

# COMMUNICATING RADIATION RISKS IN PAEDIATRIC IMAGING

Information to support healthcare discussions about benefit and risk



World Health  
Organization



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Cover photo: Garrett Allison and his mom Gemini Janas speak with Dr. Rajan Gupta at Duke University Hospital (Durham, US) about the risk of radiation during diagnostic testing, such as a CT scan. © Shawn Rocco/Duke Medicine (with permission)

Photo page 2: Billington Jesse Semwogerere and his mom Victoria Nandagire have a conversation with Dr. Deborah Babirye at Ecurei-Mengo Hospital (Kampala, Uganda) about the risk of radiation during diagnostic testing, such as a CT scan. Source: Miss Elizabeth Nabunya Kawooya (with permission).

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# Foreword

Advancing imaging technology has opened new horizons for clinical diagnostics and has greatly improved patient care. As a result, the use of medical imaging has increased rapidly worldwide during the past several decades and the spectrum of its applications in paediatric health care has expanded. Paediatric computed tomography (CT) can provide fast and accurate information to help diagnosis; it saves lives and in many cases prevents the need for more invasive procedures. However, inappropriate use may result in unnecessary and preventable radiation risks, particularly in children. A balanced approach is needed that recognizes the multiple health benefits that can be obtained, while assuring that risks are minimized.

Patients and families should be part of risk–benefit discussions about paediatric imaging so they can best understand the information and use it for making informed choices. If they are not properly informed about risks and benefits of an imaging procedure, they may make choices that are not beneficial and may be even harmful (e.g. to refuse a CT that is needed or to demand a CT that is not justified). Radiation risk communication and risk–benefit dialogue is also necessary between health-care providers who request or perform radiological medical procedures in children. Effective communication between referrers and imaging team members may prevent inappropriate referral. By enabling informed decision-making, effective radiation risk communication contributes to ensure the greatest possible benefit of paediatric imaging, at the lowest possible risk.

In response to this need, the World Health Organization (WHO) convened a global collaboration to implement a project on radiation risk communication to support risk–benefit dialogue in paediatric imaging. This document has been developed by a group of recognized experts and extensive consultations with relevant stakeholders, including health-care providers, patient advocates, health authorities, radiation protection regulators, researchers and communication experts. Subsequent revisions of the document were made based on feedback collected through a number of workshops held in different regions of the world.

This document is intended to serve as a communication tool about known or potential radiation risks associated with paediatric imaging procedures, to support the risk–benefit dialogue during the process of paediatric health-care delivery. It provides information and resources to support communication strategies including examples of key messages to use in different scenarios. This tool is primarily intended for health-care providers who refer children to perform imaging procedures involving ionizing radiation exposure. In addition to this target audience, this document may be a useful tool for other relevant stakeholders.

WHO looks forward to continuing and expanding its collaboration with relevant stakeholders at global, regional and national levels to improve radiation safety and quality in paediatric health care.

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# Preface

Radiation risk communication is a key component of a radiation protection programme in health care. The level of awareness of health professionals about radiation doses and associated risks in medical imaging can be low. Referring medical practitioners need sufficient background, education and resources to communicate clearly and effectively about the benefits and risks of paediatric imaging procedures. In response to this need, the World Health Organization (WHO) started a project on radiation risk communication in paediatric imaging.

WHO convened an International Workshop on Radiation Risk Communication in Paediatric Imaging in September 2010. This meeting was held at WHO headquarters in Geneva, Switzerland, and it gathered 35 participants from 23 professional societies, international and regional organizations and United Nations (UN) agencies.<sup>1</sup> It included representatives of key stakeholders in the field of paediatric imaging such as radiologists, radiographers/radiological technologists, medical physicists, referring physicians, nurses, patients/parents, regulators, researchers and communication experts. The group mapped out existing guidance and tools to communicate radiation risks in diagnostic imaging, identified gaps and agreed on the need to support risk–benefit dialogue in paediatric imaging. It was proposed to develop an educational tool for health-care providers with guidance on how to effectively communicate radiation risks related to radiological medical procedures in children<sup>2</sup> to different target audiences. It was also proposed to make available more concise information for patients and families.

To this end, an expert group was established and a first draft document was produced. This was presented at a workshop on radiation risk communication in paediatric imaging jointly organized by WHO and the World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA) during the 17<sup>th</sup> WONCA Conference of Family Medicine held in Warsaw, Poland, in September 2011. WHO convened a 2<sup>nd</sup> International Workshop on Radiation Risk Communication in Paediatric Imaging in December 2012 in Bonn, Germany. The meeting gathered 56 participants including individual experts from 19 countries and representatives from 12 international organizations, UN agencies, professional organizations, scientific societies, academic institutions,

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<sup>1</sup>. The following organizations were represented at this workshop: African Society of Radiology (ASR), Alliance for Radiation Safety in Pediatric Imaging/Image Gently campaign, Canadian Association of Radiology (CAR), European Commission (EC), European Society of Radiology (ESR), Federal Agency for Nuclear Control, U.S. Food and Drug Administration (FDA), German Radiation Protection Authority (BfS), International Atomic Energy Agency (IAEA), International Commission on Radiological Protection (ICRP), International Council of Nurses (ICN), International Organization for Medical Physics (IOMP), International Radiology Quality Network (IRQN), International Society of Radiographers and Radiation Technologists (ISRRT), International Society of Radiology (ISR), Sociedad Latino Americana de Radiología Pediátrica [Latin American Society of Paediatric Radiology] (SLARP), National Council of Radiation Protection and Measurements (NCRP), National Institute of Radiological Sciences of Japan (NIRS), Patients for Patient Safety (PFPS), Royal College of Radiology (RCR), United States Environmental Protection Agency (USEPA), and World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA).

<sup>2</sup>. In the context of this document, a child is a person below the age of 18.



research institutions, patients networks and organizations, regulatory authorities and ministries of health.<sup>3</sup> Participants reviewed experience and lessons from recent radiation risk communication actions, discussed good practices and provided feedback on the document from their various perspectives.

An updated document was pilot tested in 2013, and subsequent revisions were made based on the feedback collected. This included a WHO-WONCA workshop on the Role of Family Doctors in Communicating Radiation Risks in Paediatric Imaging organized in Prague, Czech Republic, in June 2013, during the 20<sup>th</sup> World Conference of Family Medicine. In December 2014 the document was presented at an International Dialogue Seminar for Medical Practitioners co-organized by WHO and the National Institute of Radiological Sciences (NIRS) in Tokyo, Japan.

This document is intended to serve as a tool for health-care providers to communicate known or potential ionizing radiation risks associated with paediatric imaging procedures, to support risk–benefit dialogue during the process of paediatric health-care delivery. It provides the end-users with information and resources to support communication strategies including examples of key messages to use in different scenarios. The document is organized in three chapters, which have been given a specific colour-code for ease of navigation. Additional information is provided in three annexes.

This tool is primarily targeted to any health-care provider who refers children to perform imaging procedures involving radiation exposure, but may be a useful tool for other relevant stakeholders as well. This communication tool can serve as a basis to further develop a format that targets patients, parents, family members and the general public.

Potential end-users of this communication tool include:

- paediatricians, surgeons, general practitioners/family physicians, emergency medicine physicians, physician assistants, nurses, and other health-care providers involved in the process of prescription of radiation for paediatric imaging;
- health-care providers who perform, support or direct imaging procedures in children (e.g. radiologists, nuclear medicine physicians, medical physicists, radiographers, radiological technologists, dentists, interventional cardiologists, orthopaedic surgeons, paediatric surgeons, vascular surgeons, gastroenterologists, urologists and other health professionals performing imaging outside the Radiology Department);
- health policy- and decision-makers, health authorities, regulatory bodies and other governmental agencies;
- medical and dental schools, other academic and research institutions.

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<sup>3</sup>. The workshop report is available at [http://www.who.int/ionizing\\_radiation/medical\\_exposure/Bonn\\_Workshop\\_Risk\\_Communication\\_Report01.pdf](http://www.who.int/ionizing_radiation/medical_exposure/Bonn_Workshop_Risk_Communication_Report01.pdf)

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# Executive summary

Advances in technologies using ionizing radiation have led to an ever-increasing number of clinical applications in the diagnosis and treatment of human disease. This has led to the expanded use of these technologies worldwide, which has positively impacted the paediatric population.

- Computed and digital radiography (CR and DR) are replacing conventional film-based radiography, providing images that are instantly available for analysis and electronic distribution, with lower costs and facilitated access.
- Computed tomography (CT) is a valuable tool for assessing paediatric illness and injury, often replacing less accurate or more invasive diagnostic procedures.
- Fluoroscopy-guided interventional procedures can replace surgical options which carry a relatively higher risk of adverse events in children.
- Nuclear medicine allows structural and functional evaluations, especially evident through hybrid techniques (e.g. PET-CT).
- Dental radiology has evolved and cone-beam CT is increasingly used in children by dentists and orthodontists in some regions to obtain 3D views of the face and teeth.

The use of radiation in paediatric imaging saves lives – the clinical value of imaging involving the use of radiation for the diagnosis of paediatric illness and injury is unquestionable. However, inappropriate or unskilled use of such technologies may result in unnecessary exposures that may increase risk and provide no added benefit to paediatric patients. While the radiation dose delivered during diagnostic procedures is low and is not expected to cause acute injuries, image-guided interventional procedures may deliver doses high enough to cause deterministic effects such as skin injuries. Stochastic risks are of special concern in paediatric imaging since children are more vulnerable than adults to the development of certain cancer types, and have longer lifespans to develop long-term radiation-induced health effects. While individual radiation risks are at most quite small, enhancing radiation safety in paediatric imaging has become a public health issue due to the increasingly large paediatric population exposed, as well as the increased public awareness and often alarm on the part of the public.

The benefits of imaging children must be weighed against the potential risks of the radiation exposure. The ultimate purpose is that the benefit will outweigh harm. This demands policies and actions that recognize and maximize the multiple health benefits that can be obtained, which at the same time minimize potential health risks. This can be achieved by implementing the two principles of radiation protection in medicine: justification of the procedures and optimization of protection, summarized as “to do the right procedure” and “to do the procedure right”. Existing imaging referral guidelines can be used to support justification and enhance appropriateness of referral. These decision support tools can inform referrers and radiologists, together with patients/caregivers, for the choice of the appropriate examination. In radiation protection, optimization signifies keeping doses “as low as reasonably achievable” (ALARA). For medical imaging, ALARA means delivering the lowest

possible dose necessary to acquire adequate diagnostic data images. Multiple opportunities exist for radiation dose reduction without any significant loss of diagnostic information.

Health-care providers requesting and/or performing radiological imaging procedures in children have a shared responsibility to communicate radiation risks accurately and effectively to patients, parents and other caregivers. They should be able to conduct risk–benefit discussions to inform the decision-making process as well – radiologists, radiographers, medical physicists and other members of the imaging team should be able to conduct risk–benefit discussions with their colleagues, in particular paediatricians, family physicians, emergency medicine physicians and other referrers. Awareness among health professionals about radiation doses and associated risks in medical imaging can be low, however.

Effective and balanced communication of radiation risks requires sufficient background, education and resources to support the risk–benefit dialogue, particularly in paediatric patients. For example, it is important to communicate that risks can be controlled and benefits maximized by selecting an appropriate procedure, and using methods to reduce patient exposure without reducing clinical effectiveness. While the fundamentals of risk communication and risk–benefit dialogue are common to all health-care settings, the implementation of an effective communication strategy in paediatric imaging often requires unique considerations.

This document discusses different approaches to establish this dialogue in clinical settings including communication with the paediatric patient. It provides practical tips to support the risk–benefit discussion, including examples of frequently asked questions and answers, which may also be used to develop information materials for patients and their families. The document also discusses ethical issues related to the communication of radiation risks in paediatric imaging and proposes different scenarios and stakeholders involved when creating a dialogue in the medical community. Also discussed are concepts and principles of radiation protection, how they are applied to paediatric imaging and the key factors needed to establish and maintain a radiation safety culture in health care to improve practice – a pillar of radiation protection in medicine.

Those discussions are prefaced by a chapter that describes the types of radiation and sources of medical exposure of children, and provides an overview of the current trends in the utilization of ionizing radiation in paediatric imaging. It presents estimates of radiation doses for paediatric procedures and provides an overview of known and potential risks associated with radiation exposure during childhood.

Good medical practice encompasses effective communication about benefits and risks of health interventions. In this context, radiation risk communication is an essential component of good practice in medical imaging and has a key role to inform the appropriate risk–benefit dialogue between health professionals as well as with children, their families or caregivers.



# Chapter 1: Scientific background

The medical use of ionizing radiation has expanded worldwide. Advanced imaging technology has opened new horizons to diagnostics and improved patient care. This demands policies that recognize and maximize the multiple health benefits that can be obtained, and at the same time address and minimize potential health risks. This section includes scientific information about radiation that may be helpful to support risk–benefit dialogue in paediatric imaging.

**Section 1.1** describes the types of radiation and sources of exposure, and provides an overview of the current trends in the utilization of ionizing radiation in medical imaging.

**Section 1.2** presents the radiation doses in paediatric procedures and provides an overview of known and potential risks associated with radiation exposure during childhood.

# 1. Scientific background

## 1.1 Introduction to radiation and overview of trends in medical imaging

### 1.1.1 Types of radiation and ionizing radiation dose units

Radiation is energy emitted in the form of waves or particles, transmitted through an intervening medium or space. Radiation with enough energy to remove electrons during its interaction with atoms is called “ionizing radiation”. Ionizing radiation is produced by atoms that have an excess of energy. The atoms in radioactive material release this energy (e.g. in the form of gamma rays) as they “decay” (i.e. transform) to a lower energy state. The gamma rays emitted from radioactive tracers (radiopharmaceuticals) administered to patients allow for their distribution in the body to be determined with nuclear medicine imaging equipment. X-rays are another form of ionizing radiation that can be produced artificially in special vacuum tubes. They are used in computed tomography (CT) scanners and other X-ray devices. In contrast, “non-ionizing radiation” is the term given to the type of radiation that has insufficient energy

### Box 1.1 Quantities and units

The *absorbed dose* is the amount of energy deposited in tissues/organs per unit of mass and its unit is the *gray* (Gy). One gray is a very large unit for diagnostic imaging and it is often more practical to talk in terms of *milligrays* (mGy). One gray is equal to one thousand milligrays.

Risks due to exposures to different radiation types can be compared in terms of *equivalent dose*. The equivalent dose is defined for a given type of radiation by using a radiation-dependent weighting factor, which in the case of the X-rays and gamma rays is 1, but may be higher for other types of radiation.

The *effective dose* is the weighted sum of the equivalent dose in a number of tissues/organs, using tissue-specific weighting factors for each of them, primarily reflecting a rough approximation of their relative sensitivity to radiation-induced cancer.

The concept of effective dose was developed as a tool for occupational and public radiation protection. It can be of practical value for comparing doses from different diagnostic examinations and interventional procedures. It also allows for the comparison of doses resulting from different techniques or technologies used for the same medical examination, and/or

doses resulting from similar procedures performed in different facilities. An inherent assumption is that the representative patients for which the effective dose is derived are similar with regard to sex, age and body mass. The effective dose was not intended to give an accurate estimate of the risk of radiation effects for individuals undergoing medical radiation procedures. For individual risk assessment as well as for epidemiological studies, the organ dose (either absorbed or equivalent organ dose) would be a more appropriate quantity.

For medical exposures, the *collective effective dose* is used for comparison of estimated population doses, but it is not intended for predicting the occurrence of health effects. It is obtained by multiplying the mean effective dose for a radiological procedure by the estimated number of procedures in a specific population. The total effective dose from all radiological procedures for the entire population can be used to describe global trends in the medical use of radiation.

The unit of equivalent and effective dose is the *sievert* (Sv). One sievert is a very large unit for diagnostic imaging and it is often more practical to talk in terms of *millisieverts* (mSv). One sievert is equal to one thousand millisieverts. The collective effective dose is measured in *person-sieverts* (person-Sv).

to remove electrons during its interaction with atoms. Non-ionizing radiation consists of low-energy electric and magnetic fields. Examples include radio waves, microwaves, infrared, ultraviolet and visible light. Ultrasonography imaging systems utilize sound waves to generate images of tissues and organs, and magnetic resonance imaging (MRI) scanners utilize strong magnetic fields and radio waves to produce images of internal body structures. Unless noted otherwise, the term radiation in this document refers to ionizing radiation.

The radiation dose is the amount of energy absorbed per unit mass in the exposed tissues and organs. Some basic understanding of the quantities and units of radiation may help to better communicate with colleagues or patients (see **Box 1.1**). There are specific terms and units to express the amount of radioactive material used in nuclear medicine proce-

## Box 1.2 How to express an amount of radioactive material

The *becquerel* (Bq) is the unit of radioactivity used in the International System of Units. In nuclear medicine it is used to express the amount of radioactivity administered to a patient. One Bq is an extremely small amount of radioactive material: it corresponds to one radioactive disintegration per second. The *curie* (Ci) is a unit of radioactivity used in the past. One Ci

is a quite large amount of radioactive material: it corresponds to  $3.7 \times 10^{10}$  (37 billion) radioactive disintegrations per second<sup>a</sup>. Today, the unit Ci is hardly ever used worldwide but it is still useful for comparison purposes. Some examples are provided below.

International System of Units (ISU)	Equivalence with ISU	Disintegrations per second
1 terabecquerel (TBq)	27 curie (Ci)	1 000 000 000 000
1 gigabecquerel (GBq)	27 millicurie (mCi)	1 000 000 000
1 megabecquerel (MBq)	27 microcurie (μCi)	1 000 000
1 kilobecquerel (kBq)	27 nanocurie (nCi)	1000
1 becquerel (Bq)	27 picocurie (pCi)	1
37 gigabecquerel (GBq)	1 curie (Ci)	37 000 000 000
37 megabecquerel (MBq)	1 millicurie (mCi)	37 000 000
37 kilobecquerel (kBq)	1 microcurie (μCi)	37 000
37 becquerel (Bq)	1 nanocurie (nCi)	37
0.037 becquerel (Bq)	1 picocurie (pCi)	0.037

Examples of levels of natural radioactivity in the daily life are provided below:

Natural Radioactivity in Food			Typical Amount of Natural Radioactivity in the Body <sup>b</sup>	
Food	<sup>40</sup> K (Potassium)	<sup>226</sup> Ra (Radium)	Nuclide	
Banana	130 Bq/kg	0.037 Bq/kg	Uranium	1.1 Bq
Brazil Nuts	207 Bq/kg	37–260 Bq/kg	Thorium	0.11 Bq
Carrot	130 Bq/kg	0.02–0.1 Bq/kg	Potassium	4.4 kBq
White Potato	130 Bq/kg	0.037–0.09 Bq/kg	Radium	1.1 Bq
Beer	15 Bq/kg	NA	Carbon	3.7 kBq
Red Meat	110 Bq/kg	0.02 Bq/kg	Tritium	23 Bq
raw	170 Bq/kg	0.07–0.2 Bq/kg	Polonium	37 Bq

<sup>a</sup> Although the use of the International System of Units is encouraged, the Ci and its related units have been included in this information box because they are still used occasionally in the medical community to refer to the amount of radioactivity administered during nuclear medicine procedures.

