Chapter 2: Radiation protection concepts and principles

New health technologies and medical devices using ionizing radiation have led to major improvements in the diagnosis and treatment of human disease. However, inappropriate or unskilled use of such technologies and devices can lead to unnecessary or unintended exposures and potential health hazards to patients and staff. When establishing a risk–benefit dialogue about paediatric imaging it is important to communicate that risks can be controlled and that benefits can be maximized by selecting an appropriate procedure and using methods to reduce patient exposure without reducing clinical effectiveness.

Section 2.1 presents concepts and principles of radiation protection and discusses how they are applied to paediatric imaging.

Section 2.2 summarizes the key factors to establish and maintain a radiation safety culture in health care to improve practice.

2. Radiation protection concepts and principles

2.1 Appropriate use of radiation in paediatric imaging

2.1.1 Fundamentals of radiation protection in health care

2.1.1.1 Medical imaging referrers and providers

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) establish specific responsibilities for health professionals related to radiation protection and safety in medical exposures (BSS, 2014). The BSS define a health professional as "an individual who has been formally recognized through appropriate national procedures to practice a profession related to health (e.g. medicine[1], dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology,[2] radiopharmacy, occupational health)".

The BSS defines a radiological medical practitioner (RMP) as "a health professional with specialist education and training in the medical uses of radiation, responsible for administering a radiation dose to a patient and competent to perform independently or to oversee procedures involving medical exposure in a given specialty" (BSS, 2014). The radiological medical practitioner has the primary responsibility for radiation protection and safety of patients. While some countries have formal mechanisms for accreditation, certification or registration of RMPs, other countries have yet to adequately assess education, training and competence on the basis of either international or national standards.

In the context of this document, the term RMP will be used to generically refer to the large group of health professionals that may perform radiological medical procedures (i.e. as defined in the BSS) and more specific terms will be used when/as appropriate (e.g. "radiologist[3]"). The concept of a RMP primarily includes classical medical specialties using ionizing radiation in health care: diagnostic radiology, interventional radiology (image-guided procedures), radiation oncology and nuclear medicine. However, in some cases, specialization of a RMP may be narrower, as with dentists, chiropractors, or podiatrists. Likewise, for diagnostic imaging and/or image-guided procedures, cardiologists, urologists, gastroenterologists, orthopaedic surgeons or neurologists may use radiology in a very specialized way. Moreover, clinicians in some countries perform and/or interpret conventional imaging such as chest X-rays.

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1. Including physicians as well as physicians' assistants
2. This includes radiographers and other radiological technologists working in diagnostic radiology, interventional radiology and nuclear medicine
3. In the context of this document, the term "radiologist" is used in a generic way to include diagnostic and/or interventional radiology. In some countries diagnostic radiology and interventional radiology are established as different disciplines, each of them with specific residency and board certification

In the context of this document a "referrer" is a health professional who initiates the process of referring patients to a RMP for medical imaging. For paediatric imaging in particular, the health professionals who most often refer patients for diagnostic imaging are paediatricians, family physicians/general practitioners. Emergency department physicians, paediatric sub-specialists, physicians' assistants and other paediatric health-care providers also often refer children for paediatric imaging within their daily practice. Ultimately, any medical specialist may need to refer paediatric patients for medical imaging and, under those circumstances, would be considered a "referrer". Usually, the referrer and the RMP are different people. However, both roles are sometimes played by the same person – often deemed self-referral. For example, dentists decide whether an X-ray exam is indicated, they interpret the images and, in many countries, they also perform the procedure.

Medical imaging staff of a radiology department typically comprise a multidisciplinary team which include radiologists, radiographers/radiological technologists, medical physicists and nurses.

2.1.1.2 The principles of radiation protection in medicine

Although individual risk associated with radiation exposure from medical imaging is generally low and the benefit substantial, the large number of individuals being exposed has become a public health issue. Justification and optimization are the two fundamental principles of radiation protection in medical exposures,[4] as follows:

1. Medical exposures shall be justified by weighing the expected diagnostic or therapeutic benefits against the potential radiation detriment, with account taken of the benefits and the risks of available alternative techniques that do not involve exposure to radiation. The procedure should be judged to do more good than harm.
2. The principle of justification applies at three levels in medicine (ICRP, 2007a) as described below:
    - At the first level, the proper use of radiation in medicine is accepted as doing more good than harm to society;
    - At the second level, a specified procedure is justified for a group of patients showing relevant symptoms, or for a group of individuals at risk for a clinical condition that can be detected and treated; and
    - At the third level, the application of a specified procedure to an individual patient is justified if that particular application is judged to do more good than harm to the individual patient.
3. The justification of a particular radiologic medical procedure is generally endorsed by national health authorities and professional societies (e.g. to recommend a procedure for those at risk of a particular condition).[5]
4. The responsibility of justifying a procedure for a patient[6] falls upon individual professionals directly involved in the health-care delivery process (referrers, RMPs). Imaging

4. Although the radiation protection system is based on three principles: *justification*, *optimization* and dose limitation, in the case of medical exposures dose limits are not applied because they may reduce the effectiveness of the patient's diagnosis or treatment, thereby doing more harm than good (ICRP, 2007a)

5. This is the "generic justification" (level 2)

6. This is the "individual justification" (level 3)

referral guidelines help health-care professionals make informed decisions by providing clinical decision-making tools created from evidence-based criteria (see **section 2.1.2** for more information). Justification of an exam must rely on professional evaluation of comprehensive patient information including: relevant clinical history, prior imaging, laboratory and treatment information.

5. When indicated and available, imaging media that do not use ionizing radiation, e.g. ultrasonography (sound waves) or MRI (radiofrequency and electromagnetic waves) are preferred, especially in children and in pregnant women (particularly when direct fetal exposure may occur during abdominal/pelvic imaging). The possibility of deferring imaging to a later time if/when the patient's condition may change also must be considered. The final decision may also be influenced by cost, expertise, availability of resources and/or patient values.

In the context of the system of radiation protection, optimization signifies keeping doses "as low as reasonably achievable" (ALARA). In particular for medical imaging, ALARA means de-

Box 2.1 Possible reasons for inappropriate ionizing-radiation procedures in children

- Low awareness of radiation doses & associated risks
- Appropriateness criteria/imaging referral guidelines not available or ignored
- Insufficient, incorrect or unclear clinical information provided for justification
- Lack of confidence in clinical diagnosis & over-reliance on imaging
- Consumer's demand (patient's and/or family's expectations)
- Self-referral, including requesting inappropriate additional imaging studies
- Concern about malpractice litigation (defensive medicine)
- Pressure to promote and market sophisticated technology
- Lack of dialogue/consultation between referrers and radiologists
- Not considering or aware of more appropriate imaging modalities that do not use ionizing radiation (e.g. ultrasound or MRI, when available)
- Too frequent or unnecessary repeat examinations
- Pressure from referring clinicians or other specialists
- Reliance on personal or anecdotal experience not supported by evidence-based medicine
- Pressure to perform (e.g. quickly processing patients in the emergency department)
- Lack of availability of alternate imaging resources-expertise and/or equipment (e.g. to perform ultrasonography beyond regular working hours)
- Inappropriate follow-up imaging recommendations from imaging expert reports.

