INTERVENTIONAL RADIOLOGY PRACTICE

Another challenge that developing nations are likely to face is defining the milieu and improving the visibility, penetration and geographical reach of IR practice. Mostly, IR specialists work from within diagnostic radiology departments and remain unknown to the patients and public. Many radiology departments are not configured to examine and care for patients who present with clinical indications that warrant IR procedures. This transformation of a conventional diagnostic radiologist into one with clinical responsibilities is an important first step in the development of an optimal IR service, which includes outpatient clinics and a radiology department IR ward. Efforts should be made to create a personal identity for the speciality. The key lies in establishing admission privileges for the interventional radiologist who assumes overall responsibility for the patient.

There is a need for creating awareness of the speciality and of the benefits of IR procedures among physicians, surgeons and other referring doctors, medical and postgraduate students, and other medical personnel, to educate them about the scope of IR and ensure optimal utilization of these techniques in clinical practice. Efforts need to be made to ensure efficient dissemination of knowledge concerning IR techniques to all levels of health care delivery systems, irrespective of their geographical location in the Member State. Efforts have to be made to ensure that all medical colleges and hospitals across the country have an IR facility or have an affiliation and access to IR care in the vicinity.

Further, the teaching curricula in most countries in the developing world offer limited training in IR and the related research methodologies. A gap also needs to be bridged between researchers at public institutions and medical universities and those in the industry. This issue needs to be urgently addressed to ensure timely indigenization of technologies and to make them both cost effective and affordable in the context of the developing world. Funding for research needs to be allocated to provide young and established researchers with opportunities. National speciality societies and other organizations, including government bodies and agencies involved in overseeing clinical and experimental research

in the Member States, should come forward to fund IR related research. It is pertinent to add that the face of research is changing worldwide and, as new discoveries emerge at the molecular level, the types of scientist who are trained should also change. The curricula for training also need to evolve accordingly.

Patients' searches for health care information on-line may eventually translate into unprecedented involvement of the interventional radiologist in the care of motivated patients. Specialists should understand the particular pathologies amenable to available techniques and know the outcomes of treatment, the risks and benefits, and all the available therapeutic alternatives. Such expertise will translate into justified, judicious utilization of resources available in limited resource settings [143, 144].

12.4. BUILDING BLOCKS OF THE PRACTICE

The optimal requirements for infrastructure, human resources and accessories for the practice of IR have been outlined in earlier sections. There may be additional demands for creating functional and productive infrastructure for IR in low and middle income countries. These include: economic factors; lack of supportive infrastructure, such as reliable electricity supply; inadequate knowledge of requirements for equipment and consumables; unavailability of trained staff; absence of a system to deal with repair and maintenance; lack of radiation protection; misalignment with current government policies; and hospital management priorities.

It would be ideal to have an IR facility in every multispeciality hospital. However, to ensure optimization of resources in lower resource settings, hospitals and medical centres in a finite geographical area with easy connectivity may share such facilities. Further, for utilization of skilled human resources in places with a deficit of such staff, comprehensive training of paramedical personnel may be considered to train workers who could perform particular tasks in a given department and utilize these scarce resources.

12.5. RECOGNITION OF THE INTERVENTIONAL RADIOLOGY SUBSPECIALITY

IR should be formally recognized as a subspeciality by the national medical council or appropriate designated authority. Interventional radiologists treat a wide variety of diseases and abnormalities involving any organ system by using a combination of clinical and image based diagnostic skills and image guided therapy. They may run patient clinics alone or in conjunction with members

of other medical specialities (seeing patients in consultation before and after procedures), admit patients to hospitals and refer patients to other specialists. Moreover, IR treatments are often superior, both in terms of success rates and minimized complication rates, and are usually cheaper than open surgical procedures. The inability of a health care delivery system to properly utilize cost effective IR therapies results in substantial additional spending in direct health care costs, additional patient bed days and loss of lives in any index time frame. As IR practice has grown increasingly complex, proportionate necessity has developed for IR to become a complete clinical service. To realize the potential advantages of IR, there is a need for strong advocacy and support for this speciality. To this end, IR should be accorded the status of a separate speciality or subspeciality to ensure its eventual equitable incorporation into clinical practice.