<sup>b</sup> The typical amount of disintegrations per second (DPS) in the human body from naturally occurring radioactivity is approximately 7400 DPS.

dures (see **Box 1.2**). Terms used in this document with specific meanings are explained in this chapter (see **Box 1.3**). **Annexes A to C** provide additional information: definitions of acronyms and abbreviations (**Annex A**), glossary (**Annex B**) and links to organizations with information about imaging medicine practices and guidance (**Annex C**)

### 1.1.2 Sources of radiation exposure

Exposure to small doses of radiation is a natural and constant part of our environment. Human beings are exposed to cosmic radiation from outer space including the sun as well as to naturally occurring radioactive materials found in the soil, water, air, food and in the body. Machine-produced radiation in the form of X-rays was developed in the late 1800s. The experimental work of Roentgen demonstrated that X-rays are capable of imaging the skeleton on a photographic plate. A rapid expansion of the applications of radiation in medicine, industry, agriculture and research took place during the twentieth century. The testing of nuclear weapons, routine discharges from industrial facilities and industrial accidents have added human-made radioactivity to the environment. However, the use of radiation in medicine is the largest human-made source of radiation exposure today (UNSCEAR, 2010).

The average annual radiation exposure from all sources for the world population is approximately 3 mSv/year per person. On average, 80% (2.4 mSv) of the annual dose that a person receives from all sources is due to radon and other naturally-occurring radiation sources (natural background radiation), 19.7% (0.6 mSv) is due to the medical use of radiation and the remaining 0.3% (around 0.01 mSv) is due to other sources of human-made radiation (**Fig. 1**). There can be large variability in the dose received by individual members of the population depending on where they live. For example, natural background radiation levels vary due to geological differences and, in certain areas, they can be more than 10 times higher than the global average. In the United States of America in 2006, radiation exposure from medical imaging replaced naturally-occurring sources as the largest contributor to human exposure for the first time in history (**Fig. 2**). **Fig. 3** shows the growth in medical-related exposure in the USA population from 1987 and 2006. Annual average radiation doses and typical ranges of individual doses are presented in **Table 1**. **Fig. 4** shows the variation in the contribution of medical exposure to the annual average radiation dose per person in countries with similar health care levels.

## Box 1.3 Definitions of some common terms used in this document

*Health risk* is the probability of a health effect occurring under defined circumstances or exposure to a certain hazard. Unless otherwise stated, the term *risk* is generically used in this document to refer to radiation risks without distinction between known/recognized risks (e.g. high-dose procedures) and potential/assumed risks (e.g. low-dose procedures, which represent the majority of diagnostic imaging procedures). The implicit assumption is that uncertainty may not always be stated.

Unless otherwise stated, the term *radiation* is used in this document to refer to ionizing radiation.

In the context of this document the term *dose* is used to refer to radiation dose estimates for a number of typical diagnostic

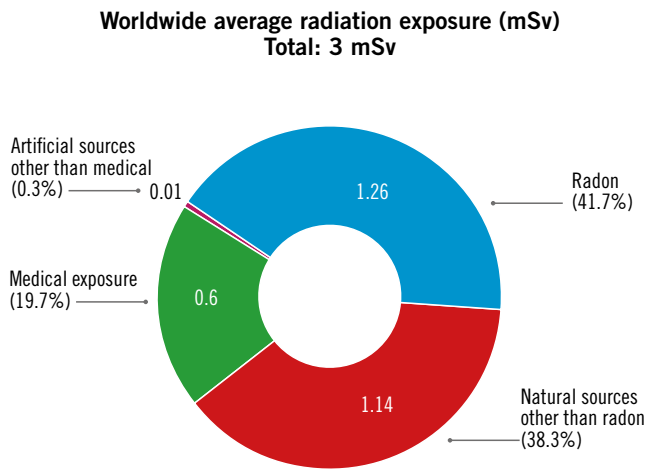
medical procedures. These are only typical values rather than accurate radiation dosimetry data.

Unless otherwise stated, the term *family* is used in this document to refer to parents and other family members who act as caregivers for a child, and would be potentially involved in risk–benefit discussions about the use of radiation in paediatric imaging.

Unless otherwise specified, the term *procedure* is generically used in this document to refer to either diagnostic examination or an image-guided intervention.

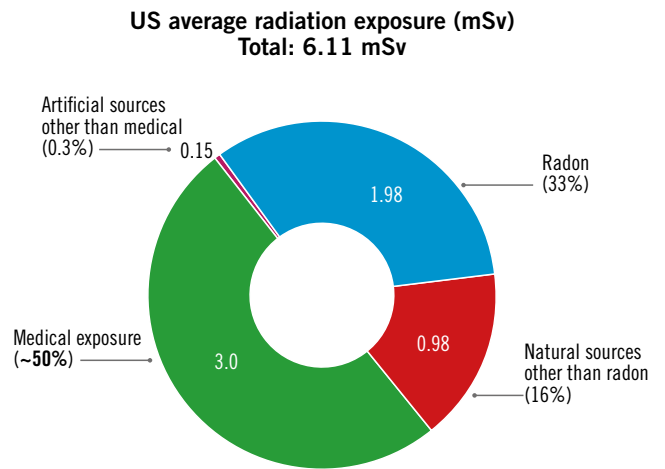
Additional terms are defined in the glossary (Annex B).

**Figure 1:** Distribution of average annual radiation exposure for the world population



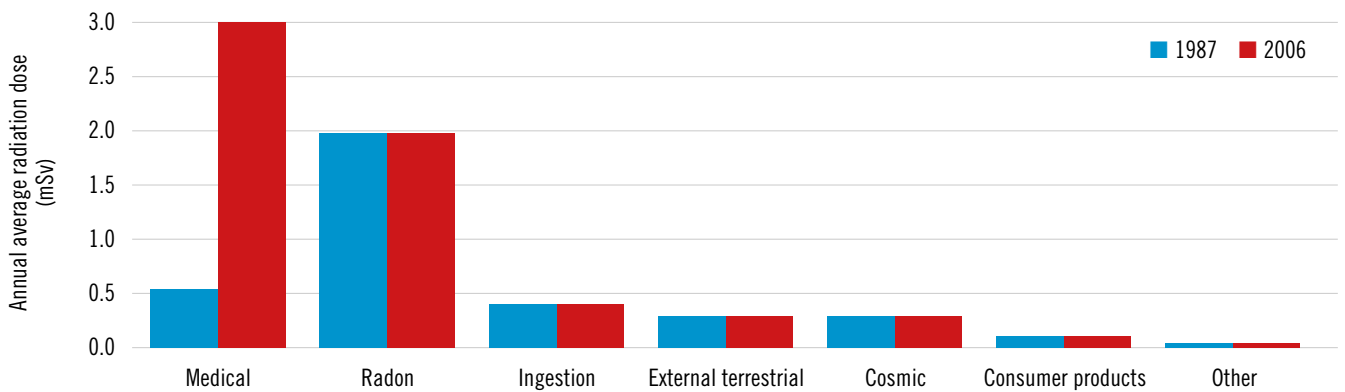
Source: Adapted, with permission, from UNSCEAR (2010)

**Figure 2:** Average annual radiation exposure for the USA population presented in the same way as Fig. 1 for comparison purposes



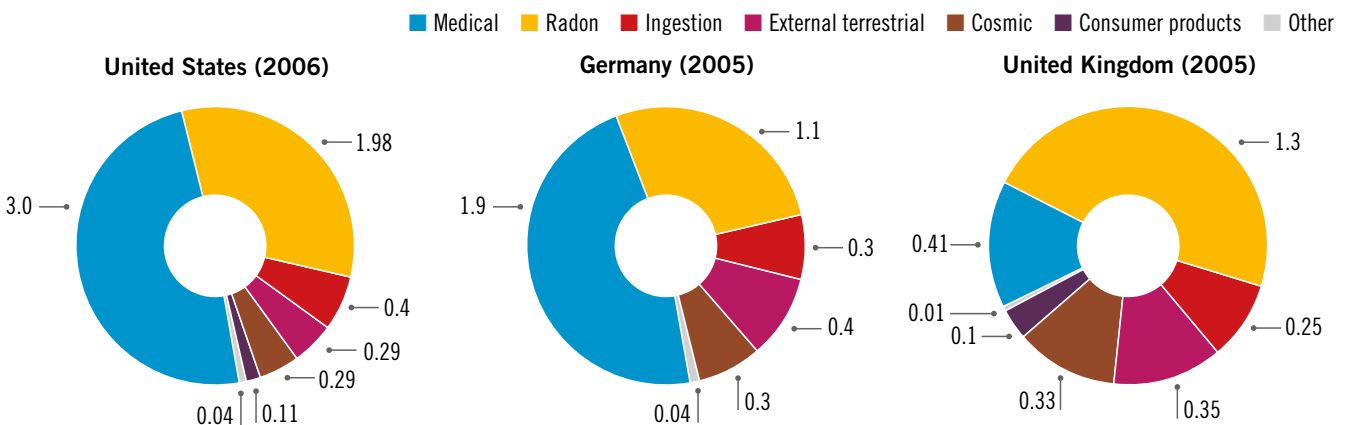
Source: Adapted, with permission, from NCRP (2009)

**Figure 3:** Annual average radiation dose per person (mSv) in the USA population: note the rise in exposure due to medical imaging over the years



Source: Adapted, with permission, from NCRP (2009)

**Figure 4** Variation in the contribution of medical exposure to the annual average radiation dose per person in countries with similar health care level



Source: Adapted, with permission, from UNSCEAR (2010)

**Table 1.** Annual average radiation doses and ranges per person worldwide

Source or mode	Annual average doses worldwide and their typical ranges (mSv <sup>a</sup> )
<b>Natural sources of exposure</b>	
Inhalation (radon gas)	1.26 (0.2–10) <sup>b</sup>
Ingestion (food and drinking water)	0.29 (0.2–1)
External terrestrial	0.48 (0.3–1) <sup>c</sup>
Cosmic radiation	0.39 (0.3–1) <sup>d</sup>
<b>Total natural</b>	<b>2.4 (1–13)<sup>e</sup></b>
<b>Human-made sources of exposure</b>	
Medical diagnosis (not therapy)	0.6 (~0–20+)
Others (e.g. nuclear energy and previous nuclear weapons tests)	~0.005
<b>Total artificial</b>	<b>0.6 (~0–20+)</b>
<b>Total</b>	<b>3 (1–20+)</b>

<sup>a</sup> mSv: millisievert, a unit of measurement of effective dose

<sup>b</sup> The dose is much higher in some dwellings

<sup>c</sup> The dose is higher in some locations

<sup>d</sup> The dose increases with altitude

<sup>e</sup> Large population groups receive 10–20 mSv

Source: Adapted, with permission, from UNSCEAR (2010)

### 1.1.3 Radiation exposures from medical imaging today

The growth in the availability and use of medical imaging (especially CT) during the last several decades has saved countless lives and in many cases prevented the need for more invasive procedures and their associated risks. Nevertheless there is a need to optimize medical imaging exams so that individuals (especially children) are not exposed to ionizing radiation needlessly or at higher doses than are necessary to produce an image of adequate diagnostic quality.

From 1991 to 1996 the annual number of diagnostic medical examinations worldwide was about 2.4 billion, and it was estimated that about 250 million of these were performed in children below 15 years of age.<sup>1</sup> The total number of diagnostic medical examinations increased to more than 3.6 billion in the period 1997–2007, with about 350 million examinations performed in children below 15 years of age (UNSCEAR, 2000; UNSCEAR, 2010).

Chest radiograph represents 40% of all imaging procedures performed worldwide. In high- and middle-income countries about 9% of chest radiographs are performed in children (UNSCEAR, 2010). The radiation dose resulting from chest radiography is very low, and this explains why its contribution to the population dose ("collective dose") is relatively low compared with other less-frequent imaging modalities (**Table 2**). In contrast this table shows that CT, with a relative frequency lower than chest radiography (6.3% of all the X-ray examinations), is the main contributor to the collective dose (43.2%).

<sup>1</sup>. While these data have been collected for children up to 15 years of age, UNICEF defines the upper age limit for childhood as 18 years and this concept is adopted for the purpose of this document. The term "neonate" is used to refer to children below 28 days.



Limited data on the frequency of medical diagnostic procedures on children are available and some examples are presented in **Table 3**. Although the frequency varies significantly among countries it is estimated that approximately 3–10% of all radiological procedures are performed in children (UNSCEAR, 2013).

**Table 2.** Global average relative frequency and collective dose of various types of diagnostic X-ray procedures (all ages, both sexes)<sup>a</sup>

X-ray examination	Relative frequency (%)	Collective dose (%)
Chest examinations (PA, lateral, others)	40	13.3
Limb and joint	8.4	< 1
Skull	3.2	4.2
Abdomen, pelvis, hip	5.2	4.5
Spine	7.4	4.2
Fluoroscopic studies of the gastrointestinal tract	4.8	14.5
Mammography	3.6	< 1
Computed tomography	<b>6.3<sup>b</sup></b>	<b>43.2<sup>b</sup></b>
Angiography and fluoroscopy-guided interventional procedures	< 1	6.1
Other X-ray medical imaging procedures	3	11
Dental procedures <sup>c</sup>	13	< 1

<sup>a</sup> Typical procedures and doses for paediatric patients are presented in **Table 3**

<sup>b</sup> These numbers are written in bold to highlight the fact that a radiological medical procedure (CT) that represents only 6% of all X-ray examinations, contributes to 43% of the global collective dose

<sup>c</sup> Although this does not include global data on frequency of dental cone-beam CT, this percentage would not change significantly by its inclusion

Source: Table based on data from UNSCEAR (2010); used with permission

**Table 3.** Radiological procedures performed in children (0–15 years) in health-care level I countries<sup>a</sup>

Regions examined	Percentage of all the examinations of this type in each of these anatomical regions that are performed in children < 15 years
<b>Radiography</b>	
Head/skull	19%
Extremities	15%
Abdomen	13%
Spine AP (cervical, thoracic or lumbar)	7–12%
Chest (PA and lateral)	9–12%
Pelvis/hips	9%
Other radiographic procedures	3–9%
<b>CT Scans</b>	
CT head	8%
CT abdomen	4%
CT thorax	5%
CT spine	3%

<sup>a</sup> UNSCEAR (2010) defined health-care level I countries as those in which there was at least one physician for every 1 000 people in the general population.

Source: Adapted, with permission, from UNSCEAR (2013)

The use of cone-beam CT (CBCT) in dentistry is a relatively new practice. CBCT results in substantially higher doses compared to other dental X-ray exams. The clinical indication (justification), optimization, quality assurance, and training on CBCT in dentistry are of increasing concern (NCRP, 2003; European Commission, 2004, 2012).

Fluoroscopy remains an important imaging procedure in paediatric patients. Fluoroscopic studies in children may be used for the evaluation of bladder/urethra (voiding cystourethrograms, VCUG), upper gastrointestinal tract (contrast swallows and follow through), and lower gastrointestinal tract (contrast enemas). In addition to diagnostic imaging, fluoroscopy is being increasingly used to guide paediatric interventional procedures in the field of cardiology and gastroenterology, as well as for neurovascular, orthopaedic and surgical image-guided procedures. Fluoroscopy-guided interventional procedures may result in greater radiation exposure to patients and staff than associated with typical diagnostic imaging, but do not entail many of the substantial risks inherent in complex paediatric surgical procedures. The dose will depend on the type of procedure, equipment and operator practice (Tsapaki et al., 2009).

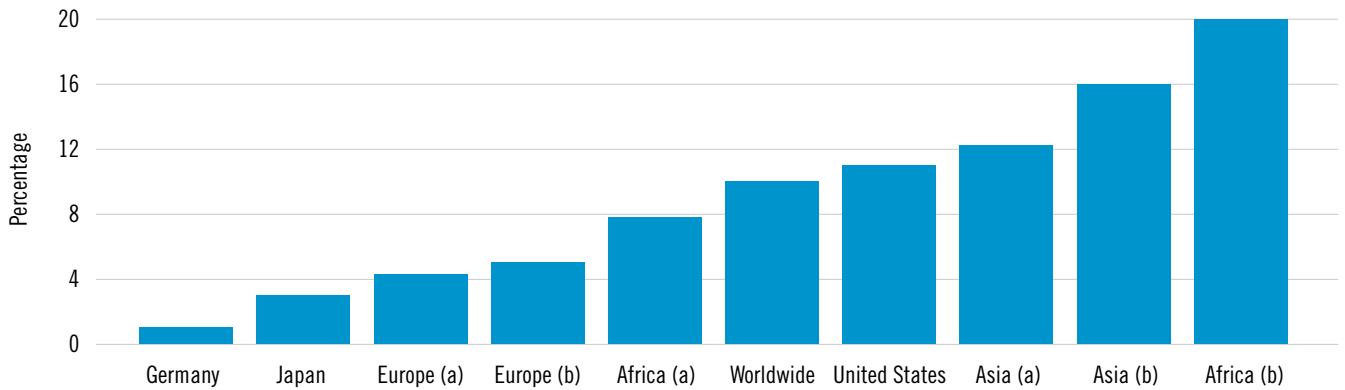
CT represented about 6% of all medical imaging procedures performed worldwide between 1997 and 2006, and accounted for the 43% of the total dose resulting from those procedures. The contribution of CT to the collective dose in 1991–1996 was 34% (UNSCEAR, 2010). Even though modern CT equipment has reduced radiation dose dramatically, CT is today a major source of medical radiation exposure in children and adults. Head scans are the most common CT examination performed in children, representing 8% of the total number of CTs performed in high- and middle-income countries (UNSCEAR, 2010). Even though, when indicated, ultrasonography and MRI are preferred imaging modalities in the paediatric population because they do not involve exposure to ionizing radiation, CT remains the imaging modality with the highest increase in utilization due to its widespread availability and rapid image acquisition (Broder et al., 2007; Shenoy-Bhangle, Nimkin & Gee, 2010).

- Over 10% of CT examinations in the world are performed on patients under 18 years of age (UNSCEAR, 2010).
- Although the total number of CT scans in the world is unknown, there are available data of the frequency of CT scans in the three countries where this modality is most used, which indicate that more than 100 million CT examinations are performed annually in the world.
- About 3% of all CT scans done annually in Japan are performed in children (UNSCEAR, 2010).
- About 11% of all CT scans in the USA are performed in children (UNSCEAR, 2010).
- The percentage of paediatric CT examinations in Germany during the period 2005–2006 was in the order of 1% (Galanski, Nagel & Stamm, 2006).
- Data from 101 facilities in 19 developing countries of Africa, Asia and Eastern Europe found that, on average, the frequency of paediatric CT examinations was 20, 16 and 5% of all CT examinations, respectively (Muhogora et al., 2010). A more recent study on CT frequency in 40 countries also found the lowest frequency of paediatric CT examinations in European facilities. According to this study, head CT accounts for nearly 75% of all paediatric CT examinations (Vassileva et al., 2012).