Box 2.2 Defensive medicine: a strong driving force

The term "defensive medicine" is used to refer to a deviation from standard medical practice to reduce or prevent complaints or criticism. Physicians may respond to the perceived threat of litigation by ordering more referrals and more tests, some of which may be recommended by clinical guidelines and beneficial, but others might be wasteful and harmful. See below as an example a summary of the results of the Massachusetts State-wide Survey on Defensive Medicine (http://www.massmed.org/defensivemedicine/):

- 3 650 physicians surveyed between 2007 and 2008
- 83% reported that they practiced defensive medicine
- Their defensive clinical behaviour was related to overuse of:
  - plain film X-rays: 22%
  - CT scans: 33% among emergency physicians & obstetrics/gynaecologists and 20% in other specialties
  - laboratory tests: 18%
  - hospital admissions: 13%.

livering the lowest possible dose necessary to acquire adequate diagnostic data images: best described as "managing the radiation dose to be commensurate with the medical purpose" (ICRP, 2007a & 2007b).

2.1.2 Justification and appropriateness of procedures

The most effective means to decrease radiation dose associated with paediatric imaging is to reduce or preferably eliminate unnecessary or inappropriate procedures.

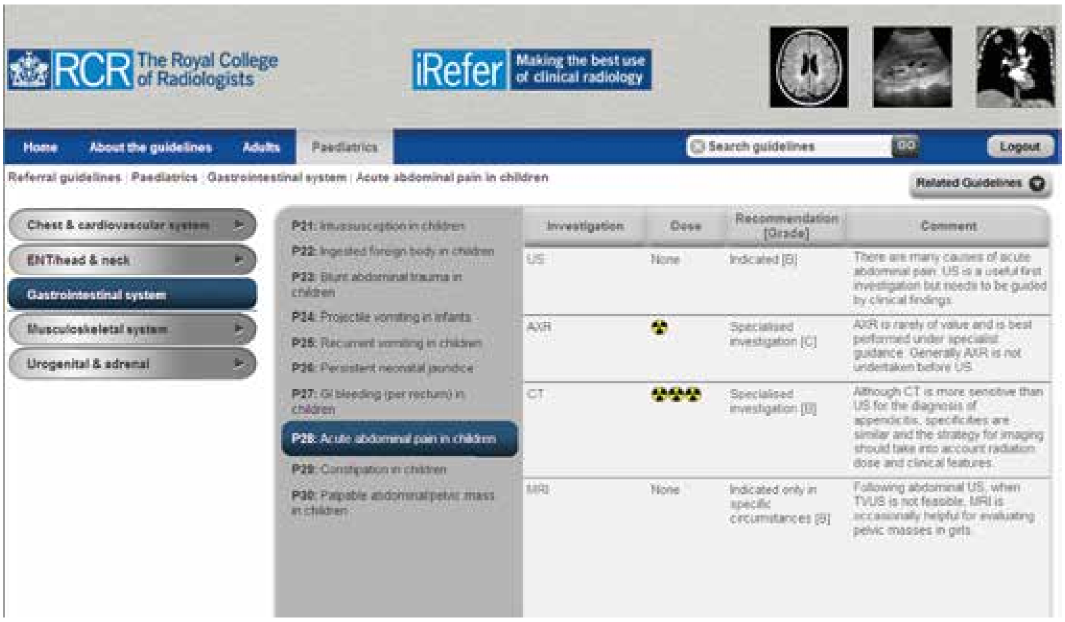
Justification of a procedure by the referrer and RMP (see **section 2.1.1**) is a key measure to avoid unnecessary radiation dose before a patient undergoes medical imaging. Most radiologic investigations are justified; however, in some instances, clinical evaluation or imaging modalities that do not use ionizing radiation could provide accurate diagnoses and eliminate the need for X-rays. For example, although CT can be justified for investigating abdominal pain in children, ultrasound is often more appropriate (see **Figs. 10**, **11** and **12**).

2.1.2.1 Unnecessary procedures

Overuse of diagnostic radiation results in avoidable risks and can add to health costs. In some countries, a substantial fraction of radiologic examinations (over 30%) are of questionable merit and may not provide a net benefit to patient health care (Hadley, Agola & Wong, 2006; Oikarinen et al., 2009). **Boxes 2.1** and **2.2** identify some possible reasons for inappropriate use of radiation in medical imaging.

The real magnitude of unjustified risk resulting from inappropriate use of radiation in paediatric imaging remains uncertain; for example, it has been estimated that perhaps as many as 20 million adult CTs and more than one million paediatric CTs are performed unnecessarily in the USA each year (Brenner & Hall, 2007).

Figure 10: The Royal College of Radiologists' guidance for abdominal pain in children



Source: RCR (2012); reproduced with kind permission of The Royal College of Radiologists.

Figure 11: The American College of Radiology's Appropriateness Criteria® guidance for right lower quadrant pain in children

Variant 4: Fever, leukocytosis, possible appendicitis, atypical presentation in children (less than 14 years of age)

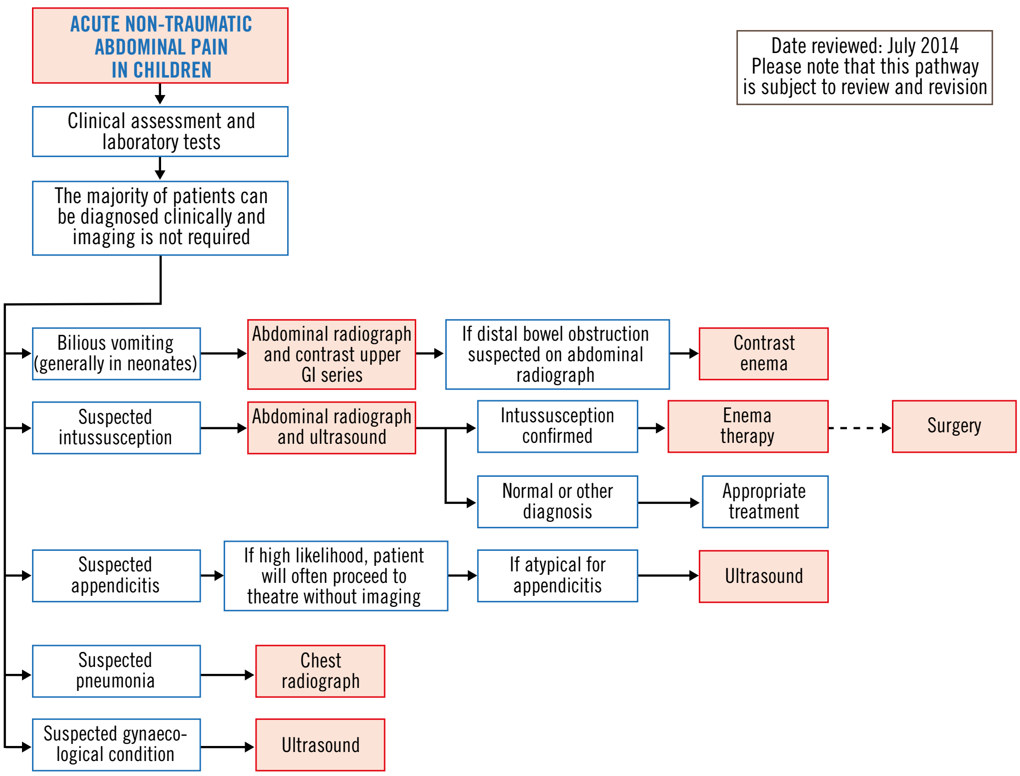
Radiological Procedure	Rating	Comments	RRL*
US abdomen RLQ	8	With graded compression	O
CT abdomen and pelvis with contrast	7	May be useful following negative or equivocal US. Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☢☢☢☢
X-ray abdomen	6	May be useful in excluding free air or obstruction.	☢☢
US pelvis	5		O
CT abdomen and pelvis without contrast	5	Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☢☢☢☢
MRI abdomen and pelvis without and with contrast	5	See statement regarding contrast in text under "Anticipated Exceptions".	O
CT abdomen and pelvis without and with contrast	4	Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	☢☢☢☢
MRI abdomen and pelvis without contrast	4		O
X-ray contrast enema	3		☢☢☢☢
Tc-99m WBC scan abdomen and pelvis	2		☢☢☢☢