To encourage a paradigm shift and facilitate the inclusion of IR in clinical medicine, support and leadership from other IR societies, medical regulatory bodies and medical administration are essential. These bodies can provide resources, funding, infrastructure and other necessary support. Formal recognition of IR would promote these objectives and also increase the overall prominence of the field (including representation on regional and national medical committees and representative bodies), as well as bolster the prioritization and commitment of all stakeholders. Formal recognition of the speciality would also increase the commitment of both the relevant regulatory medical body and the relevant IR society in formalizing and standardizing IR training programmes, which are essential for providing state of the art health care to all. Such recognition will also elevate the status and quality of training within the field and, consequently, its appeal to current and potential trainees. In the absence of formal recognition, IR training fellowships may vary widely in quality and competencies and will not be as competitive [145].

12.6. TRAINING AND CERTIFICATION

All procedural and clinical skills involving disease based knowledge in multiple organ systems and the imaging modalities used to obtain the above require specific training and knowledge. The number and range of procedures in IR continue to grow rapidly, as does the spectrum of pathology that may be treated therein. As a result, IR training has become very intensive. This explains why prospective interventional radiologists require a dedicated fellowship instead of a dedicated IR residency; the latter is now available as an alternative to a fellowship in the USA.

There is a gap between the number of available IR practitioners and the minimum requirement in unlimited resource settings in most Member States.

The problem is twofold: the existing curricula in undergraduate and postgraduate medical education, including radiodiagnosis, have little or no exposure to IR in most countries. Further, there are very few IR training programmes available in these regions. Optimally designed IR training programmes, duly accredited by the national medical council, should be created in each Member State to ensure a steady supply of qualified and certified IR practitioners for optimal health care delivery. A problem long recognized by interventional radiologists is the lack of clinical training emphasis in general diagnostic radiology residencies. Existing training curricula could be redesigned to provide a more in-depth clinical experience. The strength of IR is rooted in clinical knowledge and patient care. In addition, care is needed to prevent the rapid expansion of quick-fix type certificate courses to overcome the current acute shortage of IR subspecialists. Such acts will harm more than help the cause of the speciality and patient health over the long term.

Legislation is needed to ensure that an optimized and well structured training programme, accredited by the designated authority, becomes an essential requirement for the practice of IR in every country. This will facilitate the prevention of malpractice of this subspeciality and provide specialized and optimized health care to the population. Generally, most Member States in the developing world have limited opportunities for well designed IR training. Major changes are needed to achieve full utilization of IR procedures and integrate them into clinical practice [143].

12.7. QUALITY BENCHMARK

Efforts should be made by individual Member States to implement standardized and uniform QA in the training and delivery of IR expertise in all health care delivery systems in the country. Infrastructure and human resources need to be governed by well designed QA programmes tailored to local and regional needs. As far as possible, international and societal norms, as approved by the designated authorities and pertinent international organizations, need to be uniformly practised to create a quality benchmark in accordance with global standards [146].

12.8. REGULATORY ENVIRONMENT

Regulatory requirements have not evolved and largely have not kept pace with advances in techniques, devices and technologies and their required registration, or with changing work cultures. This stagnancy obstructs progress

in clinical medicine. Such requirements need to be standardized and made transparent, outcome oriented and user friendly to promote research and exert a positive impact on the growth of the speciality [146].

12.9. EQUIPMENT AND HARDWARE AVAILABILITY

Despite increased visibility and more efficient networks of industry partners over the past decade, there are major issues with the non-availability of optimal hardware in the low and middle income countries. Frequently there is a mismatch between the numbers of available and desired devices owing to a complex interplay of commercial and financial factors. This needs to change urgently and in a substantial way if IR is to take root across low and middle income countries. Efforts should be directed towards indigenization of devices and technologies, tailored to local and regional needs of Member States or geographical locations. Radiation reduction and detection devices and features should be integral to the equipment rather than offered as options by the vendors.