**Fig. 5** summarizes the trends in the use of paediatric CT in different regions of the world, as described above.

The population age distribution in different countries and regions might impact the number of exams done in children. **Fig. 6** shows the population age distribution in Japan, the United

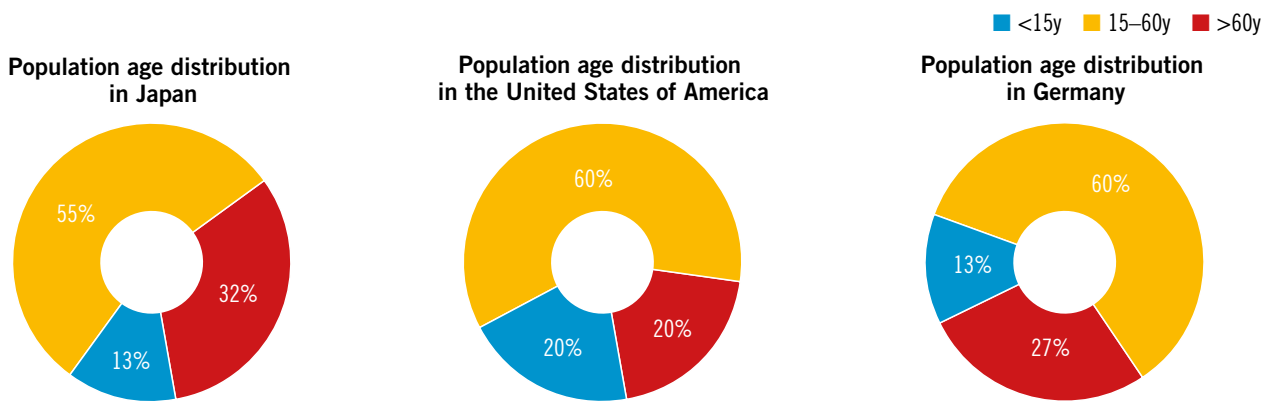
**Figure 5:** Percentage of the total CT scans which are performed in children in different regions of the world<sup>a</sup>



<sup>a</sup> Different data from Europe, Africa and Asia are shown: (a) from Vassileva et al. (2012) and (b) from Muhogora et al. (2010)

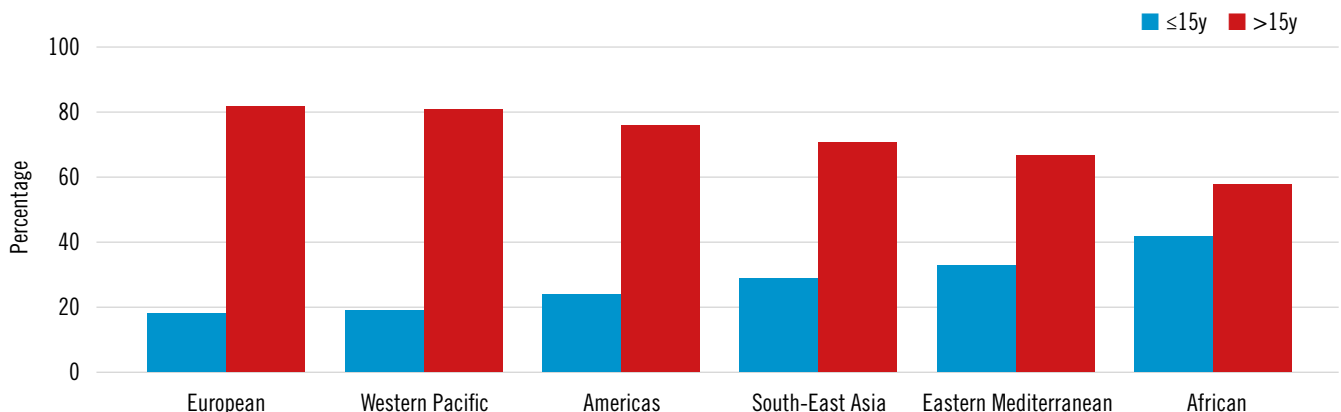
Source: Based on data published in (UNSCEAR, 2010). (Galanski, Nagel & Stamm, 2006). Vassileva et al. (2012) and Muhogora et al. (2010)

**Figure 6:** Population age distribution in the three countries where CT scans are most used



Source: WHO (2015a)

**Figure 7:** Percentage of population below 15 years of age, compared with the rest of the population in the six WHO regions



Source: Adapted from WHO (2015a)

States and Germany, three countries where CT scans are most used. **Fig. 7** shows the percentage of the population below 15 years of age, compared with the rest of the population in the six WHO regions: African, the Americas, the Eastern Mediterranean, European, South-East Asia and the Western Pacific.

Paediatric nuclear medicine provides important information to assist in the diagnosis, staging, treatment and follow-up of a variety of paediatric diseases. Its non-invasive nature makes it useful for the evaluation of children (Fahey, Treves & Adelstein, 2011). Overall, the total number of diagnostic nuclear medicine scans remained rather stable during the past two decades (32.5 million per year in 1991–1996 and 32.7 million per year in 1997–2007), these numbers being much lower than the annual frequency of medical diagnostic procedures using X-rays (UNSCEAR, 2010). Patients' doses are higher for positron emission tomography (PET) and PET/CT scans, a nuclear medicine imaging modality that provides functional and anatomical information most commonly used for the evaluation and monitoring of malignancies (Accorsi et al., 2010). However, the availability of PET and PET/CT is still limited in many countries. The geographical distribution of nuclear medicine procedures is quite uneven, with 90% of examinations occurring in industrialized countries (UNSCEAR, 2010).

## 1.2 Radiation doses and risks in paediatric procedures

### 1.2.1 Radiation doses for paediatric procedures

Estimating individual patient risk entails further understanding of individual organ dose with organ-specific risk coefficients adjusted for both patient age and sex. Radiation doses in diagnostic imaging are often presented in terms of "effective doses". As discussed in Box 1.1 (Chapter 1), effective dose is not appropriate for quantifying individual patient risk from the radiation dose of a particular medical imaging procedure. Only if the patient populations are similar (with regard to both age and sex) can effective doses be of potential practical value for comparing relative examination doses.

CT use has undergone explosive growth in the past decade, constituting the paediatric imaging modality with the highest utilization increase. CT scans confer radiation doses far larger than chest X-rays (Table 4), but it has to be noted that the information they provide is considerably greater. While the frequency of CT scans in children has gone up, the improved technology has decreased substantially the radiation doses per procedure. Today, by using the latest generation CT scanners to perform an abdominal CT, it is possible to deliver a dose lower than that of a conventional X-ray. However, the dose varies substantially between old and modern technology and techniques (Larson et al., 2015).

Nuclear medicine examinations require the administration of small quantities of radioactivity in radiopharmaceuticals administered either by inhalation, ingestion or injection. Such examinations are performed in children, however much less frequently than in adults. For selected radionuclides, the dose per unit activity can be tenfold higher for infants compared to adults (UNSCEAR, 2013). A wide variety of radiopharmaceuticals used in nuclear medicine distribute quite differently in the body. The spectrum of nuclear medicine examinations performed on children is different from that performed on adults. In children, studies of the kidney and skeleton predominate. Organ doses per unit-administered radioactivity are often higher in children; however, in practice, this can (and should) be offset by the use of lower

**Table 4.** Typical effective doses for diagnostic imaging examinations and their equivalence in terms of number of chest X-rays and duration of exposure to natural background radiation<sup>a</sup>

Diagnostic procedure	Equivalent number of chest X-rays	Equivalent period of exposure to natural radiation <sup>b</sup>	Typical effective dose (mSv)
<b>Chest X-ray (single PA film)</b>			
Adult	1	3 days	0.02 <sup>c</sup>
5-year-old	1	3 days	0.02 <sup>c</sup>
<b>CT head</b>			
Adult	100	10 months	2 <sup>c</sup>
Newborne	200	2.5 years	6
1-year-old	185	1.5 years	3.7
5-year-old	100	10 months	2 <sup>d</sup>
10-year-old	110	11 months	2.2
Paediatric head CT angiography <sup>f</sup>	250	2 years	5
<b>CT chest</b>			
Adult	350	3 years	7 <sup>c</sup>
Newborn <sup>g</sup>	85	8.6 months	1.7
1-year-old	90	9 months	1.8
5-year-old	150	1.2 years	3 <sup>d</sup>
10-year-old	175	1.4 years	3.5
<b>CT abdomen</b>			
Adult	350	3 years	7 <sup>c</sup>
Newborn	265	2.2 years	5.3
1-year-old	210	1.8 years	4.2
5-year-old	185	1.5 years	3.7
10-year-old	185	1.5 years	3.7
<b>Nuclear medicine examinations (5-year-old)</b>			
FDG PET CT	765	6.4 years	15.3 <sup>f</sup>
Tc-99m cystogram	9	1 month	0.18 <sup>f</sup>
Tc-99m bone scan	300	2.5 years	6 <sup>f</sup>
<b>Dental examinations</b>			
Intra-oral radiography	0.25	< 1 day	0.005 <sup>c</sup>
Panoramic (dental)	0.5	1.5 days	0.01 <sup>c</sup>
Craniofacial cone-beam CT	< 50	< 5 months	< 1h
<b>Fluoroscopy-guided paediatric interventional cardiology</b>	300 (range from 50 to 1850)	2.5 years (range from 5 months to 15 years)	Median 6 (range 1–37) <sup>i</sup>
<b>Fluoroscopic cystogram (5-year-old)</b>	16	1.7 months	0.33 <sup>j</sup>

<sup>a</sup> Paediatric CT effective doses based on data provided in Table B17 “Summary of patient dose data for paediatric CT examinations” (UNSCEAR, 2010) except for those explicitly indicated with a different source.

<sup>b</sup> Based on a worldwide average of 2.4 mSv/year

<sup>c</sup> Mettler et al. (2008)

<sup>d</sup> From the Image Gently website (<http://www.imagegently.org/>)

<sup>e</sup> Rather than actual age, this refers to phantoms equivalent to a reference child of typical physical dimensions for that age

<sup>f</sup> Johnson et al. (2014)

<sup>g</sup> Rather than actual age, this refers to phantoms equivalent to a reference child of typical physical dimensions for that age

<sup>h</sup> European Commission (2012)

<sup>i</sup> Bacher et al. (2005)

<sup>j</sup> Brody et al. (2007)

administered doses (UNSCEAR, 2013; Lassmann et al., 2014). Recently, Internet-based calculators have been made to make the recommended reductions in the administered dose for paediatric patients more accessible.<sup>2</sup>

In the discussion of diagnostic procedure radiation doses, comparison to more familiar radiation exposures (such as chest X-rays or natural background radiation) has been suggested to facilitate comprehension of the dose. **Table 4** depicts such comparative radiation doses for several paediatric diagnostic-imaging procedures. However, these comparisons may have some caveats. The dose delivered during a chest X-ray is so low that using it as denominator to calculate the equivalent number of chest X-rays comparable with the level of dose of any other radiological procedure may be misleading and may unnecessarily alarm patients and parents. The concept of natural background radiation is not necessarily familiar to patients and parents or even health-care providers, so the comparison between the dose associated to a radiological medical procedure and the equivalent period of exposure to natural radiation may not be understandable. An additional potentially misleading feature of comparing patient radiation doses to equivalent natural background exposures is that background radiation involves whole body exposure whereas diagnostic radiation exposures more often have regional (more localized) exposures.

### **1.2.2 Radiation risks of medical imaging: health effects of radiation exposure**

Energy absorbed in tissues and organs exposed to radiation may induce two different types of effects. At doses much higher than that of typical diagnostic imaging exams, radiation can induce cell death. The damage may be extensive enough to affect tissue functions and become clinically observable (e.g. skin redness, hair loss, cataract). Effects of this type are called "tissue reactions or deterministic effects" and will occur only if the radiation dose exceeds a certain threshold (ICRP, 2012).

Despite robust DNA repair mechanisms within the body, radiation exposure can also induce non-lethal transformation of cells. The transformed cells that are not removed may become malignant after a long latency period (several years to decades). Effects of this nature are termed "stochastic effects". For the purpose of radiation protection, it is assumed that a linear relationship may exist between exposure and cancer risk, with no threshold value below which this risk is zero. Based on this linear non-threshold (LNT) model, the probability of developing cancer is presumed to increase with radiation dose even for low dose medical imaging procedures (Brenner et al., 2001; Brenner, 2002; Brenner et al., 2003; Brenner & Hall, 2007; Chodick et al., 2007; Johnson et al., 2014).

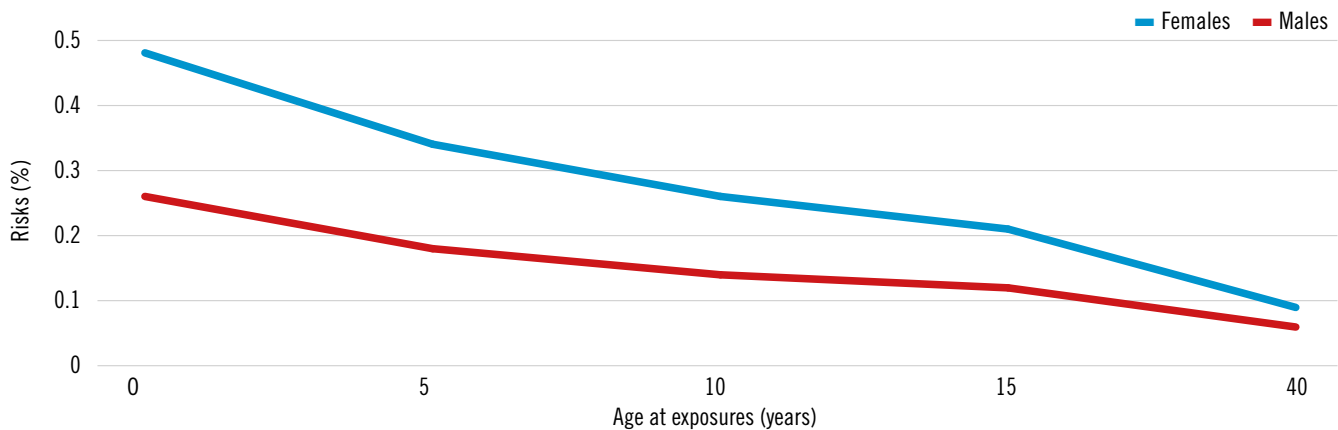
The risk of developing cancer from low-level radiation such as with diagnostic imaging procedures is not known with certainty. While a risk estimate from such examinations can be calculated using the assumptions previously mentioned, at present it is not known if such estimates are correct. The risk may be very small and it is also possible that it may be lower than estimated. While this qualification will be made at times in this document, the implicit assumption is that there is uncertainty, although this may not always be stated. In the absence of certainty in this regard, a precautionary approach is taken to assure that the radiation dose used to perform the procedure does not exceed the dose necessary to produce an image of adequate diagnostic quality.

Some epidemiological studies suggest that exposure to ionizing radiation increases the risks of some cancers at organ dose ranges of approximately 50–100 mSv (Pearce et al., 2012;

<sup>2</sup>. <http://www.snmmi.org/ClinicalPractice/PediatricTool.aspx>



**Figure 8:** Lifetime attributable risk of cancer incidence as a function of sex and age at exposure for a single whole-body dose of 10 mSv, based on estimates for the USA population



Source: BEIR (2006)

Matthews et al., 2013; Miglioretti et al., 2013; Boice Jr, 2015). This is a dose range which can be achieved after several CT scans. Given the current state of knowledge, and despite the uncertainties regarding the risks associated with multiple exposures/cumulative doses, even the low-level of radiation dose used in paediatric diagnostic imaging may result in a small increase in the risk of developing cancer in the future (UNSCEAR, 2008; UNSCEAR, 2013).

The radiation dose delivered during diagnostic procedures should not cause deterministic effects.<sup>3</sup> However, image-guided interventional procedures may deliver doses high enough to cause deterministic effects such as skin injuries in some patients, principally adults and large-size adolescents. Stochastic risks are of special concern in paediatric imaging since children are more vulnerable than adults to the development of certain cancer types, and have longer lifespans to develop long-term radiation-induced health effects like cancer.

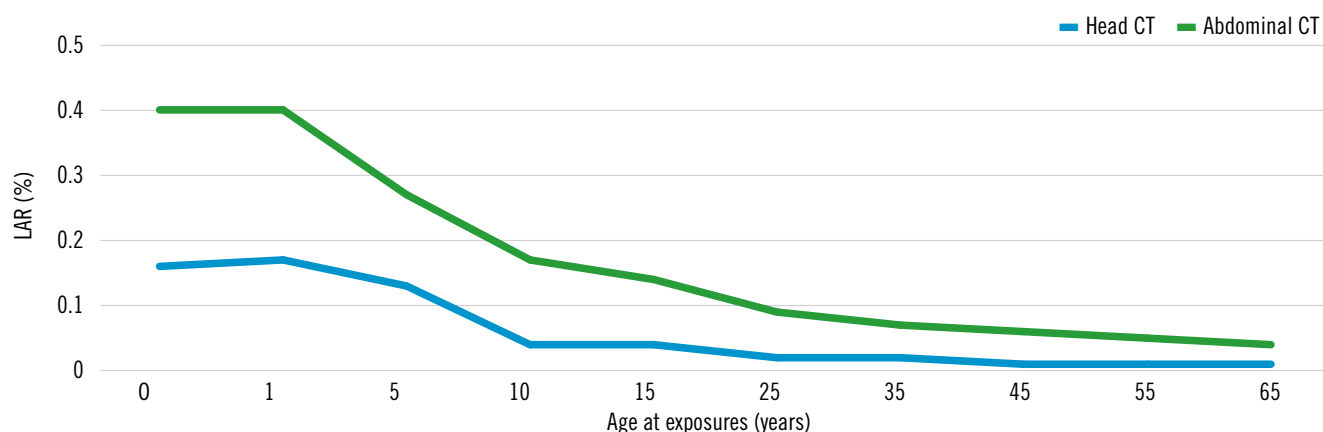
Everybody has a chance of having a cancer (incidence) and/or dying from cancer (mortality) over the course of her/his lifetime. This is the so-called “lifetime baseline risk” (LBR). The additional risk of premature incidence or mortality from a cancer attributable to radiation exposure is called the “lifetime attributable risk” (LAR). The LAR is an age- and sex-dependent risk quantity calculated by using risk models derived from epidemiological studies (UNSCEAR, 2008; BEIR, 2006; UNSCEAR, 2013).

**Fig. 8** presents the LAR of cancer incidence as a function of sex and age at exposure, for a single whole-body dose of 10 mSv, based on estimates for the United States population (BEIR, 2006). This figure illustrates that cancer risk from radiation exposure is higher in children compared to adults, with infants at the greatest risk. It also shows that cancer risk associated with radiation exposure is lower in males compared with females. The numbers on the y-axis might be better understood by explaining that a LAR of 0.2% means a risk of 2 in 1000, which is equal to a risk of 1 in 500 children.

The whole-body dose of 10 mSv used in **Fig. 8** was arbitrarily chosen as an example to present age- and sex-specific LAR values. This level of dose is substantially higher than the typical

<sup>3</sup>. This excludes unintended/accidental overexposures

**Figure 9:** Sex-averaged lifetime attributable risk of cancer incidence associated with radiation exposure during head and abdominal CT, as a function of the age at exposure



effective doses for diagnostic imaging procedures (see **Table 4**). Moreover, when referring to radiation risks associated with medical exposures, the organ dose (rather than the effective dose) is a more appropriate quantity to measure. **Fig. 9** shows the sex-averaged LAR values for cancer incidence associated with head CT and abdominal CT performed at different ages, based on typical organ dose estimates for 16 different organs<sup>4</sup> (Bushberg JT, University of California, Davis School of Medicine, Sacramento, USA, Personal communication 15 December 2015). Assuming the LNT model described above, and keeping in mind the uncertainty on risk estimates from low-dose radiation exposure, the practical value of this figure would be for comparing risks from these two different examinations with regard to the age at exposure. The lifetime risk presented in **Fig. 9** should be compared with the high LBR for cancer incidence (i.e. more than 1 in 3<sup>5</sup>), and the substantial benefits provided by a medically necessary CT scan. Nevertheless, the public health issue at hand concerns the increasingly large paediatric population being exposed to these small risks (Brody et al., 2007; UNSCEAR, 2013).

The numbers presented in **Fig. 9** may be explained by using a quantitative approach (e.g. a LAR of 0.1% means that the risk is equal to 1 in 1000). It may be easier to explain the levels of risk by using a qualitative approach, as illustrated in **Tables 5 to 8**. **Table 5** provides examples of a qualitative approach to explain levels of risk of cancer mortality and **Table 6** refers to risk of cancer incidence. For illustrative purposes, both tables compare the levels of additional risks (presented as LAR) with the LBR for cancer mortality and incidence, respectively.

Recently Johnson et al. calculated the LAR for cancer incidence for some specific radiological procedures in children, using the data from the BEIR VII report for the USA population (Johnson et al., 2014). Some of the results of this study are presented in **Table 7**, in terms of age- and sex-averaged additional cancer incidence risk associated with those procedures,

<sup>4</sup>. The following 16 groups of organ doses were estimated: oral cavity & pharynx, oesophagus, stomach, colon, liver, gall bladder, pancreas, lung, breast, ovary, uterus/prostate, bladder, kidney, nervous system, thyroid and bone marrow. Data compiled from Advanced Laboratory for Radiation Dosimetry Studies, College of Engineering, University of Florida, using ICRP 89 reference phantoms (for more information see <http://www.icrp.org/publication.asp?id=ICRP%20Publication%2089>). Exam protocols determined using current standard CT protocols from University of Florida and Image Gently guidelines. Risk calculated by using the National Cancer Institute's Radiation Risk Assessment Tool (RadRAT).