Rating scale: 1,2,3 Usually not appropriate; 4;5;6 May be appropriate; 7,8,9 Usually appropriate

* Relative Radiation Level

Source: ACR (2015); reproduced with kind permission of the American College of Radiologists.

Figure 12: Western Australia's Diagnostic Imaging Pathways guidance for abdominal pain in children



Source: Western Australian Health Department, Diagnostic Imaging Pathways; reproduced with kind permission http://www.imagingpathways.health.wa.gov.au/index.php/imaging-pathways/paediatrics/acute-non-traumatic-abdominal-pain#pathway.

Duplication of imaging already performed at other health-care facilities constitutes a significant fraction of such unnecessary examinations. To prevent this repetition, previous investigations (including images and reports) should be recorded in sufficient detail and be available to other health-care providers i.e. at the point of care. This would help record an individual patient's imaging history. Methods used for tracking radiation exposure include paper records (e.g. dose cards) as well as electronic records (smart cards and software) (Seuri et al., 2013; Rehani et al., 2012).

2.1.2.2 Choice of the appropriate procedure

When choosing an imaging procedure utilizing ionizing radiation, the benefit–risk ratio must be carefully considered. In addition to efficacy, safety, cost, local expertise, available resources, accessibility and patient needs and values are aspects to be considered.

Adequate clinical information enables choice of the most useful procedure by the referrer and radiologist or nuclear medicine physician. Medical imaging is useful if its outcome – either positive or negative – influences patient care or strengthens confidence in the diagnosis; an additional consideration is reassurance (for the patient, the family or caregivers).

2.1.2.3 Imaging referral guidelines

Faced with a clinical presentation, the referrer makes a decision based upon best medical practice. However, complexities and rapid advances in medical imaging make it difficult for referrers to follow changes in evidence-based standards of care. Guidance for justification of imaging is usually provided by professional societies in conjunction with national ministries of health.

These medical imaging referral guidelines support justification by giving evidence-based recommendations to inform decisions by referrers and radiologists together with patients/caregivers for the choice of appropriate investigations (Perez, 2015). The ACR Appropriateness Criteria®,[7] the RCR iRefer: "Making the best use of clinical radiology"[8] and the Western Australian Diagnostic Imaging Pathways[9] are examples of referral guidelines (ACR, 2015; RCR, 2012). Evidence-based imaging referral guidelines have gained widespread global acceptance. With similar prevalence for common conditions, it is not surprising to find comparable guidance in different regions of the world (see **Figs. 10**, **11** and **12**).

Imaging referral guidelines are systematically developed recommendations based upon the best available evidence, including expert advice, designed to guide referrers in appropriate patient management by selecting the most suitable procedure for particular clinical indications. Referral guidelines for appropriate use of imaging provide information on which particular imaging exam is most apt to yield the most informative results for a clinical condition, and whether another lower-dose modality is equally or potentially more effective, hence more appropriate. Such guidelines could reduce the number of exams by up to 20% (RCR, 1993 & 1994; Oakeshott, Kerry & Williams, 1994; Eccles et al., 2001).

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7. http://www.acr.org/~/media/ACR/Documents/AppCriteria/Diagnostic/RightLowerQuadrantPainSuspectedAppendicitis.pdf

8. http://www.rcr.ac.uk/content.aspx?PageID=995

9. http://www.imagingpathways.health.wa.gov.au/index.php/imaging-pathways/paediatrics/acute-non-traumatic-abdominal-pain#pathway

Evidence-based referral guidelines consider effective doses, and support good medical practice by guiding appropriateness in requesting diagnostic imaging procedures. They give generic (level 2) justification, and help to inform individual (level 3) justification (see **section 1.1.3**). Global evidence is used to assess the diagnostic and therapeutic impact of an imaging exam to investigate a particular clinical indication, granting the inherent differential diagnostic considerations.

Imaging referral guidelines are advisory rather than compulsory. Although they are not mandatory, a referrer should have good reasons to deviate from these recommendations. **Table 9** provides some examples of questions that, together with the use of imaging referral guidelines, may support a referrer when making a decision about the justification of a medical imaging procedure. If in doubt, the referrer should consult an RMP.[10] Monitoring of guideline use may be assessed with clinical audits to enhance compliance.

Table 9. Socratic questions[a] for referring clinicians when considering imaging procedures

What the referrer should answer	Preventable, wasteful medical exposures to radiation
Has it been done already?	Unnecessarily repeating investigations that have been already done
Do I need it?	Undertaking investigations when results are unlikely to affect patient management
Do I need it now?	Investigating too early
Is this the best investigation?	Doing the wrong investigation
Have I explained the problem?	Failing to provide appropriate clinical information and questions that the imaging investigation should answer

[a] Classical method to stimulate erudite thought, which has been used in radiology education (Zou et al., 2011)

Source: Adapted from RCR (2012), with kind permission of The Royal College of Radiologists.