12.10. ACCESSIBILITY AND AFFORDABILITY

A mismatch between the costs of consumables and the per capita income is a frequent problem in low resource countries. It is preferable to find local solutions for local problems. At present, there is little local manufacturing of these devices and technologies in the developing world. Most devices are still imported and are priced for the European and US markets. As a result, these devices are unaffordable in the local and regional context. This acts as a serious obstacle to the growth of IR in these regions. Optimizing prices for these locations and promoting local manufacturing and packaging will help to solve this problem [144].

12.11. EVIDENCE BASED CLINICAL PRACTICE GUIDELINES

Medical practices should be encouraged to use evidence based clinical practice guidelines in day to day clinical duties. This will help to create an informed patient (who will then demand the best clinical practices and optimal growth of IR) and address malpractice and jurisdictional issues. Guidelines based primarily on clinical patient outcomes can enhance and optimize their utilization. The implementation of such procedures on a national scale may have profound health care implications. IR has the potential to greatly improve health care

delivery in low, middle and high income countries. National medical councils and health administrators need to be encouraged to compile a list of documents, including current evidence based clinical practice guidelines for various IR procedures, and upload them to a site accessible to physicians, surgeons, other clinical specialists and the general public. It should be updated constantly with current literature [147, 148].

12.12. INTERVENTIONAL RADIOLOGY PROCEDURES, PERSONNEL AND FACILITIES

It is expected that current and future IR procedures will dominate the practice of clinical medicine. Even though most non-vascular IR procedures are usually performed in radiology departments with areas customized to IR requirements, the mix of specialists involved in performing some vascular IR procedures has changed drastically in the past decade. Interventional radiologists are most qualified to perform these procedures as a result of their strong foundation in diagnostic radiology, their ability to understand the images and the interplay between the devices and techniques during a given procedure, and their in-depth understanding of the risks of radiation and its protection measures. The interventional radiologist can potentially offer the best procedure and technique for a given pathological or anomalous morphology that is imaged dynamically during a procedure. If the procedure competes with alternative therapies, involves a new technology or is financially rewarding, disagreements may arise. Various specialists from other clinical disciplines may reposition themselves as vascular disease management specialists and undertake some vascular IR procedures and may want to maintain their stake in the future. However, these skills require special training not only in performing the procedures, but also in pre-procedure and follow-up imaging techniques and their interpretation, and most importantly in the hazards of radiation and the relevant protection measures. Lack of appropriate training, especially in radiation protection, can risk the health of the patient, the physician performing the procedure and the paramedical staff in the vicinity. There is no shortcut to formal training for providing optimal care. The issues related to the working environment for the practice of IR have been addressed in the previous sections. Efforts are needed to ensure that IR is practised in well designed and well equipped facilities that are staffed by trained personnel [147, 148]. On some occasions, joint multidisciplinary procedures may be performed; for example, abdominal aortic stent grafts may be deployed in the presence of both an IR physician and a vascular surgeon.

12.13. CONTINUING MEDICAL EDUCATION

Interventional radiology is a rapidly evolving treatment modality. These advances are constantly changing the treatment algorithms of many disease states. The practitioners of IR have to keep abreast of new knowledge. Structured educational programmes need to be in place for training and for regular updates in knowledge. Some cost effective solutions may include conducting web seminars and CME programmes for various stakeholders involved in IR practice and providing access to teaching materials and on-line tutorials. Member States should make efforts to create in-house talent to implement such solutions and may wish to liaise with international speciality societies to supplement them.

12.14. INTERACTION WITH GOVERNMENT

Interaction with government bodies or funding, administrative support and legislation to prevent malpractice will help to strengthen IR practice and ensure affordable health care and best medical practice standards for patients. Stakeholders involved in health care delivery should take into consideration the forces and dynamics surrounding the profession by assessing them with foresight and flexibility.