<sup>5</sup>. For instance, the lifetime baseline risk of cancer incidence in the USA was reported to be 46.3% in males and 37.5% in females; average for both sexes 41.9% (BEIR, 2006)

compared with the LBR of cancer incidence. A qualitative presentation of cancer incidence risk for some common paediatric examinations is proposed in **Table 8** for three different patient ages, taking into account the set of data presented in this section.

### 1.2.3 Susceptibility to ionizing radiation in children: unique considerations

Radiation risk to human health has been the subject of much research and debate. Exposure to low radiation doses such as those delivered to patients during diagnostic procedures may pose a risk, albeit small, of inducing cancer years to decades following the examination (UNSCEAR, 2008). The benefits for patients far outweigh the radiation risks when these procedures are appropriately prescribed and performed.

**Table 5.** Examples of a qualitative approach to communicate different levels of risk of cancer mortality compared with the lifetime baseline risk of cancer mortality

Risk qualification	Approximate level of additional risk of fatal cancer	Probability of fatal cancer in the general population (% LBR) <sup>a</sup>	Probability of fatal cancer in the general population if adding this extra level of risk (% LBR + % LAR)
Negligible	< 1 in 1 000 000	20	20.00
Minimal	Between 1 in 1 000 000 and 1 in 100 000	20	20.00
Very low	Between 1 in 100 000 and 1 in 10 000	20	20.01
Low	Between 1 in 10 000 and 1 in 1 000	20	20.10
Moderate	Between 1 in 1 000 and 1 in 500	20	20.20

<sup>a</sup> The 20% presented in this column is a sex-averaged rounded value of LBR for cancer mortality due to leukaemia and solid cancer based on BEIR VII Table 12-4 (BEIR, 2006)

**Table 6.** Examples of a qualitative approach to communicate different levels of risk of cancer incidence compared with the lifetime baseline risk of cancer incidence

Risk qualification	Approximate level of additional risk of cancer incidence	Probability of developing cancer in the general population (% LBR) <sup>a</sup>	Probability of developing cancer in the general population if adding this extra level of risk (% LBR + % LAR)
Negligible	< 1 in 500 000	42	42.00
Minimal	Between 1 in 500 000 and 1 in 50 000	42	42.00
Very low	Between 1 in 50 000 and 1 in 5 000	42	42.02
Low	Between 1 in 5 000 and 1 in 500	42	42.25
Moderate	Between 1 in 500 and 1 in 250	42	42.50

<sup>a</sup> The 42% presented in this column is a sex-averaged rounded value of LBR for cancer incidence including leukaemia and solid cancer based on BEIR VII Table 12-4 (BEIR, 2006)

**Table 7.** Age- and sex-averaged additional cancer incidence risk associated to radiological procedures in children compared with baseline cancer risk

Risk qualification	Probability of cancer incidence in the general population (% LBR)	Probability of cancer incidence in the general population if adding this extra level of risk (% LBR + % LAR)	Proposed risk qualification
Catheterization intervention	42	42.36	Moderate
Catheterization diagnostic	42	42.25	Low <sup>a</sup>
CT angiography head	42	42.16	Low
CT chest	42	42.15	Low
CT abdomen	42	42.12	Low
CT angiography abdomen	42	42.12	Low
CT pelvis	42	42.10	Low
CT head	42	42.06	Low
Barium swallow oesophagus	42	42.05	Low
Barium enema colon	42	42.04	Low
Perfusion lung scan	42	42.04	Low
Fluoroscopy tube placement	42	42.04	Low
Chest PA and lateral	42	42.00	Negligible

<sup>a</sup> Level of risk between low and moderate needs to consider the patient age in the risk–benefit discussion. PA, posterior anterior

Source: Data for the USA population, adapted from Johnson et al. (2014), with permission

**Table 8.** Proposed qualitative presentation of risk at three different ages for some common paediatric examinations based on data presented in this section

Examination	Age 1 year	Age 5 years	Age 10 years
Dental intra-oral	NA	Negligible	Negligible
Chest X-ray	Negligible	Negligible	Negligible
Head CT	Low	Low	Low
Chest CT	Low	Low	Low
Abdominal CT	Moderate	Low	Low
FDG PET CT	Moderate	Moderate	Moderate

NA, not applicable; FDG, fludeoxyglucose; PET, positron emission tomography

Particular attention has been focused on children as they are often considered to be especially vulnerable to environmental threats. Indeed, for some tumour types, the paediatric population is more sensitive to radiation exposure than adults. This increased sensitivity varies with age, with the younger ages being more at risk (UNSCEAR, 2013). Scientific studies have also shown that radiogenic tumour occurrence in children is more variable than in adults and depends on tumour type, and on the child’s sex and age at exposure. These studies on the differences in radiosensitivity between children and adults have found that children are more sensitive for the development of thyroid, brain, skin and breast cancer and leukaemia (UNSCEAR, 2013). The available data are insufficient for a number of other cancer sites to determine whether or not children are more sensitive to those cancer types (UNSCEAR, 2013).

The Life Span Study of the atomic bomb survivors in Hiroshima and Nagasaki showed an excess of cancer risk higher for people exposed to the bombs at a younger age than those exposed at an older age. The risk is about twice as high after exposure at age 10 than at age 40. Children under 10 are particularly susceptible to radiation (Douple, 2011). The Life Span Study and other studies have also shown that females exposed at young age (< 20 years) are about twice as likely to develop breast cancer later in life as compared with females exposed as adult women. Indeed, children are more likely than adults to develop most kinds of cancer after irradiation, but the disease may not emerge until later in life when they reach an age at which cancers normally become evident (UNSCEAR, 2013).

Certain rare genetic conditions make children more vulnerable to ionizing radiation resulting in hypersensitivity to radiation exposure and higher cancer risks. Although only a small percentage of individuals are “hypersensitive” to radiation, health professionals prescribing or using radiation in children should be aware of these conditions that include, for example, ataxia-telangiectasia, Nijmegen breakage syndrome and Fanconi anemia. Other conditions associated with some degree of radiosensitivity are systemic sclerosis, Behçet disease and Down syndrome. Paediatric cancer patients with a family history of cancers could also be predisposed to radiation-induced second cancers and clinical hyper-radiosensitivity (Bourguignon et al., 2005).

Four major issues should be considered when imaging children:

1. For some radiation-induced cancers, children are more vulnerable than adults; for some others there is not yet sufficient information available (UNSCEAR, 2013). The general perception that children are more vulnerable to radiation exposure than adults is only partly true. The susceptibility of children to radiation-induced cancer has been a focus of interest for over half a century. Recent reviews report that (in general) children might be two or three times more sensitive to radiation than adults.<sup>6</sup>
2. Cancers related to childhood exposure on average result in more years of life lost than those related to exposure in adulthood. Children have a longer life expectancy resulting in a larger window for manifesting long-term radiation-induced health effects.
3. Radiation-induced cancer may have a long latency period that varies with the type of malignancy and the dose received. The latency period for childhood leukaemia is generally less than 5 years, while the latency period for some solid tumours can be measured in decades.
4. When imaging small children and infants, failure to adjust exposure parameters/settings that are used for adults and larger children will result in a higher dose than is necessary (Frush, Donnelly & Rosen, 2003; Frush & Applegate, 2004; Brody et al., 2007). Such unnecessary higher doses (i.e. higher risks) can be substantially reduced without affecting image quality (optimization of protection).

The clinical value of imaging involving the use of radiation for the diagnosis of paediatric illness and injury is unquestionable. Multiple opportunities for radiation dose reduction without any significant loss of diagnostic information do exist. Even if individual radiation risks are quite small, radiation protection in paediatric imaging is a public health issue due to the large paediatric population exposed to those risks.

<sup>6</sup> Although the scientific evidence for late health effects following low-dose radiation exposure relates to the induction of cancer, some studies suggested an increased risk of non-cancer effects such as cardiovascular diseases. Further research is required to confirm the existence of a causal association (ICRP, 2012; UNSCEAR, 2013).



# 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<sup>1</sup>, dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology,<sup>2</sup> 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<sup>3</sup>”). 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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<sup>1</sup>. Including physicians as well as physicians' assistants

<sup>2</sup>. This includes radiographers and other radiological technologists working in diagnostic radiology, interventional radiology and nuclear medicine

<sup>3</sup>. 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 subspecialists, 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,<sup>4</sup> 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).<sup>5</sup>
4. The responsibility of justifying a procedure for a patient<sup>6</sup> falls upon individual professionals directly involved in the health-care delivery process (referrers, RMPs). Imaging

<sup>4</sup> 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)

<sup>5</sup> This is the “generic justification” (level 2)

<sup>6</sup> 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%.

delivering 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

Investigation	Dose	Recommendation (Grade)	Comment
US	None	Indicated [B]	There are many causes of acute abdominal pain. US is a useful first investigation but needs to be guided by clinical findings.
AXR	☠	Specialised investigation [C]	AXR is rarely of value and is best performed under specialist guidance. Generally AXR is not undertaken before US.
CT	☠☠☠	Specialised investigation [D]	Although CT is more sensitive than US for the diagnosis of appendicitis, specificities are similar and the strategy for imaging should take into account radiation dose and clinical features.
MR	None	Indicated only in specific circumstances [B]	Following abdominal US, when TVUS is not feasible, MRI is occasionally helpful for evaluating pelvic masses in girls.

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)**

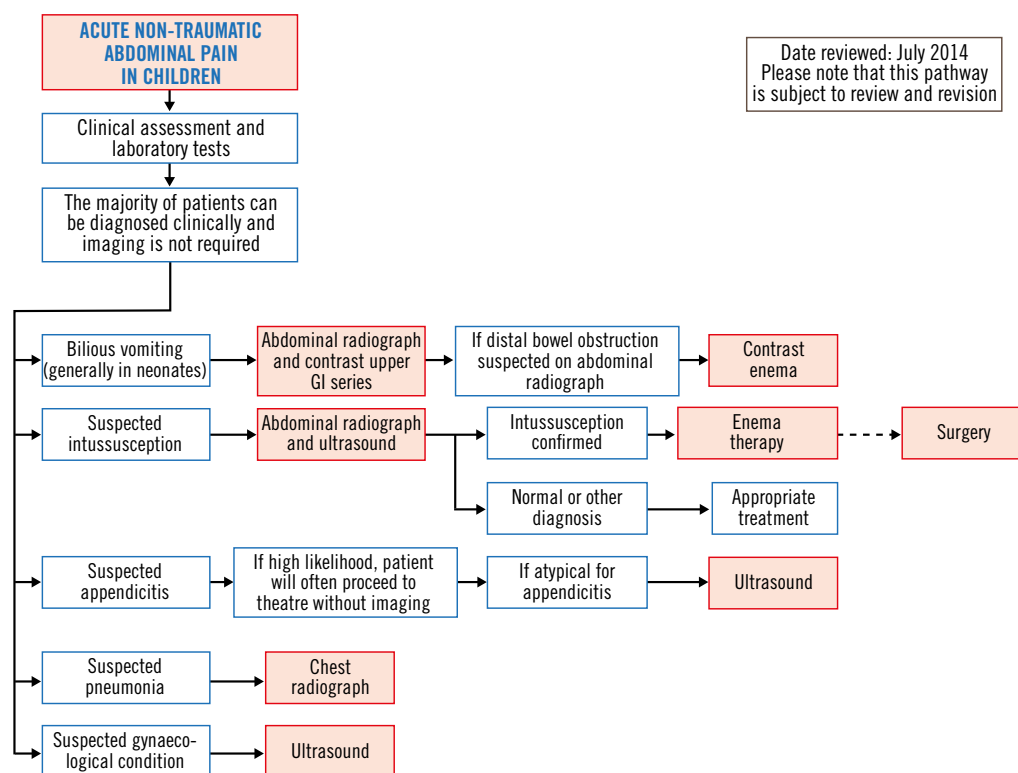
Radiological Procedure	Rating	Comments	RRL*
US abdomen RLQ	8	With graded compression	○
CT abdomen and pelvis with contrast	7	May be useful following negative or equivocal US. Use of oral or rectal contrast depends on institutional preference. Consider limited RLQ CT.	⚠⚠⚠⚠⚠
X-ray abdomen	6	May be useful in excluding free air or obstruction.	⚠⚠
US pelvis	5		○
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".	○
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		○
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<sup>®</sup>,<sup>7</sup> the RCR iRefer: "Making the best use of clinical radiology"<sup>8</sup> and the Western Australian Diagnostic Imaging Pathways<sup>9</sup> 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).

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

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

<sup>9</sup> <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.<sup>10</sup> Monitoring of guideline use may be assessed with clinical audits to enhance compliance.

**Table 9.** Socratic questions<sup>a</sup> 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

<sup>a</sup> 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.

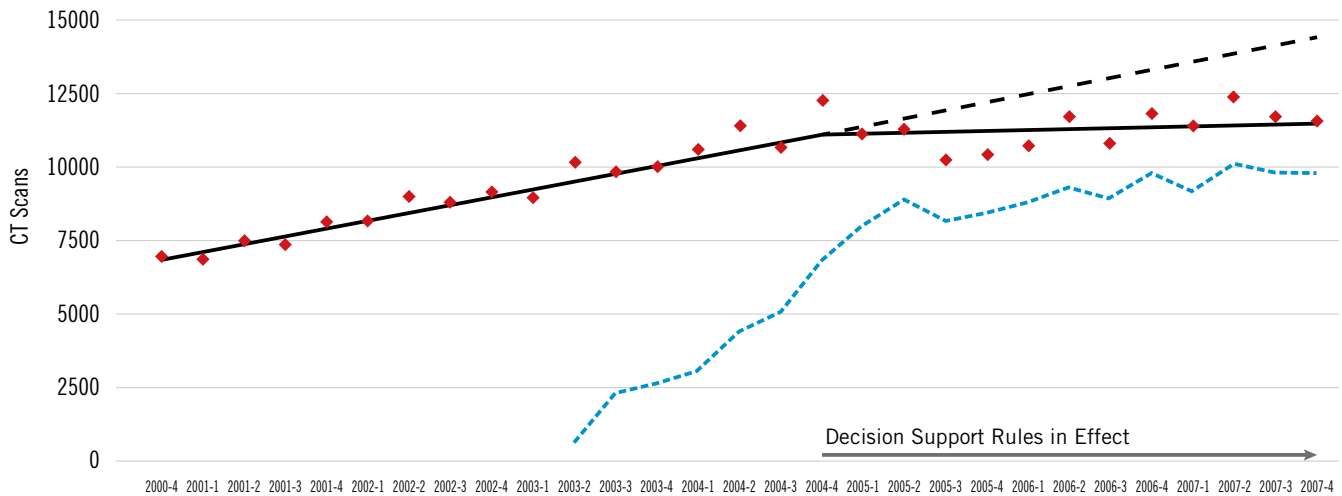
#### 2.1.2.4 Appropriateness and clinical decision support

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

<sup>10</sup>. 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<sup>a</sup>

<sup>a</sup> 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: Siström 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<sup>11</sup> phrase “One size does not fit all”.

<sup>11</sup> 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<sup>12</sup> 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

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<sup>12</sup>. 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,<sup>13</sup> 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.<sup>14</sup> 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

<sup>13</sup>. 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](http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/Radiology.htm)).

<sup>14</sup>. 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

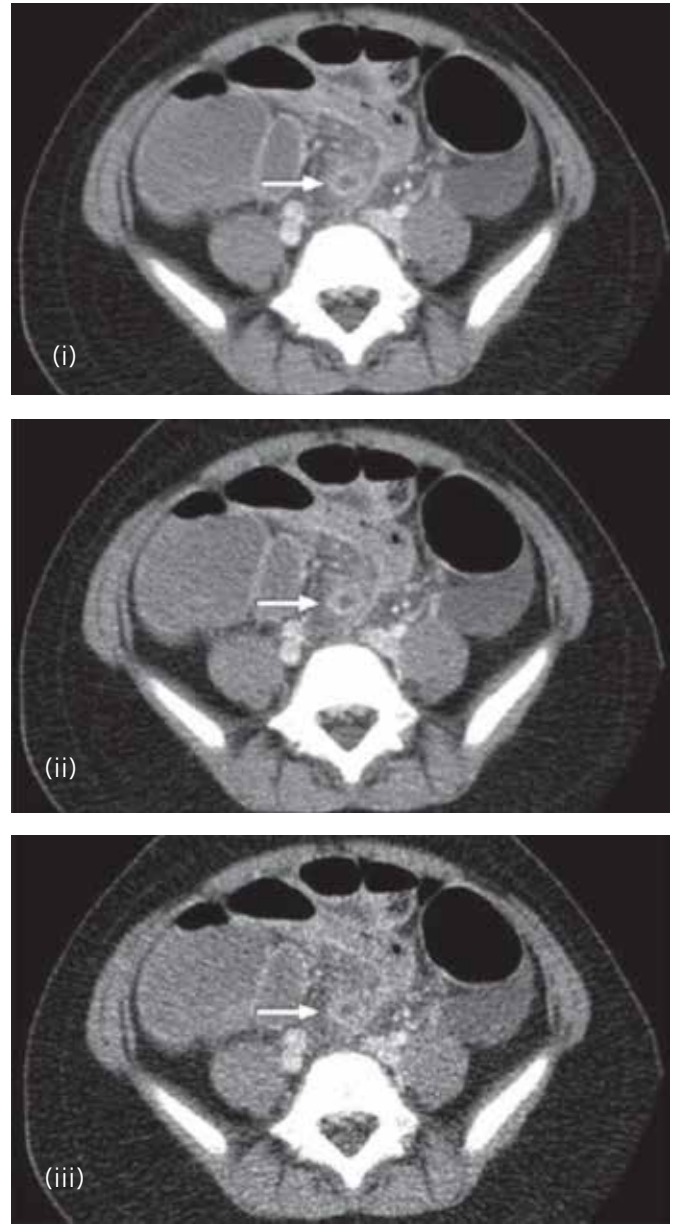
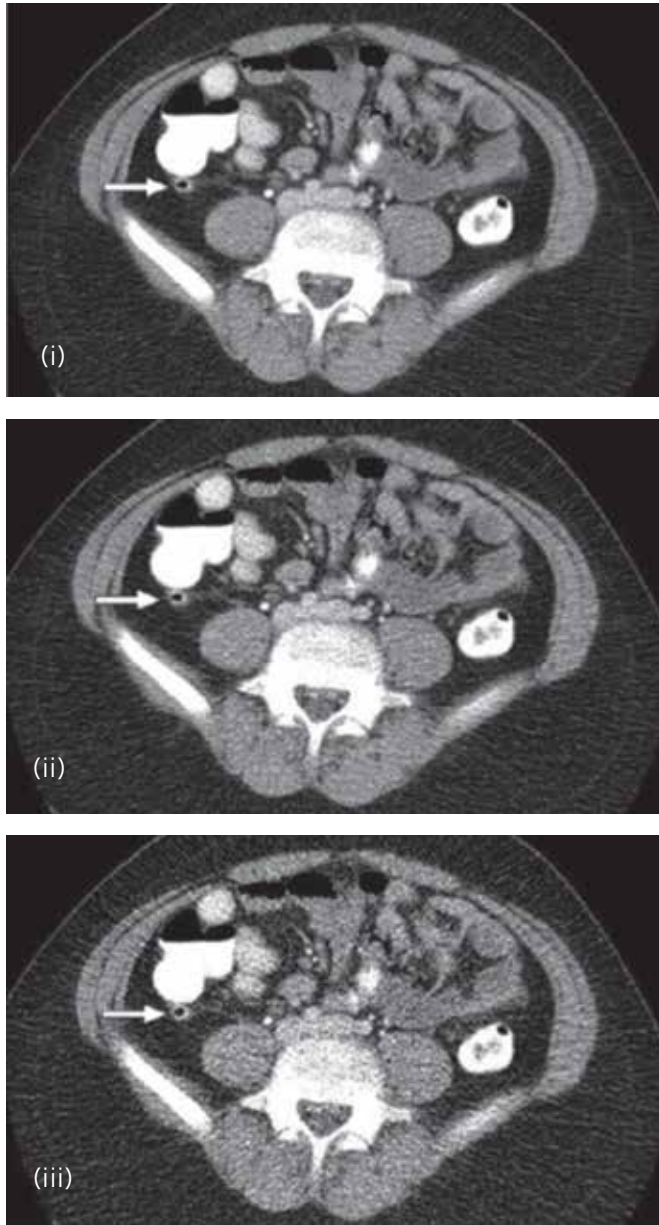
CT Technique	Influence on Radiation Dose
X-ray energy (kilovoltage peak -kVp) <sup>a</sup>	Decreased kVp → decreased dose
Tube current (milliamperes-mA) <sup>a</sup>	Decreased mA → decreased dose
X-ray tube rotation speed (seconds) <sup>a</sup>	Faster tube (gantry) spinning → decreased dose
Scanning 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

<sup>a</sup> 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, Parisi & 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<sup>15</sup> 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

<sup>15</sup>. 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”,<sup>16</sup> 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,<sup>17</sup> 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.