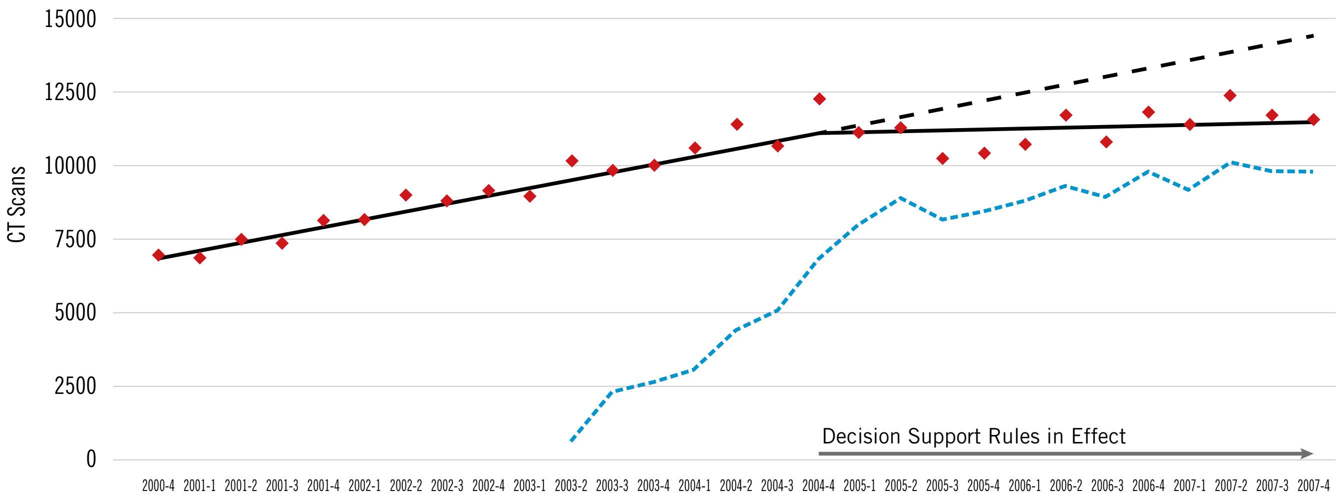
2.1.2.4 Appropriateness and clinical decision support

Systems for improving appropriateness of imaging requests include patient care pathways and computerized decision support implemented through clinical workflows and preferably executed in "real time". For such systems to be successful, recommendations reached through support should occur at the time and location of dynamic decision-making (Kawamoto et al., 2005). The integration of clinical decision support (CDS) into radiology requesting systems can slow down the rate of increasing CT utilization. A substantial decrease in CT volume growth and growth rate has been reported after the implementation of CDS systems, as shown in **Fig. 13** (Sistrom et al., 2009; Sistrom et al., 2014).

Long-term studies show that integration of CDS within the radiology requesting process is acceptable to clinicians and improves appropriateness of exam requisitions, particularly in the emergency department (Raja et al., 2012). Apart from the technical challenges of connectivity and interfacing with existing radiological and clinical information systems, the limitations of CDS include behaviour that bypasses "soft stops" in the computer order entry

[10] See the glossary for the definition of this term in the context of this document. It has to be noted that it includes not only radiologists and nuclear medicine physicians but also interventional cardiologists and any other practitioners who have the responsibility of performing a radiological medical procedure

Figure 13: Effect of the implementation of a decision support system on the growth of CT procedures[a]



[a] Scatterplot of outpatient CT examination volumes (y-axis) per calendar quarter (x-axis) represented by red diamonds. Appropriateness feedback was started in qtr. 4 of 2004 and continued through the duration of the study (arrow at lower right). The solid line represents the linear component of the piecewise regression with a break point at qtr. 4 of 2004. The dashed line shows projected linear growth without implementation of decision support system. The dotted line and teal circles depict number of CT examinations ordered through computer order entry system.

Source: Sistrom et al. (2009); reprinted with permission

system, the inability to cover all clinical presentations and the applicability of guidance to the individual patient. Nevertheless CDS is a useful tool to make available evidence-based imaging referral guidance at the time of referral and has the potential to provide other relevant and helpful information such as previous imaging procedures.

2.1.3 Optimization: child-size and indication-adjusted exam performance

With the development of advanced imaging techniques, imaging has become an increasingly important component of the clinical evaluation of children. The practice of paediatric radiology includes a number of different modalities such as conventional radiography (screen-film, computed and digital radiography), fluoroscopy and computed tomography; these all use X-rays to acquire a "picture" of anatomic structures through which radiation has passed. The latest advances in imaging technologies provide many benefits for acquisition and post-processing of images. Lack of understanding of these technological advances may result in unnecessary radiation exposure; specifically, measures can often be taken to reduce the radiation dose that children receive without adversely affecting the diagnostic benefit of the examination.

Use of adult parameters may result in greater than needed radiation exposures for children. Exposure settings should be customized for children to deliver the lowest radiation dose necessary for providing an image from which an accurate diagnosis can be gleaned, summarized by the Image Gently campaign[11] phrase "One size does not fit all".

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11. The Image Gently campaign is the educational and awareness campaign created by the Alliance for Radiation Safety in Pediatric Imaging. More information available at http://imagegently.org

2.1.3.1 Optimization of radiation protection[12] in paediatric radiology

Multiple opportunities to reduce patient dose in paediatric radiology exist. Dialogue and collaboration among all those involved in providing health care can help to identify and take advantage of these opportunities. Greater and more effective communication between referrers and radiologic medical practitioners would facilitate the optimization process. Information provided by the referrer (i.e. legible and clearly expressed requests) should include the clinical questions to be addressed by the imaging procedure. This information is necessary to determine if the procedure is justified, and it may also help to optimize the examination protocol by adjustment of radiologic technical parameters in order to obtain image quality adequate for particular differential diagnostic considerations, at the lowest possible radiation dose (Linton & Mettler, 2003).

2.1.3.2 Conventional paediatric radiology

Conventional paediatric radiography consists of standard film-based imaging as well as computed radiography (CR) and digital radiography (DR), the latter two digital technologies. CR uses a plate which stores exposure information subsequently transferred to an image reader, a technique often used for portable exams. A DR receptor immediately creates a post-exposure image without the use of an intermediate storage/transfer plate. Regardless of the modality chosen, various techniques and technologies are available to ensure that doses are optimized and coincide with clinical purpose (ICRP, 2013b).

CR and DR offer substantial benefits compared to screen-film radiography, such as an enduring and accessible archive (no lost films; immediate electronic availability) and image manipulation (e.g. magnification, adjustment of contrast and brightness and greater dynamic range that can produce adequate quality with lower exposures, which are used to produce lighter underexposed film-based images). However, there is also a risk of unwittingly increasing the patient dose, as seen in the examples explained below. Overexposed film-based images used to be dark; digital technology can compensate this overexposure by altering brightness and contrast after acquisition. In addition, unless there exists a robust quality-control programme, multiple exposures may be simply eliminated, and never make it to viewers for interpretation (film-based technology was monitored by the use of film and the "film barrel" where poor exposures could be monitored). In addition, manual collimation as part of post processing can create an image sent to the viewer for interpretation that does not indicate how much of the original picture was actually exposed (cropped out). Unfamiliarity with the technology, such as post processing algorithms, may also decrease displayed image quality.

Education and training, as well as effective team approaches to dose management (i.e. involving the radiologist, medical physicist and radiographer/radiological technologist) are crucial to ensure optimization of protection in CR/DR (Uffmann & Schaefer-Prokop, 2009, ICRP, 2007b).