12.15. FUNDING FOR INTERVENTIONAL RADIOLOGY PROCEDURES

Some devices and technologies used in IR practice are expensive and may be beyond the reach of the patient despite their life-saving potential and favourable impact on overall morbidity and mortality. There is a role for the insurance sector, governmental bodies and philanthropic organizations in ensuring that eligible patients are not denied this treatment. Necessary administrative steps need to be initiated in this direction.

12.16. NATIONAL ORGANIZATION OF INTERVENTIONAL RADIOLOGY SPECIALISTS

IR practitioners in Member States need to be encouraged to create a national level professional organization to provide a platform for the dissemination of knowledge and a forum for the exchange of views, in addition to coordinating the above activities. This organization will also help regional IR facilities to liaise

with international organizations for coordinated development. This organization has to perform many additional activities, including setting up a nationwide network of state or provincial branches; conducting local, zonal and annual regional and national level scientific meetings; organizing public awareness programmes in different regions on locally relevant subjects; conducting short term postgraduate training fellowships; maintaining an interactive web site; and creating disease and technique specific national registries to create a national database. The organization should also work with the industry to address issues related to availability, pricing and policies regarding the timely delivery of optimal devices and technologies [147].

12.17. LOCAL AND REGIONAL NEEDS AND LOCAL RESEARCH

Member States need to identify an expert committee to oversee the development of IR practice in terms of the procedures performed and regional needs for devices and technologies, including their customization to local needs and prevalent disease states. This exercise will help to create disease databases and devise solutions for local and regional problems. Furthermore, promotion of local research into regionally prevalent diseases and relevant IR techniques will help to strengthen the standards of clinical practice and provide a platform for indigenization of technologies. Such efforts will help to provide cost effective solutions for clinical care, inculcate research methodologies and promote the involvement of scientifically minded personnel in IR practices.

The past two decades have witnessed unprecedented changes in IR from a purely technological perspective. This progress has introduced new modalities and applications in clinical medicine and created a new class of innovative image guided interventional therapies and diagnostic techniques. All stakeholders managing health care need to join hands to promote the integration of IR into clinical practices worldwide, help to innovate and reduce the cost of devices and procedures, and effect better integration of societies, individuals and industry to improve the quality of health care delivery. Collaborative programmes and campaigns are needed for qualitative and quantitative improvement in teaching and research. There are many opportunities for collaboration at various levels: individual, institutional and societal. There is great scope for IR practice in emerging economies and the subject is strategically poised for growth. It is the responsibility of administrators and those involved in health care delivery to ensure that this science is used judiciously and efficiently to improve the health of people around the world [148].

13. RECOMMENDATIONS OF THE IAEA EXPERT COMMITTEE

IR can have a favourable impact on the health sectors of Member States. An expert committee convened by the IAEA has formulated the following prioritized recommendations for Member States:

- (a) Prioritize the incorporation of IR into clinical practice as part of the national health agenda by creating a position statement as a white paper for health administrators.
- (b) Raise awareness about IR through publications, web sites, electronic media and on-line teaching, including tutorials and webinars. If necessary, professional IR societies such as SIR, CIRSE and APSCVIR can be approached for content.
- (c) Member States should consider incorporating funds for IR in the annual health care budgets at local and national levels in view of its favourable influence on patient care and cost effectiveness, as IR has the potential to yield long term socioeconomic benefits to Member States.
- (d) Member States should move towards creating uniform curricula and certifications for training programmes in IR and radiation safety at national and state levels.
- (e) Member States should create opportunities for improving awareness and education on established radiation protection standards and strategies for patient and staff dose reduction in IR procedures. In addition, more guidance on the stepwise process to set up an optimal IR service, including infrastructural details, needs to be developed by professional scientific organizations.
- (f) Member States need to identify and promote training programmes in IR for low and middle income settings.
- (g) Member States need to promote local research on the role of IR in local diseases and identify regional centres of excellence for its coordination.
- (h) All stakeholders in the practice of IR have to be identified and the highest standards of their education need to be ensured (e.g. convening a committee to develop strategies to address human resource requirements in IR, with a focus on low and middle income countries).
- (i) Member States should encourage local development of devices and technologies for low and middle income countries.
- (j) Member States need to initiate sound, sustainable initiatives, including educational programmes and audits, to ensure QA and improvement in IR procedures as a standard of practice.