<sup>16</sup>. Available at [http://www.imagegently.org/Portals/6/Parents/Dose\\_Record\\_8.5x11\\_fold.pdf](http://www.imagegently.org/Portals/6/Parents/Dose_Record_8.5x11_fold.pdf)

<sup>17</sup>. 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.<sup>18</sup> 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).<sup>19</sup>

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-

<sup>18</sup>. 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>

<sup>19</sup>. 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” (Sally & 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).

# Chapter 3: Risk-benefit dialogue

Good medical practice encompasses effective communication about benefits and risks of health interventions. In this context, radiation risk communication is a key component of good practice in medical imaging. The implementation of an effective communication strategy in paediatric imaging often requires unique considerations. This section discusses different approaches to establish this dialogue.

**Section 3.1** provides practical tips to support the risk–benefit discussion including examples of questions and answers.

**Section 3.2** discusses some ethical issues related to the communication of radiation risks in paediatric imaging.

**Section 3.3** considers different scenarios and key players involved when creating a dialogue in the medical community.

# 3. Risk-benefit dialogue

## 3.1 Practical tips for risk–benefit discussion

### 3.1.1 Communication goals and challenges

Communicating the benefits and risks of recommended medical interventions is an essential component of medical care, and this includes communicating radiation risks and benefits of radiological procedures (Levetown, 2008). When determining the appropriate imaging procedure or examination the medical need (the benefit) must be considered, in addition to the costs and potential radiation risks from procedures using ionizing radiation. If there is doubt about the best procedure to answer the clinical question, a dialogue between the referrer and the RMP (e.g. radiologist, nuclear medicine physician) can aid in the decision-making process.

A recent study that assessed patient knowledge and communication preferences has concluded that there is a substantial gap between patient expectations and current practices for providing information about ionizing radiation medical imaging (Thornton et al., 2015). A major goal of radiation risk communication in medicine is to ensure that patients, parents and/or caregivers receive the information they need in a way that they can understand (Dauer et al., 2011; McCollough et al., 2015). They need sufficient and straightforward information to understand the imaging care being performed. The risks inherent in the disease and/or patient's clinical condition have to be considered when discussing the need to perform a paediatric imaging procedure. It is important for referrers and other health professionals to identify the communication needs and preferred communication style of their patients and their caregivers. Each patient and family may be different – their specific cultural background, as well as their personal health history may require individually-adapted risk communication (Guillerman, 2014).

To ensure that paediatric patients and their families are fully informed of the benefits and risks of a procedure, the risk communication strategy may include all relevant health-care providers in the patient's care pathway. When a child is referred for an imaging examination the referrer is requesting the opinion of the radiological medical practitioner to assist in the clinical management of the patient. However, there may be other, equally important participants in care, such as nurses and radiographers/radiological technologists. These health-care providers often act as the primary professional interface between the referrer, patient, parents, family and/or caregivers, and the radiological medical practitioner. Radiographers/radiological technologists play a pivotal role in the optimization of each procedure, and can seek further clinical information from patients, family and physicians as necessary to help assist in the creation of the most appropriate risk communication strategy. Also, in some facilities they may be the only health professional with training in radiation safety. As key players in the quality assurance/improvement programmes of imaging departments, medical physicists may be included when the procedure is more complex or may deliver relatively higher doses.



Communicating the benefits and risks of paediatric medical imaging procedures which use ionizing radiation does present challenges. First, individuals often have a variety of personal influences affecting their risk perception. Social factors, belief systems, previous health care experiences, values and the individual's unique worldview can all influence their risk perception. People often evaluate risk by combining the hazard with their personal risk perspective, which is weighted according to values, preferences, education and personal experience (see **Box 3.1**). It is of the utmost importance that the benefits and risks of the intended procedure are communicated to the parents and the child in a way that they are able to understand, taking into account their unique cultural and social attitudes. Identifying the patient and/or

### Box 3.1 Some factors that influence risk perception

Experts and the public perceive risk differently (see **Fig. A**). Experts consider risk to be directly related to the magnitude of the hazard, amount of exposure and the vulnerability of the

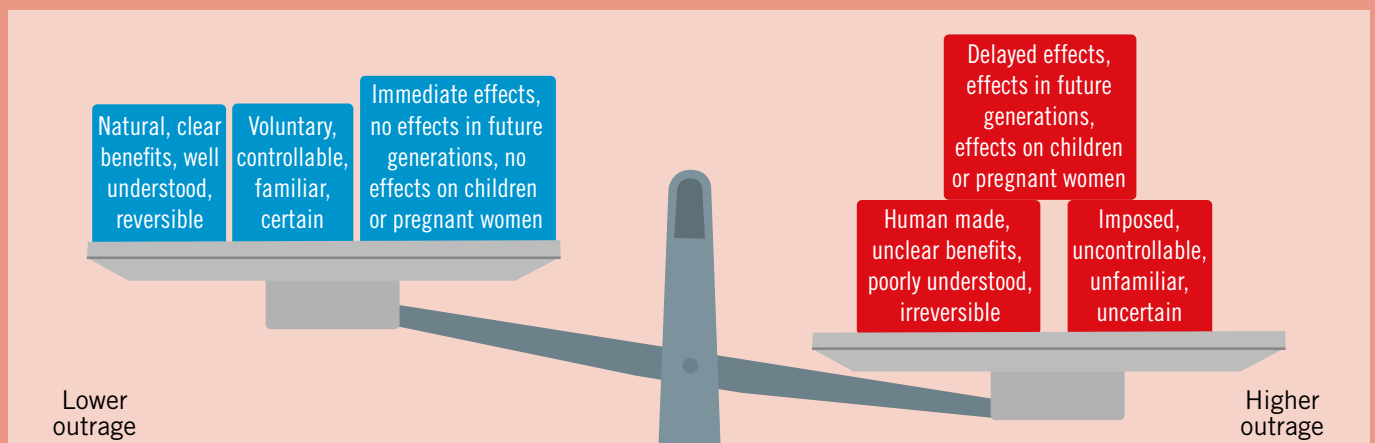
exposed population. People “at risk” do not necessarily perceive risk in the same way; they often see the hazard through the lens of emotions such as fear, anger and outrage (Sandman, 1993).



**Fig. A.** How experts and public perceive risk

Several factors have been identified as affecting the way risk is perceived (see **Fig. B**). These factors can influence the perception of radiation risks in medical imaging among the various stakeholders (e.g. patients, parents, health-care providers). One of the objectives of risk communication is to

bridge the gap between how the experts define risk and how the public perceives it. The essence of risk communication is not just explaining risk numbers but also managing the potential outrage (i.e. reducing or increasing it).



**Fig. B.** Factors influencing risk perception

caregiver's risk perceptions and recognizing their importance encourages informed dialogue and contributes to more effective risk communication.

A major challenge in communicating the benefits and risks of paediatric medical imaging procedures that use ionizing radiation is the existence of insufficient awareness and understanding of radiation protection issues by health professionals. Research has shown that there is widespread underestimation of doses and risks (Lee et al., 2004; Thomas et al., 2006; Lam et al., 2015). There is a need to ensure that all referring medical practitioners have sufficient background, education and resources to communicate clearly and effectively about the benefits and risks of paediatric imaging procedures.

Effective communication with patients and caregivers is increasingly recognized as critical to patient-centred care, and an important component of effective health-care delivery. This is also true in the paediatric population related to communicating radiation benefits and risks from medical imaging. However, the quantity and quality of communications training that most health-care professionals receive, and the lack of resources available to them, present a hurdle to effective communication in these settings. The following sections provide more in-depth information on communication strategies for health-care providers.

### **3.1.2 Communicating radiation benefits and risks**

Radiation risk communication in paediatric imaging can take place through different pathways: professional-centred communication (communication between the different professionals involved in children's health care i.e. referrers, RMPs, other health-care providers) and patient-centred communication (communication between health-care providers and patients, parents and caregivers).

#### **3.1.2.1 Professional-centred communication**

Radiologists play a unique role in explaining benefits and risks of medical imaging to the referrer. The imaging team (radiologists, radiographers/radiological technologists, medical physicists) can help by guiding the referrer's decisions on a particular imaging procedure. This conversation may be improved by the inclusion of other health-care providers and relevant consultants (e.g. nurses, surgeons, emergency medicine physicians). While such a multidisciplinary radiation risk dialogue is not feasible for every patient, it should be supported as a good practice in medical facilities (e.g. regular dialogue seminars). For example, the family physician or paediatrician can answer questions from patients and families as informed by the radiology team. With all members of the health-care team working together, the best strategy to minimize the dose while maintaining diagnostic image quality can be created, therefore reducing unnecessary radiation risks to paediatric patients. Communication between health-care professionals will be discussed in greater detail in **section 3.3**.

#### **3.1.2.2 Patient-centred communication**

The roles of referrers and RMPs in communicating benefits and risks of medical imaging procedures are different but complementary. Usually the referrer (e.g. a paediatrician or family physician) is the first and most trusted source of direct communication with the patient and family. Often the referrer is the only source of information for the imaging procedure. The referrers' ability to listen, answer questions, and address concerns about radiation benefits and risks is crucial in this situation. While a more generic radiation risk dialogue usually occurs between the referrer and the patient and family or caregivers, the radiologist

can contribute to a more detailed dialogue, if it occurs, focused on the radiation doses and risks related to the particular procedure to be performed. Examples of such messages are provided in **sections 3.1.5** and **3.1.7**.

Patients and their families/caregivers and radiographers/radiological technologists often discuss the medical imaging procedure. This is an opportunity to provide information and answer questions or address concerns. In rare circumstances the medical physicist may be invited to the discussion with patients/parents. Nurses, assistants, and receptionists, interact with patients and families, and questions may be posed at any time to any of them as well. It is important to prepare the staff to manage those questions (e.g. to provide resources or clear guidelines to those staff who might potentially be involved in such discussions).

In addition to the two communication arenas discussed above, additional organizations with unique communication considerations are health authorities, radiation regulatory bodies and research institutions. They have an important role in explaining the radiation risks to the public, policy-makers and other decision-makers. Competent authorities have to encourage all stakeholders to recognize the benefits and risks of radiation exposure of children and to join efforts towards appropriate utilization of paediatric imaging to improve radiation safety and quality of health care. Through an effective risk communication strategy, professional associations can advocate that procedures be justified and that dose-reduction strategies be implemented. This unique group will be discussed further in **section 3.3**.

### **3.1.3 Communication with the paediatric patient**

Primary health-care providers (e.g. family physicians, paediatricians) are usually the first responsible in the health-care pathway to communicate with paediatric patients. Depending on the characteristic of the procedure, this dialogue may be complemented by members of the imaging team (radiographer, radiological medical practitioner).

Paediatric imaging involves a wide range of patient's ages from neonates through the teenage years. These age-related differences in emotional development and cognitive abilities should be considered while tailoring the communication strategy (e.g. type, amount and complexity of the information) and setting (e.g. ensuring a private space to discuss radiation imaging and possible pregnancy for female patients). The child's age is not the only factor for health-care providers to consider; the child's family background also influences the discussion. The scenario typically involves interaction among the parent(s), the child and the physician and sometimes other family members as well. Parents are protective of and advocate for their children. There may be an inclination to shield children from some information related to the procedure, which may inappropriately exclude some paediatric patients from the risk–benefit dialogue.

Strategies for radiation risk communication between the health-care provider and the paediatric patient exist and examples are available in written material and websites (see Annex C). Information should be sufficiently comprehensive to cover any necessary issues that arise when discussing radiation risk together with other risks/fears (e.g. entering inside an unknown machine, having to stay quiet). Questions can be anticipated and addressed during the risk–benefit dialogue with the patient and family (Larson et al., 2007). The dialogue with adult patients supports an informed decision-making process in accordance with patient autonomy. In paediatric imaging it is important to understand that the parents may have to assume the responsibility for risk of harm for their child. This is quite a different situation than when discussing risk with an adult patient.

### 3.1.4 How to establish a dialogue in a clinical setting

#### Preparing for professional-centred communication

Some points to be considered for professional-centred communication are summarized below (see also **Fig. 15**).

1. Take steps to be prepared:
  - Ensure that the available imaging history is reviewed in the patient's chart or record for reference.
  - Understand past medical history and potential diagnosis and prognosis (this might influence the discussion).
  - Consider that children with chronic medical issues are more likely to undergo repeated examinations and therefore there may be concerns about cumulative dose due to repeated examinations.
  - Observe and assess your audience:
    - i. Consider the level of awareness and knowledge about radiation doses and risks of the other health professionals with whom you will communicate.
    - ii. Take into account their personal risk perspectives and their familiarity with medical imaging modalities and procedures.
    - iii. Define what style of communication would be best for this specific situation or professional(s).
2. Anticipate questions and prepare responses:
  - Define general radiation-related terms (e.g. benefits, risks, dose, type of exposure).
  - Provide comparisons of different imaging modalities/disciplines, including a comparison of imaging procedures that use ionizing radiation (e.g. diagnostic radiology, nuclear medicine, image-guided interventional procedures) and those that do not (e.g. ultrasound, MRI).
  - Identify differences between traditional, adult procedures and paediatric imaging procedures, with regard to how the procedure is performed and the typical doses.
  - Craft your message by considering the roles of others involved in the patient's care, to ensure consistency of messages.
  - Determine what information is needed from other health-care providers (medical specialists, nurses, etc.) to better prepare for this exchange.
  - Identify where to get that information:
    - i. published resources (e.g. this tool)
    - ii. reliable Internet resources
    - iii. experts.

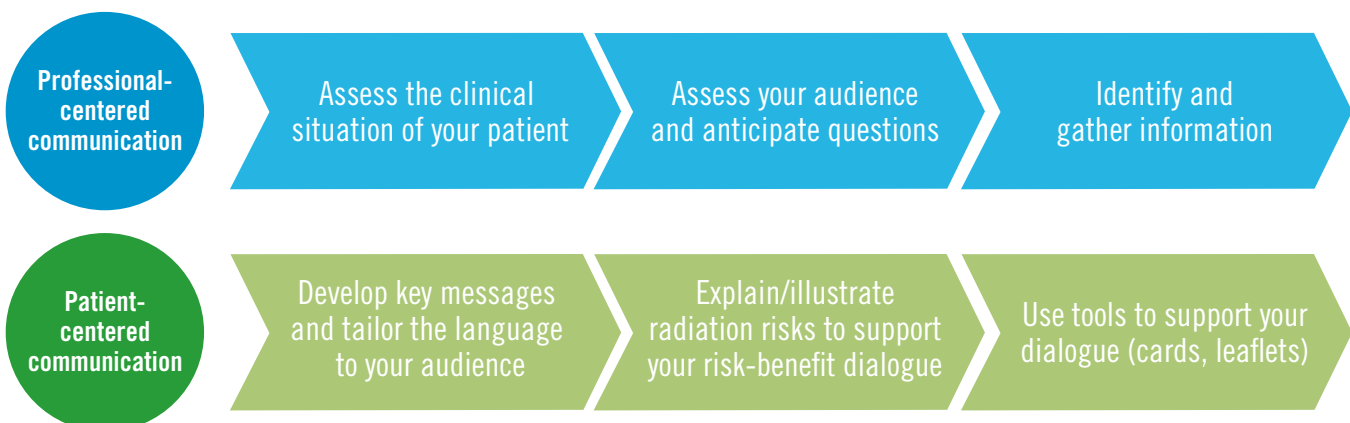
#### Preparing for patient-centred communication

Points to be considered for patient-centred communication (see also **Fig. 15**).

1. Participate in a patient-centred dialogue and communicate key messages:
  - Focus key messages on relevant information that will reassure the patient/parents. Keep the messages provided informative, understandable, precise and clear. Use plain language and avoid scientifically complex medical terms and numbers.

- Explain the rationale for recommending the specific procedure.
- Strongly emphasize benefits and the medical need when communicating known and potential radiation risks – avoid causing panic or unnecessary fear in patients and parents.
- Take care to explain what has been (or will be) done to minimize risk to the patient during the recommended procedure.
- Illustrate radiation risks by comparing them with other kinds of risks using several approaches (see section 3.1.5 for examples). Minimize the use of complex numbers and statistics in the communication of radiation risks.
- Use active listening techniques to ensure that patients and parents feel heard and understood when discussing concerns, fears and questions about the imaging procedure.
- Remember that effective communication and understanding often relies on the repetition of key messages.
- Use audience-centred communication and appropriate language for the specific patient and their caregivers:
  - i. Always acknowledge that you appreciate their questions or concerns in advocating for their child.
  - ii. Consider the specific situation of the patient and caregivers, including literacy level, native language, language fluency and their familiarity with medical topics and procedures.
  - iii. Address their specific risk perspectives (see Box 3.1),
  - iv. Communicate clearly, with empathy, considering the fear or apprehension of the patient and or caregivers.
  - v. Define what style of communication would be best for this specific situation/patient (see section 3.1.5 for practical examples).
- Preparing a generic, brief informational card/leaflet for patients/parents may be helpful in some circumstances to support the dialogue.
- Be prepared to address questions from the patient, parents or caregivers.

**Figure 15:** Aspects to be considered when establishing a dialogue in a clinical setting



### 3.1.5 Practical examples of communicating with paediatric patients

The customary language of radiation protection may not be understood by non-specialists; for example, radiation dose units, risk, nominal probabilities and coefficients for stochastic effects are difficult to understand (Picano, 2004). When patients and their parents or caregivers ask about radiation doses, in fact they are concerned about the associated risks. There are different ways to communicate the radiation doses and related risks of a specific paediatric imaging procedure to them.

Comparisons with more familiar radiation exposures are often used, even though they have some caveats that were discussed in **section 1.2.1**. For example, radiation doses in medical imaging are often communicated as multiples of a chest X-ray. Although talking about “equivalent number of chest-X rays” may help understand the magnitude of the exposure, comparison with such small doses may be misleading and unnecessary alarming if it is not properly explained.