2.1.3.3 Diagnostic fluoroscopy

Fluoroscopy is an imaging modality that uses an X-ray beam to produce essentially real-time dynamic images of the body, captured by a special detector and viewed on screen. In discussion with patients, families and other caregivers, a movie camera analogy is often helpful. A plain radiography is the equivalent of a single exposure or X-ray picture while fluoroscopy

12. Note that this document is focused on radiation protection. Other patient safety issues related to paediatric imaging are not addressed (e.g. possible adverse effects due to contrast media)

is an X-ray movie. With current digital technology, studies can easily be recorded onto CDs. The possibility of displaying and recording motion during fluoroscopy renders this technique ideal for evaluation of the gastrointestinal tract (e.g. contrast studies). Fluoroscopy is particularly helpful for guiding a variety of diagnostic and interventional procedures (see below). Fluoroscopy can result in a relatively high patient dose,[13] however, and the total fluoroscopic time the camera is "on" is a major factor influencing patient exposure. A number of practical measures can reduce unnecessary radiation exposure of paediatric patients in diagnostic fluoroscopy (ICRP, 2013b).

2.1.3.4 Image-guided interventional procedures

Interventional radiology provides an opportunity to perform minimally invasive procedures involving small medical devices such as catheters or needles, with imaging guidance provided by ultrasonography, MRI, CT or X-ray/fluoroscopy. When fluoroscopy-guided interventional procedures are performed in children, they pose unique radiation safety issues. Fluoroscopic doses may be relatively high and, though rarely, might result in tissue reactions (also called "deterministic effects") such as skin injuries, particularly in large adolescents.[14] Tissue reactions are extremely uncommon after CT-guided procedures, however. Complex interventions may require high radiation doses and their justification has to be evaluated on a case-by-case basis. Radiation risks can be minimized by implementing practical measures to optimize protection (Sidhu et al., 2010; NCRP, 2011).

Before the procedure, communication between the referrer and the RMP (e.g. interventional radiologist, interventional cardiologist, others) enables information exchange to support the decision (justification). Other imaging options should be considered, in particular those that do not require ionizing radiation (e.g. MRI, ultrasound). The referrer can help to collate the patient's past medical and imaging record to allow assessment of the patient's cumulative radiation exposure. Moreover, consideration of previous clinical findings may be relevant to the current examination.

Usually, the referrer is the first health professional in the health care pathway to talk directly to the patient and family. Communicating radiation benefits and risks of a fluoroscopy-guided interventional procedure may deserve unique radiation safety considerations. Therefore, the risk–benefit dialogue has to be supported by the radiological medical practitioner (e.g. radiologist, interventional cardiologist) and other members of the radiology team (e.g. medical physicists, radiographers/radiological technologists). This task can be facilitated by using printed and/or electronic informational materials for physicians, patients, parents, relatives and other caregivers. Such information may be reviewed during the informed consent process and/or post-procedural directives.

During the procedure, all members of the interventional radiology team cooperate to ensure optimization of protection and safety. Effective communication between staff helps to keep the radiation dose as low as possible. A number of parameters that affect patient dose can

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13. Fluoroscopy, and in particular fluoroscopy-guided interventional procedures, pose particular radiation safety issues for the staff. Doses to staff may be relatively high, and can result in adverse effects such as lens opacities. Occupational radiation protection is outside the scope of this document and further information is available elsewhere (NCRP, 2011: IAEA radiation protection of patients website http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/Radiology.htm).

14. Paediatric patients vary in size from small, premature babies to large adolescents. Patient size has an influence on the fluoroscopic dose, e.g. under automatic exposure control, tube voltage (kV) and current (mA) are both adjusted to patient attenuation, thus resulting in a higher radiation dose in large/obese patients.

be managed to substantially reduce the radiation dose while allowing for high-quality diagnostic images to guide the intervention (Miller et al., 2010).

Post-procedure information, including possible adverse effects, should be made available to the referrer and provided to the patient and/or guardian. The referrer can keep track of imaging history via a number of options (e.g. cards).

Clinical follow-up is indicated for patients who received relatively high skin doses during one or more procedures. Ideally, it should be performed by the RMP rather than the referrer. But in cases when patients live far away from the facility where the procedure was performed, the referrer will need further information to perform the follow-up (NCRP, 2011; ICRP, 2013a). The patient and family should also be informed about clinical signs of skin injury such as reddening of the skin (erythema) at the beam entrance site, and how to proceed if they appear.

2.1.3.5 Computed tomography

Computed tomography is another modality which uses ionizing radiation. The patient lies on a narrow table which moves through a circular hole in the middle of the equipment. An X-ray beam traverses a slice of patient's body and then travels toward a bank of detectors. Both the X-ray source and the detectors rotate inside the machine. While the patient is moved through the gantry inside the machine, a computer generates images of serial slices of the body and displays the images on a monitor. Radiation dose in CT depends on several factors and may result in a dose as high as (or even higher than) fluoroscopy.

Opportunities for reducing unnecessary radiation dose in paediatric CT include the adjustment of exposure parameters to consider the child's size (individual size/age) and the clinical indication, paying attention to diagnostic reference levels or ranges (DRLs/DRRs – see below). More details about aspects to be considered for optimization of paediatric CT have been provided in other publications (Strauss et al., 2010; ICRP, 2013b; Strauss, Frush & Goske, 2015).

Table 10 shows examples of the impact of adjustable CT techniques in terms of patient radiation dose. "Child-sizing" may result in substantial reduction of the dose. **Fig. 14** illustrates the influence of the (simulated) tube current reduction on the resulting image.

Table 10. Examples of the influence of some common adjustable CT techniques on patient radiation dose