Appendix

PROCEDURES

A.1. FUNDAMENTALS OF IMAGE GUIDED INTERVENTIONS

The following are relevant to interventional radiology practice²:

- Imaging for intervention and invasive diagnostic procedures;
- Invasive diagnostic procedures;
- General principles of radiation safety;
- Biological hazards;
- Musculoskeletal occupational injuries;
- QI;
- Focused history and physical examination;
- Informed consent for IR procedures;
- Procedural sedation for IR procedures;
- Recognition and initial management of intra and peri-procedural emergencies;
- Procedural reporting;
- Inpatient care;
- IR clinic;
- Pharmacology relevant to IR;
- Medical conditions relevant to IR procedures;
- Health care team coordination;
- Informatics;
- Regulatory supervision and reporting;
- Certification, maintenance of certification;
- Statistics relevant to IR;
- IR research and reporting techniques;
- Interpretation of IR literature.

² This list does not include every potential IR procedure. For example, cerebrovascular procedures have been excluded and may be performed by IR specialists with a strong background in neuroradiology.

A.2. VASCULAR IMAGING AND DIAGNOSIS

The following are relevant to vascular imaging and diagnosis using interventional radiology²:

- Clinical vascular examination;
- Non-invasive peripheral vascular laboratory;
- CT angiography;
- Magnetic resonance angiography;
- Ultrasound imaging;
- Angiographic diagnosis (with or without treatment) with catheters and guide wires;
- Selective catheterization techniques;
- Normal and variant arterial anatomy;
- Normal and variant vascular anatomy of systemic veins;
- Normal and variant vascular anatomy of the portal venous system;
- Normal and variant pulmonary vascular anatomy;
- Normal and variant anatomy of the lymphatics;
- Arterial vascular disorders;
- Systemic venous disorders;
- Dialysis access disorders;
- Portal venous disorders;
- Pulmonary arterial disorders;
- Lymphatic disorders.

A.3. VASCULAR INTERVENTIONS

The following are relevant to vascular interventions using interventional radiology²:

- Application of principles of vascular interventions and planning;
- Peripheral arterial intervention;
- Treatment of AVM;
- Aortic interventions;
- Gastrointestinal bleeding — arterial;
- Mesenteric ischaemia;
- Visceral aneurysm interventions;
- Renal artery interventions;
- Hepatic arterial interventions;

- Arterial trauma interventions;
- Uterine artery interventions;
- Bronchial artery embolization;
- TIPS;
- Variceal obliteration, sclerosis;
- Balloon occluded retrograde transvenous obliteration of gastric varices;
- Portal vein dilation and stenting;
- Portal vein recanalization;
- Pulmonary AVM;
- Management of pulmonary embolisms — catheter interventions;
- Reproductive tract interventions;
- Upper extremity/superior vena cava occlusive disease;
- Lower extremity venous occlusive disease;
- Foreign body retrieval;
- Vena cava filter placement;
- Transvenous biopsy;
- Venous sampling for endocrine disease;
- Haemodialysis access management;
- Venous access;
- Lymphangiography;
- Thoracic duct ablation.