Comparisons are also done between radiation doses in medical procedures and the equivalent period of exposure to natural background radiation. As discussed in **section 1.2.1**, natural background radiation results in whole body exposures while radiation exposure in medical imaging is focused on one region of the body. This has to be explained when making such comparisons. Equivalent exposure to cosmic radiation in commercial air travel has been suggested as a metric to compare radiation doses. Although in-flight doses due to cosmic radiation depend on the flight path (latitude, altitude and duration) and show seasonal variations, for the sake of comparison it can be considered that the typical total effective dose for a transatlantic flight is on the order of 50  $\mu\text{Sv}$  (Butikofer & Fluckiger, 2011). As noted above, comparison with such small doses may be misleading and have to be carefully explained. Radiation risks may be compared with equivalent levels of risks associated with daily activities such as crossing a street or driving a car (Picano, 2004; Fahey, Treves & Adelstein, 2011).

Determining the most appropriate comparisons for a specific patient should be based on the particular situation, the unique risk perceptions of the patient and their parents or caregiver, and the personal preferences and ability of the health professional. The message is not just about the facts, but also about how the facts are presented (see **Box 3.2**).

### Box 3.2 Messaging: An example of two ways to present the facts related to radiation exposure risk

After a pelvic CT scan of a pregnant patient in the emergency department to evaluate trauma following a motor vehicle accident, she is seen by her primary care physician. Which statement delivers the most appropriate response to her question about the risk to the fetus?

A. “The CT that you had two weeks ago has perhaps doubled the risk that your child will develop cancer before age 19.” [0.6% vs 0.3%]

B. “The CT was an important exam that allowed the physicians to rapidly evaluate and treat your injuries which otherwise could have placed your health and the health of your baby at risk. The risk of adverse outcome is very small and the likelihood of normal development is still nearly the same as it is for any child.” [96.7% vs 96.4%]

When considering benefits and risks, there is an important risk that is quite often forgotten: the risk of not performing an exam that may result in missing a diagnosis and initiating treatment too late to improve the medical outcome. The potential to improve a patient's life expectancy due to early diagnosis and treatment must be considered in comparison to the magnitude of the cancer risk and its latency compared to the age of the patient and other comorbidities.

Patients and caregivers often personalize risks, even when scientists try to de-personalize them. This is especially common if the audience has a low understanding of radiation protection concepts or statistics in general. For example, a “one-in-a-million” comparison to express cancer risk might be perceived as a low risk by the scientific community. However, patients, parents and caregivers may personalize risks and perceive that the “one” could be them or their loved one (EPA, 2007). This tendency to personalize risk may be observed more often in stressful situations, such as when an imaging procedure is needed on a child.

**Table 12** presents a few examples of clinical questions about risk of radiological examinations, with proposed answers. Further examples are provided in **section 3.1.6**.

**Table 12.** Clinical questions about risks of a radiological examination and possible answers

Question	Possible responses
<b>“Why are you recommending this radiological examination?”</b>	“We need more information to clarify your child’s diagnosis, and to direct our treatment. This radiological examination can rapidly and accurately provide that information.”
<b>“Are there any risks of this radiological examination?”</b>	“One concern is the possibility of cancer resulting from the radiation from this examination.”
<b>“How great is this risk?”</b>	“The risk from this radiological examination is very small, if a risk at all. We are not certain that there is a risk at very low doses, like those doses in the vast majority of X-ray procedures or CT.”
<b>“How does the risk from this radiological examination compare to the risk of [my child’s presenting condition]?”</b>	<p>“I have considered your current situation carefully, taking into account many factors.” Depending on the circumstances:</p> <ul style="list-style-type: none"> <li>• “I have significant concern that your child has an injury or serious medical condition. The risk of this radiological examination is at most very small by comparison, so this radiological examination is the right test to perform.”</li> <li>• “At the present time, your child appears to have very low risk of a serious medical condition. Although the potential risks from the radiological examination are very small, this is not the best test at this time. If your child’s condition worsens, this radiological examination might become necessary.”</li> </ul>
<b>“When will these risks occur?”</b>	“The risk of missing a serious diagnosis will occur now, in the coming minutes/ hours/days. The potential effects from small radiation doses such as this radiological examination would take longer (several years).”
<b>“What is the safest course of action?”</b>	“Comparing the potential risks of this radiological examination against the risk of your child’s condition, the safest course is....”
<b>“What are my options?”</b>	“The options include performing this radiological examination now, or waiting. Other options include using a different medical test, such as ultrasound or MRI, performing surgery or medical therapy based on the information at hand (without the radiological examination), or watching for changes in your child’s condition. If your child’s condition worsens, this radiological examination may be necessary.”

Source: Adapted, with permission, from Broder & Frush (2014)



In summary, several approaches are used to communicate radiation doses and related risks to patients/parents:

1. Radiation exposure compared with:
  - natural background exposure
  - flight hours in commercial air travel
  - number of chest X-rays
  - other radiation exposure situations.
2. Radiation risk presented as:
  - quantitative estimates (e.g. 1 in 10 000 or 0.01%)
  - qualitative estimate (e.g. low risk)
  - comparison with the baseline risk level (e.g. an extra risk of 0.01% that adds to the average 40% baseline cancer incidence risk)
  - Comparison with other risks faced in daily life (e.g. car driving).

#### 3.1.5.1 Message mapping

Message mapping was developed in the early 1990s as a tool for public health risk communication. The message map displays layers of information hierarchically organized as responses to anticipated questions or concerns in a clear, concise, transparent and accessible way. Message mapping requires:

1. anticipating the questions and concerns of the stakeholders;
2. organizing thoughts and ideas in response to those questions and concerns; and
3. developing key messages and supporting information.

A message map template is a grid containing boxes. The top tier of the grid identifies the audience and the question or concern intended to be addressed. The second tier of the grid contains three key messages that answer the question or concern. The third tier contains supporting information in groups of threes under each key message, in the form of visuals, analogies, examples, stories and/or sources of information. **Table 13** provides an example of message mapping in paediatric imaging using this template.

### 3.1.6 Questions and answers for patient-centred communication

#### 3.1.6.1 General questions about radiation and paediatric imaging

##### a) What is a medical imaging procedure?

- A medical imaging procedure is any procedure that creates images (pictures) for diagnosis or to guide treatment.
- Medical imaging procedures using ionizing radiation consist of: conventional radiographs and computed tomography (X-ray pictures), fluoroscopy (X-ray movies), nuclear medicine examinations (e.g. bone, renal or lung scans) and include hybrid imaging (that is, combined imaging such as positron emission tomography-computed tomography, PET-CT).
- There are other medical imaging procedures, such as ultrasound and magnetic resonance imaging (MRI), which do not use ionizing radiation.

**Table 13.** Example of message mapping in paediatric imaging

Stakeholder: parents		
Anticipated question: How much radiation will my child receive from this head CT?		
Key message 1	Key message 2	Key message 3
This CT is recommended now to aid in diagnosis and guide the treatment of your child	Your child will receive the lowest possible dose without decreasing the diagnostic quality of the images	This CT is medically indicated and will be properly done, thus the benefits will outweigh the radiation risks
Supporting information 1-1	Supporting information 2-1	Supporting information 3-1
We have evaluated the clinical condition of your child and agreed that we need to confirm the diagnosis to make a decision about the treatment (examples/stories)	There are many techniques to lower the dose without compromising the diagnosis (examples, visual communication)	The radiation dose will be small, similar to several months of exposure to natural background radiation (analogies, tables, visual communication)
Supporting information 1-2	Supporting information 2-2	Supporting information 3-2
We have considered alternative tests and agreed that this is the examination indicated for your child (referral guidelines)	This imaging facility uses equipment, protocols and techniques suitable for children (accreditation, audits)	The radiation risk is low and the likelihood of an adverse outcome (cancer risk) will be nearly the same as it is for any other child: lifetime cancer incidence risk of 35-40% (analogies, tables, pictorial resources for visual communication)
Supporting information 1-3	Supporting information 2-3	Supporting information 3-3
This examination has to be done now to avoid any delay in the treatment, in case the diagnosis is confirmed (examples, scientific data)	This facility periodically compares its doses with national and international reference values and stays within those ranges (paediatric DRLs)	The CT will be interpreted by imaging specialists trained to identify abnormalities and their significance. The report will be communicated to the referring physician who will make decisions about treatment and follow-up (stories, examples)

**b) How much medical radiation is too much?**

- When a radiological imaging procedure is justified and appropriate, the benefit to the child outweighs any risk. For this reason, there is no limitation to the relatively small radiation doses used to diagnose and manage disease.
- The small radiation doses associated with medical diagnosis and image-guided interventions have at most a low risk. This potential risk is small compared to the recognized and proven benefits of medical imaging and this is considered in the process of justification.
- Radiation risks from the low radiation doses used in diagnostic radiology procedures are generally small. The lifetime risk of developing cancer if you never have a radiology examination is more than 1 in 3. The low radiation doses used in diagnostic radiology procedures may increase this slightly. At higher doses, such as those used for some very complex interventional procedures and for radiation therapy, tissue injury such as skin redness may very rarely occur in children.

**c) What medical imaging procedures use ionizing radiation?**

- The most common radiological imaging procedures utilizing ionizing radiation are: conventional radiography, computed tomography (CT), fluoroscopy, and nuclear medicine examinations, including positron emission tomography (PET) and single-photon emission computed tomography (SPECT), as well as hybrid techniques combining these modalities (e.g. PET-CT).

**d) What medical imaging procedures do not use ionizing radiation?**

- Two common imaging techniques that do not utilize ionizing radiation are ultrasound and magnetic resonance imaging (MRI).

**e) Why can't we do a procedure that does not use radiation instead?**

- Your child's physician (e.g., paediatrician, family physicians) can talk with the imaging specialist to get help in determining which type of test might be best.
- We have considered using examinations that do not require radiation, but we have determined that they will not give us the necessary information.
- Following careful consideration of your child's unique medical needs, this is the best procedure to answer the clinical question.
- While there are other procedures that do not use radiation, this procedure will best provide us with the information needed to inform our treatment plan.

**f) Does my child need it? Does she/he need it now?**

- The referring medical practitioner and radiologist have done a risk–benefit analysis for the recommended imaging procedure. They have considered alternative tests, and this specific procedure is recommended to aid in diagnosis and/or treatment of your child.
- Although some conditions may be self-limiting and tests for such conditions may be postponed, other conditions will need investigation sooner to help with the care of your child.

**g) Is this procedure dangerous? Are there any long-term effects or increased risk that we need to consider?**

- Imaging procedures provide very important information that allows health-care providers to make informed decisions about your child's care (even if the examination is normal) and they can be lifesaving. Radiation risks for diagnostic imaging procedures are small. When an investigation is justified, the risk of not undergoing a radiation procedure is much greater than the radiation risk from the procedure itself.
- It has been reported that there is an increased, albeit very low, risk of developing cancer in people exposed to low radiation doses.
- The chance that any child has of developing cancer over the course of her/his lifetime is more than 1 in 3 (i.e. in some countries it is around 40%).<sup>1</sup> This natural chance of developing cancer may be very slightly increased by a radiation examination.
- Risks are in general higher at younger ages i.e. risks are higher in newborns, compared to infants and older children.

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<sup>1</sup>. The lifetime baseline risk of cancer incidence varies across countries, and in some countries such as the USA this percentage is more than 40% (BEIR, 2006). If national/local data are available, this answer can be tailored accordingly

**h) What are the benefits versus risks?**

- The benefits of medical imaging are extensive; for example, accurate diagnosis, precise guidance of therapy, monitoring of disease progression or remission and determining cure.
- Radiation risks from the low radiation doses used in diagnostic radiology procedures are generally small. The chance that anybody has of developing cancer over the course of her/his life is more than 1 in 3 (i.e. in some countries more than 40%). The low radiation doses used in diagnostic radiology procedures may increase this risk slightly. At higher doses, such as those used for some very complex interventional procedures and for radiation therapy, tissue reactions such as redness may occur.

**i) What are the consequences of not doing the procedure?**

- Radiological imaging procedures are intended to assist in making a timely and accurate diagnosis to improve health outcomes. The consequences of not undergoing appropriately requested procedures may affect the health outcomes through incorrect or delayed diagnosis and treatment of your child.

**j) Who interprets the results and how do we get them?**

- Imaging procedures are interpreted by specialists trained to identify abnormalities on images and their significance, as well as to give an opinion regarding further management or other tests. Such experts typically are radiologists, nuclear medicine physicians, and, in some countries, other credentialed physicians or specialist radiographers/radiological technologists.
- Imaging reports are communicated to the referring physician who shares and discusses them with patients/caregivers and with other members of the health-care team.
- Some imaging facilities send reports to patients directly, but care must be taken to ensure that reports can be explained and put into context for the patient/caregiver by a trained and experienced clinician.

**k) How much radiation will my child receive from a radiation imaging procedure?**

- It is important to keep children's doses as low as reasonably achievable, particularly as children's tissues are more radiosensitive and children have more time to develop late effects such as cancers.
- There are many ways to lower dose and risk in paediatric imaging without compromising the diagnostic imaging data and image interpretation.
- Your child's radiation dose will be adjusted based on the procedure and the detail of the images required for making the diagnosis, taking into account the size of your child. Smaller children need less radiation to make an acceptable image.

**l) Can the dose be adjusted so that my child receives the lowest possible dose?**

- Yes, there are many techniques to lower dose and risk in paediatric imaging without compromising the diagnostic quality of the images.
- Our facility utilizes child-sized dosing in our radiological examinations.

**m) How can we be sure that child-sized dosing will be used for this procedure?**

- When a radiation imaging procedure is needed and justified, it is possible to check that the imaging facility will use appropriate protocols and techniques to ensure that the correct dose is used.

- We periodically compare our doses with national and international standards and reference values, and keep with the established range.

**n) How will I know if the right radiation dose is used for my child?**

- The actual dose will vary according to your child's size and the information required.
- Useful guidance for imaging facilities is available through national and international resources (e.g. protocols recommended by Image Gently<sup>2</sup>) and, in many countries, dose registries that provide reference values called diagnostic reference levels (DRLs).
- The radiographer/radiological technologist performing your child's radiological procedure will be able to help confirm that the correct steps will be or have been taken to use the least amount of radiation necessary to get the needed information.

**o) Who can parents talk to about their concerns?**

- There are many medical professionals involved in paediatric care. The first point of contact for questions about your child's care is the primary health-care provider (e.g. paediatrician, family physician), as s/he will be most familiar with your child's condition and medical history, and the treatment plan in place.
- The imaging specialist or radiological medical practitioner and their support team (e.g. medical/health physicist, radiographer/radiological technologist) will be able to answer specific questions about procedure safety, child-sized dosing and radiation risk.
- Nurses and other health-care support staff may be able to help facilitate additional communication with health-care providers and may be able to provide leaflets/information cards.

### 3.1.6.2 Computed tomography (CT)

**a) What is a CT scan?**

A CT scan<sup>3</sup> or computed tomography (CT) is a radiological imaging procedure that uses X-rays to make detailed pictures of the internal organs and structures of your child.

**b) What are the benefits of CT scans?**

- CT scans provide cross-sectional and 3D images of the body showing organs and internal details not available on conventional radiographs.<sup>4</sup>
- CT quickly and reliably provides valuable and life-saving medical information. It is particularly useful for imaging the head, chest, abdomen/pelvis and bones.
- When its use is appropriate and the radiation dose is optimized, the benefit from CT far outweighs the potential harm. The risk of not undergoing a *justified* CT is far greater than the radiation risk.

**c) How much radiation is used in CT?**

- The radiation dose depends on the information required to answer the clinical question and the patient's size.

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<sup>2</sup> <http://www.imagegently.org/>

<sup>3</sup> In some countries people are more familiar with the term "CAT" to informally refer to computed tomography

<sup>4</sup> Some people may be more familiar with the term "X-ray" to informally refer to conventional radiographs (although CT also uses X-rays)

- The actual dose used will be determined by the specific procedure, the quality of the image needed for diagnosis, and the size of the patient. Most CT equipment has automatic dose-reduction technology to help optimize dose, including for children.
- Some organs in children's bodies are more radiosensitive than in adults, and children have a longer expected lifetime in which to develop late effects, such as cancer. Common to all CT facilities is the principle to keep doses as low as reasonably achievable (referred to as ALARA), particularly for children.
- The dose reduction should not compromise the diagnostic quality of the images. There are many techniques to lower dose and risk in paediatric imaging without compromising diagnostic quality.
- Our facility utilizes child-sized dosing in our radiological examinations.

**d) Why do you recommend a CT scan?**

- Because of your child's specific medical needs, this is the best procedure to get the information we need to care for your child, and this piece of information is not available by using conventional radiography techniques.<sup>5</sup>
- CT is ideally suited for imaging certain areas of the body (e.g. head, chest, abdomen).
- CT examinations are very quick, and are therefore particularly well suited for very young or ill patients who have difficulty remaining still for long periods of time.

**e) What will a CT tell you about my child and our treatment plan that other options/alternatives cannot?**

- CT is ideally suited for certain areas of the body (e.g. head, chest, abdomen).
- CT examinations are very quick, and are therefore particularly well suited for very young or ill patients who have difficulty remaining still.
- While there are other procedures that do not use radiation, this procedure will best provide us with the information needed to inform our treatment plan.

### 3.1.6.3 Fluoroscopy

**a) What is fluoroscopy?**

- Fluoroscopy is like an X-ray movie. Fluoroscopic procedures use X-ray pulses to show organs and organ motion within the body in real time.
- Fluoroscopy is used both for diagnostic imaging and for guiding treatment (e.g. catheter/balloon placement, and other interventional procedures in the heart, brain and elsewhere in the body).
- The amount of radiation from fluoroscopic procedures is usually higher than for plain radiography (e.g. chest X-ray), and depends on the type of procedure and the patient's size.

**b) Why do you recommend fluoroscopy?**

- Because of your child's specific medical needs, this is the best procedure to care for your child.
- The ability to see a liquid dye called "contrast media" passing through different organs and/or objects moving within the body in real time, is necessary for safe and accurate placement of catheters and for performing certain interventions.

<sup>5</sup>. Some people may be more familiar with the term "X-ray" to informally refer to conventional radiographs (although CT also uses X-rays)

**c) How much radiation is used in these exams?**

- The radiation dose will vary according to the specific procedure, the quality of the image needed for diagnosis, the size of the patient, the difficulty of the procedure, and the settings of the imaging equipment.
- Common to all fluoroscopy facilities is the principle to keep doses as low as reasonably achievable (ALARA), particularly for children. This is done because some organs in children's bodies are more radiosensitive than in adults, and children have a longer expected lifetime in which to develop late effects, such as cancer.
- There are many techniques to reduce dose and risk in paediatric imaging without compromising the diagnostic quality of the images.
- Our facility utilizes child-sized dosing in our fluoroscopic procedures.

**d) What are the benefits of fluoroscopic studies in paediatric patients?**

- It is an extremely useful procedure that can provide real-time images of the body, allowing for proper placement of internal medical devices and study of internal processes (e.g. contrast in the gastrointestinal tract).
- When the procedure is requested appropriately and it is optimized, fluoroscopy provides far more benefit than harm.
- In addition to radiation risk, potential harm from fluoroscopic procedures includes procedure-related risks from the intervention, such as infection or bleeding.<sup>6</sup> While the risk of the intervention is greater than the radiation risk, the benefit of a justified intervention is greater than all of the risks. The intervention can be lifesaving in certain circumstances (e.g. congenital heart disease).

**3.1.6.4 Nuclear medicine**

**a) What is nuclear medicine?**

- Nuclear medicine<sup>7</sup> assesses the function of an organ after a radioactive substance (e.g. tracer, radiopharmaceutical) has been administered to the patient. Nuclear medicine examinations help to identify abnormal function (e.g. thyroid) or sites of abnormal function (e.g. bone scan for cancer).
- Nuclear medicine procedures also include hybrid (i.e. combined) imaging techniques such as positron emission tomography (PET) and single-photon emission computed tomography (SPECT), coupled with CT or MRI.

**b) Why do you recommend a nuclear medicine procedure?**

- Because of your child's specific medical needs, this is the best procedure to get the information we need to care for your child.
- Nuclear medicine examinations provide unique information about organ function that is not available from other imaging tests.