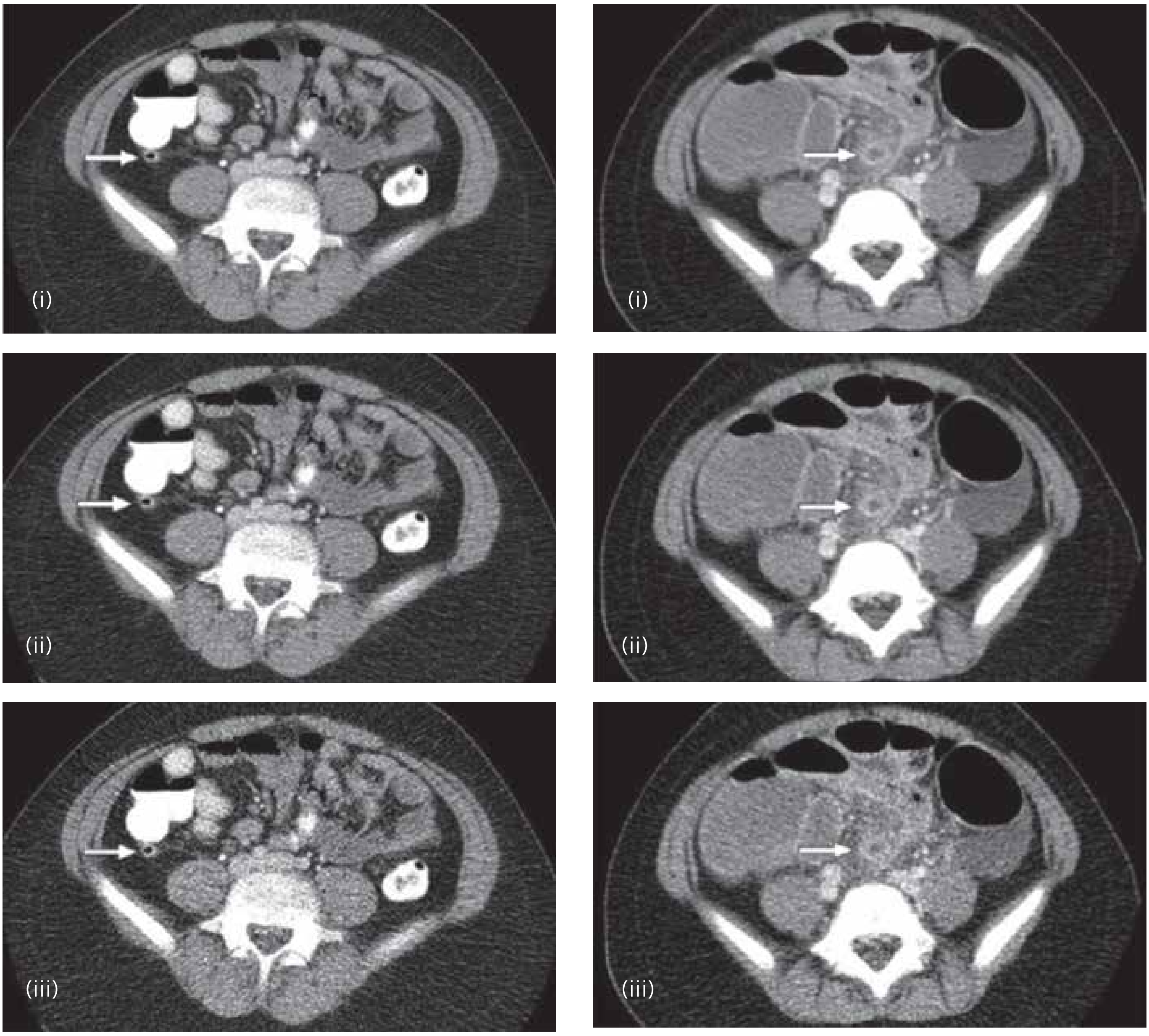
CT Technique	Influence on Radiation Dose
X-ray energy (kilovoltage peak -kVp)[a]	Decreased kVp → decreased dose
Tube current (milliamperes-mA)[a]	Decreased mA → decreased dose
X-ray tube rotation speed (seconds)[a]	Faster tube (gantry) spinning → decreased dose
Scanning range/distance (in cm)	Shorter scanning distance → decreased dose
Patient position in scanner	Improper positioning in gantry can increase dose
Number of scan sequences (phases)	Increasing phases (e.g. pre and post contrast) increases dose
Scanning multiple body regions	Minimizing scan overlap decreases dose
Optimal use of intravenous contrast (dye)	Improved structure visibility may afford lower settings (e.g. kVp)
Special technologies	Scanner dependent; additional dose reduction capabilities

[a] Assuming all other factors are held constant. Note also that the trade-off for lower dose is often increase in image noise. Quality imaging strives to obtain the proper balance between these factors.

Figure 14: Influence of the assumed simulated dose reduction (e.g. added noise, no repeat scanning) on the resulting image

a: 11-year-old child with normal appendix. (i) unadjusted tube current; (ii) 50% tube current reduction; and (iii) 75% tube current reduction. All scans show air-filled appendix (see arrows) in cross section.

b: 3-year-old child with acute appendicitis. (i) conventional tube current; (ii) 50% tube current reduction; and (iii) 75% tube current reduction. Arrows show thickened appendix. Note also that bowel obstruction is readily evident in all tube current examinations.



Source: Swanick et al. (2013); reprinted with permission.

Even for low-dose paediatric CT, protocols can be adapted to further reduce radiation doses. A study conducted in a hospital in Belgium showed that in low-dose MDCT of the sinuses in children, the effective dose was lowered to a level comparable to that used for conventional radiography while retaining the adequate diagnostic quality of paranasal sinus CTs (Mulkens et al., 2005). This study demonstrated that optimization of protocols for paranasal sinuses CT in children can yield high-quality diagnostic images using an effective dose comparable to that used for standard radiography. This is an example of good practice in which an effective dialogue between the referrer and the RMPs aided optimization, allowing scan protocols to be adjusted according to clinical questions the examination was expected to answer.

2.1.3.6 Nuclear medicine

Nuclear medicine uses radioactive substances (radiopharmaceuticals) to image and measure functional aspects of the patient's body (diagnostic nuclear medicine) and/or to destroy abnormal cells (therapeutic nuclear medicine). The radiopharmaceutical accumulates predominantly in the organ or tissue being examined, where it releases energy (radiation). In nuclear medicine imaging this radiation is received by a detector that allows for the visualization of the distribution of the radiopharmaceutical in the body. In addition to images, radioactivity can also be measured in patient's blood, urine and/or other samples. Thereby it is possible to characterize and measure the function of organs, systems and tissues (e.g. perfusion, metabolism, proliferation, receptor/antibody expression and density, etc.). The detector most often used in nuclear medicine is the gamma camera, also called a scintillation camera, either for planar (2D) or three-dimensional (3D) imaging. With the single photon emission computed tomography (SPECT) the images are acquired at multiple angles around the patient; computed tomographic reconstruction provides 3D information of the distribution of the radiopharmaceutical in the patient. Nuclear medicine images can be superimposed upon CT or MRI images, a practice called image fusion. The introduction of

Box 2.3 Ultrasonography and magnetic resonance imaging

Ultrasonography refers to the use of sound waves in medical imaging. A transducer or probe transmits sound waves and receives the reflected signals. Ultrasound should be considered a viable alternative to X-rays for imaging in paediatric settings whenever possible (Riccabona, 2006). In the paediatric population, ultrasound frequently assesses, for example, potential cardiac abnormalities, pyloric stenosis, hip dysplasia, appendicitis, neonatal intracranial abnormalities, and both the neonatal spine and spinal cord. Ultrasound is also used to evaluate many other indications involving the abdomen, pelvis, musculoskeletal system, thyroid and breasts as well as for vascular and endoluminal imaging. Innovative ultrasound approaches and new ultrasound techniques such as amplitude-coded colour Doppler, harmonic and high-resolution imaging, ultrasound contrast media and three-dimensional capability have broadened the spectrum of indications which can be evaluated by ultrasound, further establishing it as a valuable imaging technique which does not require exposure to ionizing radiation. Moreover, ultrasound-guidance is used for many interventional procedures.