A.4. NON-VASCULAR INTERVENTIONS AND INVASIVE DIAGNOSTIC PROCEDURES

The following are relevant to non-vascular interventions and invasive diagnostic procedures using IR²:

- Application of principles of non-vascular interventions and planning;
- Biopsy in the abdomen and pelvis;
- Liver biopsy;
- Thoracic biopsy;
- Bone biopsy;
- Soft tissue biopsy;
- Abdominal and pelvic drainage;
- Solid organ abscess drainage;
- Appendiceal and peri-appendiceal abscess drainage;
- Pancreatic inflammatory disease — stenting or drainage;

- Enterocutaneous fistula;
- Follow-up care and procedures;
- Paracentesis;
- Simple cyst aspiration;
- Placement of tunnelled peritoneal drain;
- Lymphocele drainage and sclerosis, seroma drainage and sclerosis;
- Oesophageal intervention;
- Gastrostomy and gastrojejunostomy;
- Percutaneous cecostomy;
- Percutaneous jejunostomy;
- Gastrointestinal tract stenting (duodenal and colonic);
- Percutaneous transhepatic cholangiography;
- Biliary drainage;
- Biliary dilation and stent;
- Percutaneous cholecystostomy;
- Percutaneous nephrostomy;
- Nephroureteral dilation and stenting;
- Renal cyst sclerosis;
- Suprapubic cystostomy;
- Renal and peri-renal fluid collection drainage;
- Urodynamics;
- Ablation of the kidney;
- Ablation of the adrenal gland;
- Hysterosalpingography and fallopian tube interventions;
- High intensity focused ultrasound;
- Treatment of uterine leiomyomata (fibroids);
- Ablation of liver masses;
- Chemical ablation of liver masses;
- Thoracentesis;
- Chest tube placement;
- Tunnelled pleural drainage catheters;
- Sclerotherapy (pleurodesis);
- Lung tumour ablation;
- Airway dilation and stenting;
- Breast drainage;
- Breast biopsy;
- Percutaneous vertebroplasty;
- Thermal ablation of bone lesions;
- Vertebral height restoration;
- Percutaneous disc interventions;

- Chemical ablation of desmoid tumours;
- Selective nerve root block;
- Stellate ganglion block;
- Facet injections.

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LIST OF ABBREVIATIONS

ACR	American College of Radiology
APSCVIR	Asia Pacific Society of Cardiovascular and Interventional Radiology
ARRT	American Registry of Radiologic Technologists
AVM	arteriovenous malformation
CIRSE	Cardiovascular and Interventional Radiological Society of Europe
CME	continuing medical education
CT	computed tomography
DAP	dose–area product
DICOM	Digital Imaging and Communications in Medicine
DIRECT	diagnostic and interventional radiology enhanced clinical training
DRL	diagnostic reference level
DSA	digital subtraction angiography
EC	European Commission
ERCP	endoscopic retrograde cholangio-pancreatography
ESR	European Society of Radiology
FDA	United States Food and Drug Administration
ICRP	International Commission on Radiological Protection
IEC	International Electrotechnical Commission
IR	interventional radiology
ISO	International Organization for Standardization
IT	information technology
KAP	kerma–area product
MRI	magnetic resonance imaging
PA	physician assistant
PACS	Picture Archiving and Communication System
PACORI	Pan African Congress of Radiology and Imaging
PAIRS	Pan Arab Interventional Radiology Society
PDSA	plan–do–study–act model
PICC	peripherally inserted central catheter
QA	quality assurance
QI	quality improvement
RIS	radiology information systems
RSNA	Radiological Society of North America
SIR	Society of Interventional Radiology
SIRT	selective internal radiation therapy

TIPS	transjugular intrahepatic portosystemic shunt
UEMS	Union Européenne des Médecins-Spécialistes
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
WHO	World Health Organization

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This publication provides a general overview of interventional radiology. It presents an evidence based rationale for establishing, improving and maintaining an interventional radiology service consistent with current clinical knowledge benchmarks. A summary is provided of the necessary elements to establish an interventional radiology clinical service and to ensure its sustainability. The publication includes information on specific challenges faced especially, but not uniquely, in developing countries, as well as a list of expert recommendations. Safety and quality standards are emphasized in addition to necessary funding, human resources, education, training and certification/recertification, as well as involvement of the main professional societies.

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