**c) How much radiation is used in a nuclear medicine study?**

- The radiation dose will vary based on the specific procedure, the data required for diagnosis purposes, the size of the patient and the settings of the imaging equipment.

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<sup>6</sup>. This may be further explained by providing examples relevant for the specific procedure e.g. "Such as infection or bleeding in the case of blood vessel interventions or studies in which contrast (dye) is given directly into organs or structures"

<sup>7</sup>. Also called radionuclide imaging or nuclear imaging



Most of the routine nuclear medicine examinations in children deliver low radiation doses (i.e. a small amount of radiation), often much less than fluoroscopy studies.

- Common to all nuclear medicine facilities is the principle to keep doses as low as reasonably achievable (ALARA), particularly for children. This is done because some organs in children's bodies are more radiosensitive than in adults, and children have a longer expected lifetime in which to develop late effects, such as cancer.
- Dose reduction should not compromise the diagnostic quality of the images. There are many techniques to lower dose and risk in paediatric imaging without compromising the diagnostic quality.
- Our facility utilizes paediatric weight-based radiopharmaceutical dosing based on established guidelines.<sup>8</sup>

**d) What are the benefits of nuclear medicine investigations in paediatric patients?**

- It is a very useful and unique modality that can provide important functional information about body processes and disease activity.
- When ordered appropriately and dosage optimized, nuclear medicine examinations provide far more benefit than risk.

**e) How long will the radioactivity be in the patient's body?**

- The radioactivity varies. Different tracers have different half-lives (amount of time for half of the radioactivity to be eliminated from the body). For instance, the most commonly used radioisotope, Technetium-99m has a half-life of 6 hours, and for all practical purposes will be gone in two and a half days (60 hours).<sup>9</sup>
- Although radioactivity following a diagnostic procedure may be detectable with sensitive equipment, the radiation levels are very rarely a risk to others. The nuclear medicine team will let you know in the very rare situation that caregivers should be careful about exposure from the child.

**f) Are there any additional risks for my family? Are there any additional precautions we should take?**

- Following diagnostic nuclear medicine procedures it is unusual for family members to need to take additional precautions (see above).
- Pregnant family members should seek advice from the nuclear medicine facility.

### 3.1.7 Key messaging examples

#### 3.1.7.1 Primary message of the Image Gently campaign

These are examples of three key messages (and related messages) adapted, with permission, from the Image Gently campaign (<http://www.imagegently.org/Procedures/Computed-Tomography>).

**a) CT helps us save kids' lives!**

<sup>8</sup>. This answer can be tailored to the local setting by referring to the criteria utilized in the facility. The European Association of Nuclear Medicine (EANM) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) of North America have provided recommendations about paediatric nuclear medicine (Gelfand, Parisi & Treves, 2011; Lassmann et al. 2007; Lassmann et al., 2008)

<sup>9</sup>. This is just an example, and this answer can be tailored to the specific procedure and half-life of the radionuclide to be used

**b) But when you image, radiation matters.**

- i. Children are more sensitive to radiation
- ii. What we do now lasts for their lifetime

**c) So, when you image, image gently!**

- i. More is usually not better
- ii. When CT is the right thing to do:
  - 1. Child-size the kV and mA
  - 2. One scan (single phase) is usually enough
  - 3. Scan only the indicated area

**3.1.7.2 Example of information for discussions of radiation risks in paediatric CT**

These are examples of information proposed as a foundation for a discussion of radiation risks in paediatric CT (adapted from Brody et al., 2007).

1. Radiation is an essential component of a CT examination.
2. The level of radiation exposure that results from a CT examination is low.
3. The cause-and-effect relationship between low-level radiation exposure, such as with CT, and cancer is not certain, but expert panels that have examined this question have suggested that there is a small risk that increases with increasing dose.
4. Although some studies have indicated that CT examinations may increase the risk of subsequent development of cancer, the exact magnitude of those risks is not yet known. So, the risks of CT scans must be estimated, and these estimates vary depending on the information used.
5. The amount of radiation that CT provides depends on many factors, especially the protocols used and equipment settings for the individual examination.
6. In general, properly performed CT examinations of children should expose a child to much less radiation than those for the same procedure on an adult.
7. The potential benefit from a clinically indicated CT examination is well documented and is far greater than the potential cancer risk.

## **3.2 Ethical considerations**

This section emphasizes the importance of an effective radiation risk communication to support the informed decision-making process in paediatric imaging from an ethical perspective, discussing the principles rather than the legal implications.

Based on the principles of non-maleficence and beneficence (i.e. first do no harm and secondly do good) health professionals have an ethical responsibility to optimize the risk–benefit ratio of all interventions. The obligation to benefit the patient must be balanced against the obligation not to cause harm, with the purpose of ensuring that the benefits will outweigh the harm (Sokol, 2013). Applying these ethical principles may become a difficult

task if the risks are uncertain, which is often the case when assessing low-dose radiations risks of imaging procedures. Overestimation of radiation risks might result in not doing an imaging procedure that could benefit the patient more than the radiation risk. There are other possible ways that health-care providers can wrongly assess the risk–benefit of imaging to the detriment of their patients (Brody & Guillerman, 2014).

In the context of ethics and health, the respect for the dignity of persons includes the right to make autonomous, informed and free choices. An informed decision-making process is valid only if the final decision is free of coercion and based on understandable and transparent information provided to the patient. There are different ways in which consent is given. In paediatric imaging the informed decision-making process usually consists of a verbal exchange between the health-care professionals and the patient and caregiver. It is important to note that a written consent form merely documents the discussion but the act of signing a consent form is not a substitute for an informed discussion. Most often written consent is not necessary in diagnostic imaging procedures. The consent does not necessarily need to be explicitly expressed (i.e. it can be “implied consent”).

The referring physician should provide information about the clinical utility and impact of the procedure for patient management. Access to transparent information about benefits and risks is a fundamental right of patients. In this exchange it is important to maintain the confidentiality of personal information and privacy. When appropriate, the measures to reduce radiation doses and associated risks can be included in the discussion with patients/parents. The information will also describe other practical aspects of the procedure that may cause discomfort or anxiety. The discussion will consider other options, with their respective benefits and risks such as alternative imaging with MRI or ultrasound, management without imaging such as clinical observation, or performing the procedure later, if the patient’s condition changes. The expected outcome of the discussion is to gain the trust of the caregivers (e.g. parents/guardians) by articulating the safest and most effective course of action for the paediatric patient, rather than to emphasize any potential cancer risk associated with the radiological procedure.

Both patient and parent/guardian have the right to accept or object to the procedure.

The informed decision-making process in paediatric health care includes the (explicit or implied) consent of the parents, and also the child’s capacity to assent. The assent and consent processes should be the result of an ongoing, interactive conversation between the health-care providers, child and caregivers. In pursuing children’s assent, health-care providers should provide age-appropriate information to help them understand the nature of the examination and its importance for their medical care. Older children or adolescents may have the capacity to actively participate in health care decisions.

In emergency situations, although there may not be time to obtain consent or assent because of medical necessity (e.g. immediate need to perform life-saving procedures), it is important to provide an explanation and information regarding the procedure to the child (as appropriate depending on age) and parents, retrospectively.

## 3.3 Creating a dialogue in the medical community

### 3.3.1 Participants

Communication with patients and caregivers is one of the requirements of the new International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS, 2014). Communication of benefits and risk of medical interventions forms the basis of good medical practice. There are several stakeholders who have an interest in providing high-quality care to the paediatric patient undergoing imaging procedures (**Fig. 16**). It is essential for them to participate in the risk–benefit dialogue. Beyond the three key stakeholders – the referrer, the patient/caregiver and the radiological medical practitioner – other health professionals<sup>10</sup> are involved. The radiographer is often the initial contact at the point-of-care and medical physicists typically advise on higher-dose procedures or in optimizing dose. The training received by the nursing staff in patient care and communication is invaluable for the worried child or parent, and others further from direct care such as regulators or payers should be involved in the communication process as well, to help ensure high-quality medical care and effective communication.

There is an opportunity to communicate and educate the larger health-care community about the benefits of properly justified and optimized paediatric imaging. The role of public health is to harness the opportunity to create and nurture a dialogue with the community. This ability to communicate and educate extends not only to health professionals, but also to research agencies, professional societies, competent authorities, policy- and decision-makers. In summary, all those responsible for assessing, minimizing, and/or regulating radiation risks in health care are included in the public health dimension.

### 3.3.2 Dialogue between referrers and radiological medical practitioners

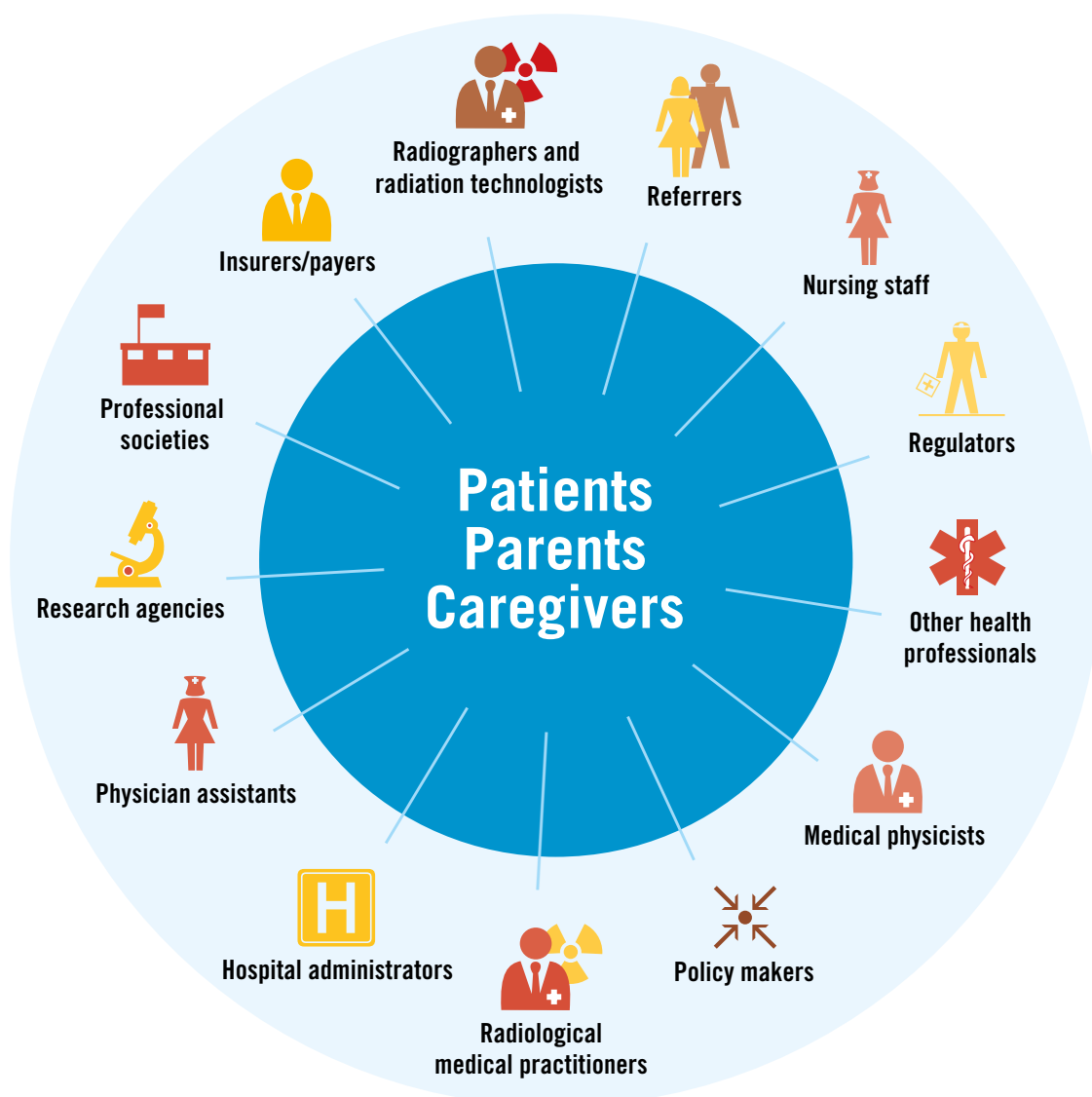
There is one-way communication from referrer to imager with regards to individual patients and their imaging. There is also a more general communication from imager to referrer of information on dose and risk for general categories of examinations (chest X-rays, scoliosis series, CT scans of the brain, etc.). As important, however, is two-way communication. Two-way communication between referrers and RMPs is essential to convey clinical information, formulate the clinical questions, consider the merits of the different procedures and justify the procedure requested.

The first step in this two-way communication is the referral or request. This is a request from the referrer to the RMP for an opinion as to the best diagnostic test, and for the interpretation of that investigation. The request should provide relevant clinical information designed to communicate the likelihood of a condition, and the clinical question that the procedure is intended to address. When initiating a request the referrer should reflect on whether the investigation is needed at all, whether it is needed now and if it is the best test for this specific patient (see **Table 9**). Reference should be made to previous diagnostics to avoid duplication and to refine the likelihood of disease. The choice of procedure requested may be clear from common practice, but guidance from imaging referral guidelines, clinical decision support or rules in electronic requesting systems should be followed. In the instance of

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<sup>10</sup>. As defined in **section 2.1.1**: “An individual who has been formally recognized through appropriate national procedures to practise a profession related to health (e.g. medicine, dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, occupational health)” (BSS, 2014)

**Figure 16:** Several stakeholders are involved in the communication of radiation risks and benefits in paediatric imaging



high dose and/or uncommon procedures (or where guidance is limited), direct discussion at multi-disciplinary meetings or by telephone would be helpful.

Where direct discussion is not possible or needed, the justifying radiological medical practitioner should be able to continue the dialogue through electronic requesting systems, particularly when a change in the requested procedure is critical to the care of the patient. Participating in a dialogue based on test efficacy and radiation safety will help both with the individual case and also to encourage a radiation safety culture in general. Involvement of the paediatric patient or parent/caregiver in such discussions would help with decision-making and support an informed decision-making process; it would improve their understanding of the procedure and its intended benefits as well.

### 3.3.3 Dialogue between medical imaging staff and medical facility administration

Discussions between medical imaging staff and medical facility managers may help to maximize the benefit and minimize the risk of radiation exposure of paediatric patients. These discussions should include a number of different topics:

1. Planning and equipping imaging facilities to ensure that imaging equipment has the necessary technology to encourage optimization of radiation protection of children.
2. Creating an environment in imaging facilities that is non-threatening and helps calm paediatric patients, through appropriate design and decoration.
3. Ensuring that appropriate quality assurance and quality improvement measures are in place and are followed by all personnel involved in paediatric imaging.
4. Facilitating the use of evidence-based referral guidelines for justification of paediatric imaging examinations.
5. Ensuring that imaging equipment and protocols provide image quality adequate for the clinical purpose at the lowest acceptable dose and that paediatric diagnostic reference levels are used, when available.
6. Including education and training on radiation protection, risk prevention and risk communication to support radiation risk–benefit dialogue in paediatric clinical settings.
7. Implementing clinical audit programmes that include paediatric imaging.
8. Managing potential conflict between financial pressures and appropriateness of examinations.
9. Ensuring facility-wide adherence to radiation protection standards and protocols.
10. Championing and implementing a safety culture in imaging facilities.

### 3.3.4 Dialogue between other health professionals involved in paediatric health care

Safety and quality in paediatric imaging requires the involvement of many different health professionals. The medical imaging staff includes a multidisciplinary team of health professionals including RMPs, radiographers/radiological technologists, medical physicists and nurses. Much of the imaging of children is performed outside departments of radiology. As discussed in **section 2.1**, the term RMP includes not only the classical medical specialists who use ionizing radiation in health care (e.g. radiologists, nuclear medicine physicians, interventionists), but also dentists, cardiologists, urologists, gastroenterologists, orthopaedists, surgeons, neurologists and others. In some countries, clinicians perform conventional imaging procedures, such as chest X-rays, in their own offices. All these specialists have a role to play in the radiation risk–benefit dialogue.

Important dialogue should take place between emergency physicians and RMPs, in advance of the emergency situation at the point-of-care. Imaging examinations should not be requested before the patient has been seen by a physician. Referral guidelines and appropriateness guidelines should be followed when requesting imaging. Such discussion is essential to establish safe patient pathways when the urgency of immediate care prevents

in-depth discussion of the individual patient. Issues include justification and optimization of CT of the child with multiple injuries or the choice of ultrasound and CT for acute abdominal pain in the paediatric patient.

Other professionals involved in patient care include policy-makers, regulators, equipment manufacturers and medical informatics support staff. For instance, dialogue between manufacturers and RMPs and medical physicists should include discussions on how to ensure that imaging equipment is designed with the imaging of adults and children in mind and includes appropriate paediatric protocols and dose-reduction algorithms.

Imaging of paediatric patients, no matter where it is performed, must take into consideration the specific needs of these patients. Most paediatric imaging is performed in facilities designed primarily for imaging adults. Imaging of children is ideally performed in radiology departments that include a regular paediatric practice.

### 3.3.5 The public health role in risk–benefit dialogue

International organizations, health authorities, regulatory bodies and research institutions have an important role in communicating and explaining the benefits and risks of medical imaging. As mentioned in section 3.3.1, the new BSS explicitly address the risk–benefit dialogue between patients and health-care providers. Indeed, the BSS require that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless (inter alia) the patient or the patient’s legal authorized representative has been informed of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks. It is therefore a responsibility of governments and regulatory bodies to support the radiation protection and safety provisions. Typically seen as a trustworthy source of information, policy-makers and decision-makers have an opportunity to encourage all stakeholders to recognize the benefits and risks of medical radiation exposure of children and to join efforts towards appropriate utilization of paediatric imaging to improve radiation safety and quality of health care. Medical students and other health-care professional trainees are a unique audience that health authorities can reach through various communication channels. It is essential to teach medical students and other health-care professional trainees both the benefits and risks of imaging examinations, as this will help them to understand the need for justification of all imaging studies, instilling a culture of justified use of imaging modalities.

Through an effective risk communication strategy, professional societies and associations and other relevant organizations (e.g. patient organizations) can advocate that all imaging examinations are justified and that dose-reduction strategies are implemented for all paediatric imaging. Health authorities have a responsibility to encourage dose optimization, the use of dose registries for diagnostic reference levels and the use of imaging referral guidelines in medicine. They also have an opportunity to educate the public through effective education and awareness campaigns. Patients need to know that they can, and should, ask their physician why an imaging examination is recommended, and should avoid imaging examinations that are not justified. It is of the utmost importance that patients and their families have an understanding of the benefits and risks of imaging procedures, so that necessary medical imaging is not refused, and the timely intervention and optimal care of a sick child is not unnecessarily compromised or delayed.