Magnetic resonance imaging (MRI) utilizes a combination of strong magnetic fields, radio waves, and magnetic field gradients to produce 2D and 3D images of organs and internal structures in the body. The high contrast sensitivity to soft tissue differences and the inherent patient safety resulting from the use of non-ionizing radiation have been key reasons why MRI has supplanted CT and projection radiography for a number of medical imaging procedures. For paediatric imaging, MRI is used for a variety of purposes, including the evaluation of diseases of the central nervous system and urinary tract, musculoskeletal disorders/injuries, congenital heart defects and other cardiovascular diseases (including blood vessel imaging: MRI angiography). It can also assist in cancer staging and cancer treatment planning. MRI spectroscopy is an emerging imaging technique for evaluating paediatric brain disorders. Interventional MRI entails performing interventional procedures, primarily involving the brain, using a specially designed MRI unit in an operating room. Because MRI does not use ionizing radiation, it is often the examination of choice for paediatric imaging.

positron emission tomography (PET) and integrated imaging systems (e.g. SPECT/CT, PET/CT, PET/MRI) expanded the applications of molecular imaging with radiopharmaceuticals.

Patients undergoing PET/CT or SPECT/CT are exposed to radiation from both the injected radiopharmaceutical and X-rays from the CT scanner. For both components the radiation dose is kept as low as possible without compromising the quality of the examination. Most radiopharmaceuticals used for diagnostic imaging have a short half-life (minutes to hours) and are rapidly eliminated. Diagnostic reference levels for nuclear medicine are expressed in terms of administered activity. To optimize protection of children and adolescents in diagnostic nuclear medicine, dose optimization schemes for the administered activities in paediatric patients are applied, generally based upon recommended adult dose adjusted for different parameters such as patient's body weight. Variations of this approach have been recently adopted by professional societies in North America and Europe (Gelfand, Parisis & Treves, 2011; Fahey, Treves & Adelstein, 2011; Lassmann et al., 2007; Lassmann et al., 2008; Lassmann et al., 2014). The ultimate goal is to reduce radiation exposure to the lowest possible levels without compromising diagnostic quality of the images.

2.1.3.7 Dental radiology

Intra-oral "bite-wing" X-rays and/or panoramic radiography are longstanding tools of dentists and orthodontists, but present availability of cone-beam CT (CBCT) and multi-slice CT (MSCT) to assess dentition and/or oral-maxillofacial pathology raises questions of justification and optimization. The SEDENTEXCT Panel[15] concluded in 2011 that there is a need for research demonstrating changed (and improved) outcomes for patients before widespread use of CBCT for this purpose could be considered. An exception to this would be where current practice is to use MSCT for localization of unerupted teeth (Alqerban et al., 2009). In such cases, CBCT is likely to be preferred over MSCT if dose is lower. In any case, radiological examination of maxillary canines is not usually necessary before 10 years of age (European Commission, 2012).

The utilization of ultrasonography and magnetic resonance imaging in children has increased over the past several years. These modalities use non-ionizing radiation to generate images. Although this document is focused on ionizing radiation risk communication, general information about those procedures is provided in **Box 2.3**.

2.1.3.8 Diagnostic reference levels

Diagnostic reference levels (DRLs) are a form of investigation levels of dose (in diagnostic and interventional radiology) or administered radioactivity (in nuclear medicine), defined for typical examinations and groups of standard-sized patients as tools for optimization and quality assurance. Size variation of adults is small compared to the range of size variation in paediatric patients. Therefore, specific DRLs for different sizes of children are needed in paediatric imaging. These are generally specified in terms of weight or age. DRLs do not limit dose; they are advisory rather than compulsory, although implementation of the DRL concept is a basic safety standard requirement. Once established, DRLs are periodically reviewed and updated to reflect benchmarks consistent with current professional knowledge. Facilities can compare doses in their practices with DRLs for suitable reference groups of

15. The SEDENTEXCT project (2008–2011) was supported by The Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007–2011), http://cordis.europa.eu/fp7/euratom/

patients to ensure that doses for a given procedure do not deviate significantly from those delivered at peer departments. DRLs help identify situations where the patient dose or administered activity is unusually high or low (ICRP, 2001 & 2007b).

2.1.3.9 Reducing repeat examinations and tracking radiation history in paediatric patients

One third of all children having CT scans have been reported to have three or more CT scans (Mettler et al., 2000). Individual patient radiation dose through repeated procedures may fall to within the range of a few tens of mSv of effective dose or may even exceed 100 mSv (Rehani & Frush, 2011). Repeated X-rays examinations are often performed for prematurely born children as well as for babies with hip dysplasia (Smans et al., 2008). Paediatric patients with chronic diseases (e.g. congenital heart disease, cancer survivors) may undergo multiple imaging and interventional procedures. They may therefore have relatively high cumulative exposures. In such patients non-ionizing imaging modalities such as MRI or ultrasound should be considered viable alternatives whenever possible (Seuri et al., 2013; Riccabona, 2006).

Paediatricians and family physicians can promote methods for tracking radiation exposure histories of their paediatric patients. A number of options have been proposed (e.g. e-health records, electronic cards, radiation exposure records integrated within e-health systems, web-based personal records, radiation passport, and paper cards). The Image Gently website provides a downloadable form entitled "My Child's Medical Imaging Record",[16] similar to immunization cards.

For relatively low-dose procedures (e.g. chest X-ray, other conventional X-ray procedures) a reasonable approach would be to track just the number of exams. However, for procedures that deliver higher doses (e.g. CT, PET/CT, image-guided interventional procedures, most nuclear medicine procedures) it is advisable to record the dose per exam (or factors that might allow a dose estimate) in addition to the number of those exams (Rehani & Frush, 2010).

2.2 Promoting a radiation safety culture to improve practice

2.2.1 What is radiation safety culture in health-care settings?

The ultimate goal of radiation protection in health care is the safety of patients and others,[17] by minimizing the risks associated with the use of radiation while maximizing benefits for patients' care.

Health-care delivery contains a certain degree of inherent risk. As health-care systems and processes become more complex and fragmented, the risk at each point of care and the number of points of care may increase. The success of treatment and the quality of care do not depend on the competence of individual health-care providers alone. A variety of other factors are important. These include organizational design, culture and governance as well as the policies and procedures intended to minimize or mitigate the risks of harm.

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16. Available at http://www.imagegently.org/Portals/6/Parents/Dose_Record_8.5x11_fold.pdf

17. In this context "others" refers to parents/caregivers, health workers and the general public

Health-care institutions are increasingly aware of the importance of transforming their organizational culture to improve the protection of patients and health-care workers. European data consistently show that medical errors and health-care related adverse events occur in 8% to 12% of hospitalizations.[18] Health-care facilities should be accountable for continually improving patient safety and service quality.

Organizational culture is typically described as a set of shared beliefs among a group of individuals in an organization. Safety culture is a part of the organizational culture that can be defined as the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an organization's safety management. Three main developmental stages of the safety culture have been identified:

- Stage 1: Basic compliance system – All safety training programmes, work conditions, procedures and processes comply with regulations. This is passive compliance.
- Stage 2: Self-directed safety compliance system – workers ensure regulatory compliance and take personal responsibility for training and other regulatory provisions. This emphasizes active compliance with the regulations.
- Stage 3: Behavioural safety system – teaching individuals to scan for hazards, to focus on potential injuries and the safe behaviour(s) that can prevent them, and to act safely. This emphasizes inter-dependence among the workforce, i.e. looking after each other's safety. The objective of any culture development programme is to move the organizational and individual behaviours towards the highest stage.

In this context, patient safety culture comprises shared attitudes, values and norms related to patient safety.