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# Annexes

**Annex A: Abbreviations**

**Annex B: Glossary**

**Annex C: Additional resources**

# Annex A. Abbreviations

ALARA	As low as reasonable achievable
BSS	Basic safety standards
CBCT	Cone-beam computed tomography
CDS	clinical decision support
CR	computed radiography
CT	computed tomography
DIP	diagnostic imaging pathways
DITTA	Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association
DPS	disintegrations per second
DR	digital radiography
DRL	diagnostic reference level
DRR	diagnostic reference range
FDG	fludeoxyglucose
ICNIRP	International Commission on Non-Ionizing Radiation Protection
ICRP	International Commission on Radiological Protection
IOMP	International Organization for Medical Physics
ISR	International Society of Radiology
ISRRT	International Society of Radiographers and Radiological Technologists
LAR	lifetime attributable risk
LBR	lifetime baseline risk
LNT	linear non-threshold
MRI	magnetic resonance imaging
MSCT	multi-slice computed tomography
PA	poster anterior
PET	positron emission tomography
PFPS	Patients for Patients Safety
RCR	Royal College of Radiologists
RMP	radiological medical practitioner
SPECT	single-photon emission computed tomography
UN	United Nations
UNICEF	United Nations Children's Fund
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
US	ultrasound
VCUG	voiding cystourethrograms
WFUMB	World Federation for Ultrasound in Medicine and Biology
WHO	World Health Organization
WONCA	World Organization of National Colleges, Academies and Academic Associations of General Practitioners and Family Physicians

# Annex B. Glossary

This document contains some terms that are commonly used in the field of radiation protection but that are not necessarily familiar to health professionals. A number of them have been included in the present glossary, to explain to the reader their meaning in the context of this document. Definitions of other relevant terms can be found in other publications such as BSS (2014) cited in the report and:

- WHO (2009). Conceptual framework for the international classification for patient safety. Geneva: World Health Organization ([http://www.who.int/patientsafety/implementation/taxonomy/icps\\_technical\\_report\\_en.pdf](http://www.who.int/patientsafety/implementation/taxonomy/icps_technical_report_en.pdf), accessed 28 January 2016).
- IAEA (2007). IAEA safety glossary. Terminology used in nuclear safety and radiation protection. Vienna: International Atomic Energy Agency ([http://www-pub.iaea.org/MTCD/publications/PDF/Pub1290\\_web.pdf](http://www-pub.iaea.org/MTCD/publications/PDF/Pub1290_web.pdf), accessed 28 January 2016).

**Absorbed dose:** Mean energy imparted by ionizing radiation to an irradiated medium per unit mass.

**Acute effects:** Adverse effects that occur within a short period of time (minutes to a few days) after an exposure.

**Acute exposure:** An exposure occurring within a short time relative to the life of a person or organism, usually consisting of a single exposure or dose administered for a period of 24 hours or less in humans.

**Age-at-exposure:** Age of an individual when the radiation exposure takes place. Cancer risk models based on human epidemiological data predict higher lifetime risks for exposure at younger ages than at older ages.

**Becquerel:** A unit of activity equal to one disintegration per second in the International System of Units.

**Cancer:** A group of related diseases characterized by the uncontrolled growth of abnormal cells.

**Cancer risk estimate:** The probability of developing cancer from exposure to radiation over a period of time.

**Carcinogen:** A physical, chemical or biological agent capable of inducing cancer.

**Caregivers:** persons who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing radiological medical procedures. They are also called “carers” or “comforters”.

**Child:** in the context of this document, a person below the age of 18. In the context of the law and human rights, UNICEF defines a child as a person below the age of 18, unless the laws of a particular country set the legal age for adulthood younger.

**Committed dose:** The dose expected to be received over the lifetime following the intake of a radioactive substance (i.e. after internal exposure).

**Deterministic effects:** Health effects, the severity of which varies with dose, and that typically occur only when a certain level of dose (threshold) is exceeded. Deterministic effects are also referred to as “tissue reactions” or non-stochastic effects.

**Dose:** A general term denoting the quantity of radiation or energy absorbed in a target. Related terms: absorbed dose, committed dose, dose estimate, effective dose.

**Dose assessment:** Assessment of the dose(s) to an individual or group of people.

**Dose coefficients:** Factors used to convert the amount of incorporated radioactive substances (radionuclide intake) to the dose in tissues or organs, or the whole-body dose. These factors (also called “dose conversion factors”) may depend on the radionuclide, the incorporation route (e.g. inhalation, ingestion), the chemical compound and the age of the person. Usually expressed as dose per unit intake, e.g. sieverts per becquerel (Sv/Bq).

**Dose estimate:** A representative value of the dose received in a particular exposure situation. They are approximate calculations of typical values rather than actual doses (e.g. patient dose estimates for different medical imaging procedures). See also dose.

**Dose limit:** In planned exposure situations the value of the individual effective dose or equivalent dose that is not to be exceeded. Dose limits apply to exposures of workers and members of the public, but they do not apply to medical exposures.

**Dose rate:** Dose delivered per unit time.

**Dose–response relationship:** Relationship between the magnitude of a dose and the biological response in an organism, system or (sub)population. Related term: dose–effect relationship.

**Effective dose:** Sum of the products of absorbed dose to each organ multiplied by a radiation-weighting factor and a tissue-weighting factor that takes into account the radiosensitivity of tissues and organs. Related term: absorbed dose.

**Effective half-life (see also half-life):** The time taken for the activity of a radionuclide in the body to halve as a result of all relevant processes (e.g. radioactive decay, biological half-life). The physical half-life is the time required for the activity of a specified radionuclide to decrease, through a radioactive decay process, by half. The biological half-life is the time taken for the quantity of a radioactive material in a specified tissue, organ or region of the body to halve as a result of biological processes.

**Equivalent dose:** Absorbed dose averaged over a tissue or organ, further applying a radiation-weighting factor that varies by radiation type and is related to the density of ionization created.

**Exposure:** The state or condition of being subjected to irradiation from a source outside the body (i.e. external exposure) or within the body (i.e. internal exposure).

**External exposure** (see exposure)

**Family:** parents or other relatives involved in a child’s care (see caregivers).

**Family physician:** a physician who practises family medicine/general practice as a clinical specialty orientated to primary care. See also general practitioner.

**General practitioner:** a physician who practises family medicine/general practice as a clinical specialty orientated to primary care. See also family physician.

**Half-life** (see also effective half-life) The time taken for the quantity of a specified material (e.g. a radionuclide) in a specified place to decrease by half as a result of any process or processes that follow similar exponential patterns as those of radioactive decay.

**Hazard:** the type and nature of adverse effects that an agent has, an inherent capacity to cause harm in an organism, system or (sub)-population. Hazard identification is the first step in the process of risk assessment.

**Health:** a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (definition provided in the WHO Constitution).

**Health effect:** changes in the health status of an individual or population, identifiable either by diagnostic or epidemiological methods.

**Health risk:** likelihood or probability of a health effect to occur under defined circumstances or exposure to a certain hazard (e.g. radiation).

**Internal exposure** (see exposure)

**Ionizing radiation:** radiation that has a high enough energy to remove electrons from atoms and is therefore capable of producing ion pairs in biological material(s). An example are the X-rays generated by the machines utilized to perform radiographies or computed tomographies (CTs).

**Late effects:** radiation effects that occur after symptom-free latent times of months to many years.

**Latency:** The time between exposure to a potential hazard (e.g. radiation exposure) and the appearance of a related health effect.

**Lifetime attributable risk (LAR):** Probability of a premature incidence of a cancer attributable to radiation exposure in a representative member of the population.

**Lifetime baseline risk (LBR):** The probability of having a specific disease over a lifetime, in the absence of radiation exposure.

**Linear no-threshold model:** Risk model that assumes that health effects are directly proportional to the dose at all dose levels (i.e. linear dose-response), without any threshold below which such effects are not expected.

**Long-term effects:** Adverse effects that can occur within a long period of time after an exposure (years to lifetime).

**Medical physicist:** a health professional with specialized education and training in the concepts and techniques of applying physics to medicine, and competent to practice independently in one or more of the subfields (specialties) of medical physics (e.g. diagnostic radiology, radiation therapy, nuclear medicine).

**Modelling (risk modelling):** Quantitative relationships established by using mathematical functions to calculate the magnitude of risks associated with an estimated exposure.

**Natural background radiation:** Amount of radiation to which a population is exposed from natural sources, such as terrestrial radiation resulting from naturally occurring radionuclides in the soil, cosmic radiation originating in outer space.

**Non-ionizing radiation:** electromagnetic waves that do not carry enough energy to ionize atoms or molecules. Example of medical use of non-ionizing radiation are ultrasonography that utilizes sound waves and magnetic resonance imaging (MRI) that utilizes a combination of strong magnetic fields, radio waves and magnetic field gradients.

**Nuclear medicine physician:** a physician who uses radioactive materials, called radiopharmaceuticals, to produce images of the body's organs or treat disease.

**Organ dose:** The mean absorbed dose in a specified tissue or organ of the human body. Sometimes called tissue dose.

**Paediatric:** referring to children (i.e. patients below 18 years of age).

**Paediatrician:** A physician who manages the physical, behavioural and mental health of children from birth until age 18 as a clinical specialty orientated to the primary care of children. There are physicians that are specialized in a number of paediatric sub-specialties (e.g. paediatric cardiologist, paediatric neurologist, paediatric surgeon, etc.). Paediatric radiology is a sub-specialty of Radiology.

**Procedure:** In the context of this document this term is used to refer to either a diagnostic examination or an image-guided intervention.

**Providers:** In the context of this document it refers to health-care providers. Examples of providers are physicians, physician assistants, radiographers, technologists, medical physicists, specialists in osteopathy, podiatrists, dentists, chiropractors, psychologists, optometrists and nurses.

**Radiation:** Energy that travels through matter. In the context of this document this term is used to refer to ionizing radiation. The radiation used for medical imaging is electromagnetic radiation that travels in "packets" of some minimum size called a quantum of energy or photon. Photons are characterized by their wavelength and energy: the shorter the wavelength, the more energetic is the photon. See also ionizing and non-ionizing radiation.

**Radioactivity (also called "activity"):** The property of the nucleus of unstable atoms that causes them to spontaneously release energy in the form of photons (e.g. gamma rays) or subatomic particles (e.g. alpha or beta particles). The amount of radioactivity is defined as the mean number of decays per unit time. The unit of activity in the International System of Units is the reciprocal second ( $s^{-1}$ ), termed the becquerel (Bq).

**Radiographer:** (see radiological technologists)

**Radiological medical practitioner:** A health professional with specialized education and training in the medical uses of radiation, who is competent to perform independently or to oversee procedures involving medical exposure to radiation in a given specialty (e.g. radiology, radiation therapy, nuclear medicine, dentistry, cardiology, etc.).

**Radiological technologists:** Also called “radiographers”. Health personnel who perform diagnostic imaging examinations, participate in image-guided interventional procedures and/or administer radiation therapy treatments.

**Radionuclide:** Radioactive species of an atom characterized by the constitution of its nucleus.

**Radiopharmaceuticals:** Molecules or chemicals that are attached to a small amount of radioactive isotope that, once administered to the patient, are able to specifically localize within organs and/or organ systems.

**Radiopharmacist:** A health professional with specialized education and training in radiopharmacy, who is competent to prepare and dispense radiopharmaceuticals used for the purpose of medical diagnosis or therapy.

**Radiotracer:** A radioactive isotope replacing a stable chemical element in a compound (said to be radiolabeled) and so able to be followed or tracked by means of a radiation detector; used especially in nuclear medicine.

**Referrer:** Also called “referring medical practitioner”. A health professional who, in accordance with national requirements, may refer individuals to a radiological medical practitioner for a medical procedure utilizing ionizing radiation (i.e. for a diagnostic or therapeutic radiological medical procedure).

**Risk:** Chance of harmful consequences associated with exposures or potential exposures. In the context of this document the term is used to refer to health risks associated with radiation exposure in medical imaging. This includes recognized risks (i.e. high-dose procedures) as well as potential risks (i.e. the overwhelming majority of diagnostic imaging procedures).

**Risk model:** Mathematical function that allows calculation of the magnitude of risks associated with a given exposure.

**Sievert:** The unit of equivalent dose and effective dose, equal to 1 J/kg, in the International System of Units.

**Solid cancers:** Cancers originating in solid organs, as opposed to blood cancers such as leukaemia.

**Source:** Anything that may cause radiation exposure by emission of ionizing radiation or release of radioactive substances or material, and that can be treated as a single entity for protection and safety purposes.

**Stochastic effect:** Adverse effects of ionizing radiation due to transformation of a single cell, which may result in an increased risk of disease a long time after exposure. These effects are probabilistic and include cancer and heritable effects. At low doses, radiation risks are primarily stochastic effects, in particular, cancer.

**Threshold (or “threshold dose”):** Minimal absorbed radiation dose that will produce a detectable degree of any given effect.

**Tissue reactions** (see deterministic effects)



# Annex C. Additional resources

## Chapter 1

### **Radiation units, sources of radiation exposure**

International Commission on Radiation Units & Measurements (ICRU)  
<http://www.icru.org/>

Australian Radiation Protection and Nuclear Safety Agency  
<http://www.arpansa.gov.au/radiationprotection/basics/units.cfm>

Canadian Centre for Occupational Health and Safety  
[http://www.ccohs.ca/oshanswers/phys\\_agents/ionizing.html](http://www.ccohs.ca/oshanswers/phys_agents/ionizing.html)

Public Health England – dose comparisons  
<https://www.gov.uk/government/publications/ionising-radiation-dose-comparisons/ionising-radiation-dose-comparisons>

US Centers for Disease Control radiation dictionary  
<http://www.bt.cdc.gov/radiation/glossary.asp>

Health Physics Society  
<https://hps.org/publicinformation/ate/faqs/radiationdoses.html>  
<https://hps.org/publicinformation/ate/faqs/radiation.html>

US Department of Health & Human Services  
[http://www.remm.nlm.gov/remm\\_RadPhysics.htm](http://www.remm.nlm.gov/remm_RadPhysics.htm)

US Nuclear Regulatory Commission (NRC)  
<http://www.nrc.gov/about-nrc/radiation/health-effects/measuring-radiation.html>

United States Environmental Protection Agency (EPA)  
<http://www.epa.gov/radiation>

### **Radiation doses and risks in paediatric imaging procedures**

The Image Gently campaign  
<http://www.imagegently.org/>

RpOP website of the International Atomic Energy Agency (IAEA)  
<https://rpop.iaea.org/>

Information site jointly produced by the American College of Radiology (ACR) and the Radiological Society of North American (RSNA)  
<http://www.radiologyinfo.org/>

National Cancer Institute at the National Institutes of Health  
<http://www.cancer.gov/cancertopics/causes/radiation/radiation-risks-pediatric-CT>

Information site from The Royal Australian and New Zealand College of Radiologists (RANZCR)

<http://www.insideradiology.com.au/pages/faq.php>

Radiation Risk to Children from Computed Tomography

Brody AS, Frush DP, Huda W, Brent RL (2007). Radiation risk to children from computed tomography. 120(3):677-682.doi: 10.1542/peds.2007-1910

<http://pediatrics.aappublications.org/content/120/3/677.short>

Information about medical exposures from Public Health England (PHE)

<https://www.gov.uk/government/collections/medical-radiation-uses-dose-measurements-and-safety-advice>

## Chapter 2

### Justification, appropriateness, referral guidelines

Appropriateness Criteria® American College of Radiology (ACR)

<http://www.acr.org/Quality-Safety/Appropriateness-Criteria>

International Society of Radiology

“Referral Guidelines for Diagnostic Imaging” pilot version

[http://www.isradiology.org/isr/quality\\_guidelines.php](http://www.isradiology.org/isr/quality_guidelines.php)

United Kingdom Royal College of Radiology iRefer

<https://www.rcr.ac.uk/clinical-radiology/being-consultant/rcr-referral-guidelines/about-irefer>

Canadian Association of Radiologists (CAR) – Diagnostic Imaging Referral Guidelines [in English and French]

<http://www.car.ca/en/standards-guidelines/guidelines.aspx>

Société Française de Radioprotection. Guide de bon usage des examens d'imagerie médicale [in French]

<http://www.sfrnet.org/sfr/professionnels/5-referentiels-bonnes-pratiques/guides/guide-bon-usage-examens-imagerie-medicale/index.phtml>

Orientierungshilfe Radiologie Austrian Referral Guidelines [in German]

[https://www.researchgate.net/publication/258836950\\_Orientierungshilfe\\_Radiologie\\_Anleitung\\_zum\\_optimalen\\_Einsatz\\_der\\_klinischen\\_Radiologie\\_4\\_Auflage\\_Hrsg\\_FFruh-wald\\_DTscholakoff\\_FKainberger\\_KWicke\\_Verlagshaus\\_der\\_Arzte\\_GmbH\\_Wien\\_2011](https://www.researchgate.net/publication/258836950_Orientierungshilfe_Radiologie_Anleitung_zum_optimalen_Einsatz_der_klinischen_Radiologie_4_Auflage_Hrsg_FFruh-wald_DTscholakoff_FKainberger_KWicke_Verlagshaus_der_Arzte_GmbH_Wien_2011)

Diagnostic Imaging Pathways – Australia

<http://www.imagingpathways.health.wa.gov.au/index.php/imaging-pathways>

Sociedad Argentina de Radioprotección (SAR)

Guía para la correcta solicitud de pruebas de diagnóstico por imágenes [in Spanish]

[http://www.sar.org.ar/web/educ\\_guias.php](http://www.sar.org.ar/web/educ_guias.php)

### Optimization

The Image Gently campaign

<http://www.imagegently.org>

RpOP website of the International Atomic Energy Agency (IAEA)

<https://rpop.iaea.org>

Radiation Protection in Paediatric Radiology (IAEA Safety Report Series 71)  
[http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1543\\_web.pdf](http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1543_web.pdf)

Information about paediatric imaging U.S. Food & Drug Administration (FDA)  
<http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm>

Journal of the American College of Radiology (JACR) radiation dose optimization in computed tomography: an online resource center for radiologists  
<http://doseoptimization.jacr.org/Home/Pediatrics>

### **Radiation safety culture**

Bonn Call for Action – 10 Actions to improve radiation protection in medicine (brochure)  
[http://www.who.int/ionizing\\_radiation/medical\\_exposure/bonncallforaction2014.pdf](http://www.who.int/ionizing_radiation/medical_exposure/bonncallforaction2014.pdf)

IRPA (International Radiation Protection Association)  
Guiding Principles for Establishing a Radiation Protection Culture  
<http://www.irpa.net/members/IRPA-Guiding%20Principles%20on%20RP%20Culture%20-2014%20.pdf>

IRPA-IOMP-WHO project on radiation protection culture  
<http://www.irpa.net/page.asp?id=179>

WHO Patients for Patient Safety – educational tools  
<http://www.who.int/patientsafety/education/en/>

## **Chapter 3**

### **Additional information for health professionals and patients**

Image Gently website  
<http://www.imagegently.org/>

IAEA website on Radiological Protection of Patients  
Information for patients and health professionals:  
<https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/Patients/index.htm>  
<https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/index.htm>

Radiology Info for patients  
<http://www.radiologyinfo.org/>

RADAR Medical Procedure Radiation Dose Calculator and Consent Language Generator  
<http://www.doseinfo-radar.com/RADARDoseRiskCalc.html>

FDA: Pediatric X-ray Imaging  
<http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm>

International Commission on Radiological Protection (ICRP) – Radiation and your patient – A guide for medical practitioners  
[http://www.icrp.org/docs/Rad\\_for\\_GP\\_for\\_web.pdf](http://www.icrp.org/docs/Rad_for_GP_for_web.pdf)

Diagnostic Imaging website  
<http://www.diagnosticimaging.com/low-dose/communicating-radiation-risk-pediatric-patients>



## COMMUNICATING RADIATION RISKS IN PAEDIATRIC IMAGING

The use of ionizing radiation in paediatric imaging saves lives and in many cases prevents the need for more invasive procedures. While every day applications of X-rays for medical imaging help millions of patients worldwide, inappropriate use may result in unnecessary and preventable radiation risks, particularly in children. A balanced approach is needed that recognizes the multiple health benefits, while addressing and minimizing health risks. Patients and families should have access to risk-benefit discussions about paediatric imaging when, where, and in the way they need to best understand the information and to be able to use it for making informed choices. Accurate and effective radiation risk communication is also necessary between health care providers who request or perform radiological medical procedures in children. By enabling informed decision-making, effective radiation risk communication contributes to ensure the greatest possible benefit of paediatric imaging, at the lowest possible risk. This document is intended to serve as a tool for health care providers to communicate known or potential radiation risks associated with paediatric imaging procedures, to support risk-benefit dialogue during the process of paediatric health care delivery.



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