Radiation safety culture in health care considers radiation protection of patients, health workers and the general public. It is embedded in the broader concept of patient safety and is included in the concept of good medical practice. Therefore, it uses the same approaches that are used to implement safety culture in health-care settings (e.g. no blame, no shame, willingness, team work, transparent communication, error reporting for learning).[19]

Radiation safety culture in medical imaging enables health-care providers to deliver safer and more effective health care tailored to patients' needs. It is mainly addressed to ensuring the justification/appropriateness of the procedure and the optimization of the protection, keeping in mind that primary prevention of adverse events will always be a major objective.

Radiation protection is an important element of overall patient safety. Equipment issues, process failures, and human errors in care delivery can jeopardize patient safety. Patient safety is an inseparable component of professional responsibility in health care (Lonelly et al., 2009).

Leadership is a key component of radiation safety culture. Building a safety culture requires leadership and support from the highest level in the organization. Leaders dedicated to improving patient safety can significantly help to build and sustain a stronger radiation protec-

18. From the website of WHO's European Region on patient safety: http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/data-and-statistics

19. More information at the following links:
http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/patient-safety/facts-and-figures;
http://healthland.time.com/2013/04/24/diagnostic-errors-are-more-common-and-harmful-for-patients/;
and http://www.oecd.org/health/ministerial/forumonthequalityofcare.htm

tion culture in medical imaging. All stakeholders in health-care pathways involving use of radiation for medical imaging have a role to play: radiologists, nuclear medicine physicians, radiographers/radiological technologists, medical physicists, referrers, nurses, support staff members and business administrators. In addition, patients, patient networks and organizations contribute to the successful implementation of a radiation protection culture. They are natural partners to collaborate in the development and promotion of a safety culture, by facilitating a constructive dialogue and advocating for patient-centred care.

2.2.2 Radiation safety and clinical governance

Clinical governance has been defined as "a framework through which organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (Scally & Donaldson, 1998). The principles of quality of health care services include safety, effectiveness, patient-centredness, timeliness, efficiency, affordability and equality (WHO, 2006; Lau & Ng, 2014; WHO 2015b). The concept of clinical governance should include radiation protection, to provide the corporate responsibility required to establish and maintain a radiation safety culture.

Four pillars of clinical governance have been proposed, and radiation safety is implicit in all of them as shown in the examples below:

- Clinical effectiveness is generically defined as a measure of the extent to which a clinical intervention works. In medical imaging this is linked to the appropriateness of procedures, which can be enhanced by the implementation of evidence-based clinical imaging guidelines.
- Clinical audit is a way to measure the quality of health care, to compare performance against standards and to identify opportunities for improvement. In radiology services it includes auditing the implementation of the justification and optimization principles. Clinical audit provides the evidence for changes in resource allocation.
- Risk management strategies in radiology services aim to identify what can go wrong, encourage reporting and learning from adverse events, prevent their recurrence and implement safety standards to enhance radiation protection.

Box 2.4 Steps to establish and maintain radiation safety culture

(a) Promote individual and collective commitment to protection and safety at all levels of the organization

(b) Ensure a common understanding of the key aspects of safety culture within the organization

(c) Provide the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals, technology and the organization

(d) Encourage the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety

(e) Ensure accountability of the organization and of individuals at all levels for protection and safety

(f) Encourage open communication with regard to protection and safety within the organization and with relevant parties, as appropriate

(g) Encourage a questioning and learning attitude and discourage complacency with regard to protection and safety

(h) Provide the means by which the organization continually seeks to develop and strengthen its safety culture.

Source: Adapted from BSS (2014), with permission from IAEA

- Education, training and continuing professional development (i.e. life-long learning) is essential to improve safety and quality in the medical uses of ionizing radiation.

2.2.3 Establishing a radiation safety culture

Establishing a radiation safety culture must start from the top of the organization but the dimensions and promotion of the culture will rely on ownership by all of the relevant stakeholders involved in provision of the service, including directors, administrators, health-care providers, other support staff, patients and families.

Radiation safety culture can be established, maintained and improved by implementing a number of possible interventions as described in **Box 2.4** (BSS, 2014) and **Table 11** (Eccles et al., 2001; Michie & Johnston, 2004).

Table 11. Strategies to improve radiation safety culture

Elements effecting the culture	Strategies to improve radiation safety culture	Examples
Basic underlying assumptions	Education, advocacy (i.e. raising awareness)	Radiation protection education in medical and dental schools, campaigns
Adopted shared values	Standards, norms, guidelines	Radiation basic safety standards, referral guidelines for medical imaging
Artefacts/visible products	Training, audit, feedback and quality improvement	On-the-job training, operational rounds, behavioural change through targeted messages

Reporting and learning systems can enhance patient safety by contributing to learning from adverse events and near misses in the health-care system. These systems should lead to a constructive response based on analysis of risk profiles and dissemination of lessons for preventing similar events, an important component of primary prevention.

Organizations with a positive radiation safety culture are characterized by communications founded on mutual trust, shared perceptions of the importance of radiation protection and safety, and by a commitment to the development and implementation of effective radiation protection measures. Effective communication has been emphasized as key for improving patient safety and is essential to establish and maintain radiation safety culture in medical settings. Health-care providers need to develop skills and self-assurance to feel comfortable speaking out in situations of uncertainty, regardless of their position in the medical and/or organizational hierarchy, and the position of the others involved in the situation. Effective health-care delivery systems rely heavily on high degrees of skill in communication. This includes communication about the results and actions of issues identified. Operational rounds at the site of imaging are helpful to discuss front-line employees' concerns about patient safety, quality of care and patient and family satisfaction (Lonelly et al., 2008).

As with other safety checklists in health care, radiation safety checklists that are based on scientific evidence are risk management tools. Their proper use is a component of a radiation safety culture. While standardization is the basis for any safety checklist, all checklists need to be continually assessed and updated as necessary to ensure that they are still accomplishing their goals.

Through clinical audit, medical procedures including medical imaging are systematically reviewed against agreed standards for good medical practice. Clinical audit also requires the application of new standards where necessary and appropriate. This aims to improve the quality and the outcome of patient care, thus also contributing to improving radiation safety culture.

Teamwork contributes to enhance patient safety (Baker et al., 2005; Baker et al., 2006). Organizations should make patient safety a priority by establishing interdisciplinary team training programmes that incorporate proven methods for team management. Team members must possess specific knowledge, skills, and attitudes that can be elicited and assessed throughout a worker's career. A report from the Department of Health in the United Kingdom of Great Britain and Northern Ireland examines the key factors at work in organizational failure and learning. The report identifies four key areas that must be developed in order to move forward:

- unified mechanisms for reporting and analysis when things go wrong;
- a more open culture, in which errors or service failures can be reported and discussed;
- mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice;
- a much wider appreciation of the value of the system approach in preventing, analysing and learning from errors.

The report concludes the discussion with a critical point: "With hindsight, it is easy to see a disaster waiting to happen. We need to develop the capability to achieve the much more difficult – to spot one coming" (NHS, 2000).