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 inherit 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 3.7×10^{10} (37 billion) radioactive disintegrations per second[a]. 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 bequerel (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 bequerel (Bq)	1 picocurie (pCi)	0.037

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

Natural Radioactivity in Food		
Food	^{40}K (Potassium)	^{226}Ra (Radium)
Banana	130 Bq/kg	0.037 Bq/kg
Brazil Nuts	207 Bq/kg	37–260 Bq/kg
Carrot	130 Bq/kg	0.02–0.1 Bq/kg
White Potato	130 Bq/kg	0.037–0.09 Bq/kg
Beer	15 Bq/kg	NA
Red Meat	110 Bq/kg	0.02 Bq/kg
raw	170 Bq/kg	0.07–0.2 Bq/kg

Nuclide	Typical Amount of Natural Radioactivity in the Body[b]
Uranium	1.1 Bq
Thorium	0.11 Bq
Potassium	4.4 kBq
Radium	1.1 Bq
Carbon	3.7 kBq
Tritium	23 Bq
Polonium	37 Bq

[a] 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.

[b] 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.

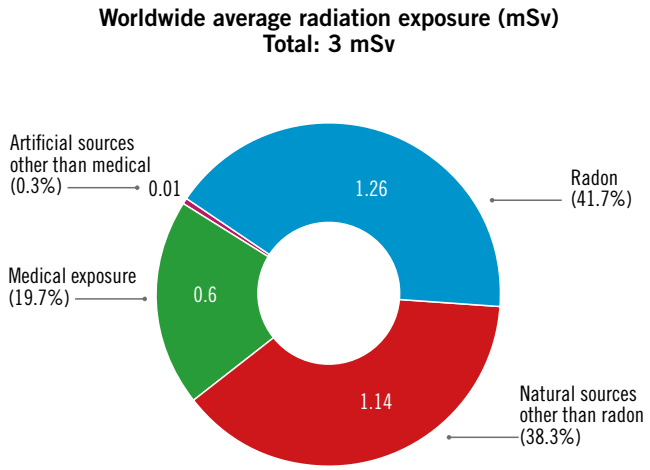
In the context of this document the term *dose* is used to refer to radiation dose estimates for a number of typical diagnostic medical procedures. These are only typical values rather than accurate radiation dosimetry data.

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.

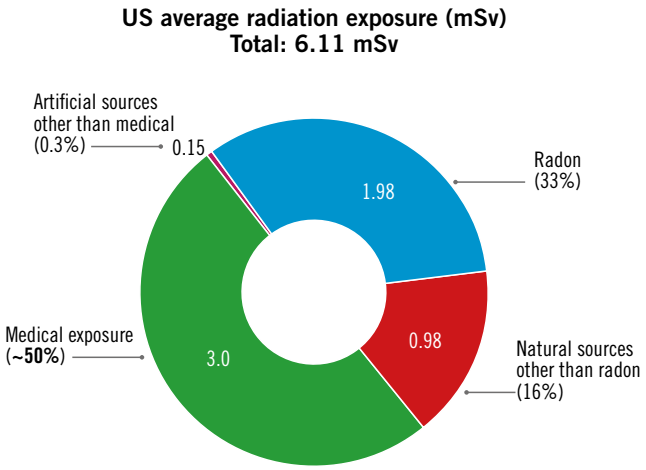
Additional terms are defined in the glossary (Annex B).

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



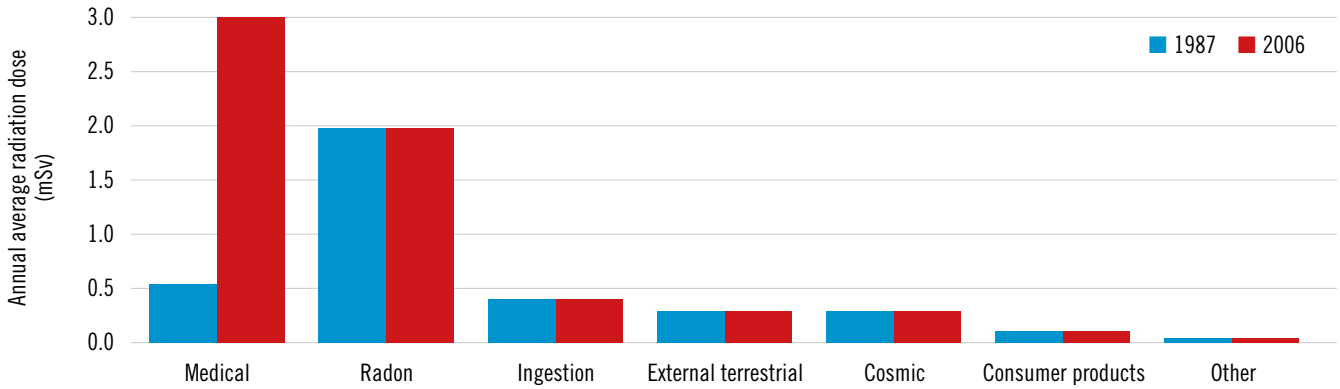
Source: Adapted, with permission, from UNSCEAR (2010)

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



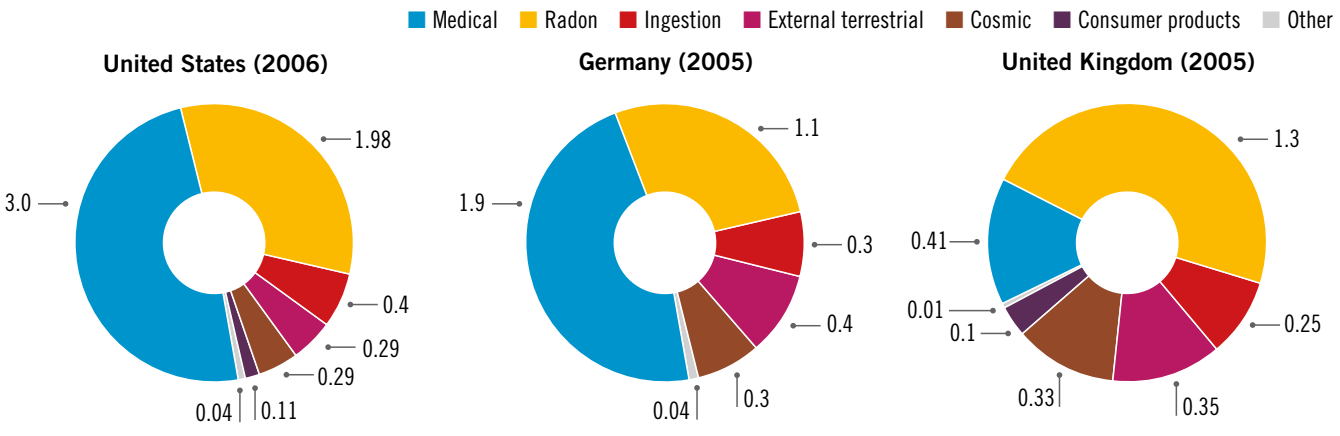
Source: Adapted, with permission, from NCRP (2009)

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[a])
Natural sources of exposure	
Inhalation (radon gas)	1.26 (0.2–10)[b]
Ingestion (food and drinking water)	0.29 (0.2–1)
External terrestrial	0.48 (0.3–1)[c]
Cosmic radiation	0.39 (0.3–1)[d]
Total natural	**2.4 (1–13)[e]**
Human-made sources of exposure	
Medical diagnosis (not therapy)	0.6 (~0–20+)
Others (e.g. nuclear energy and previous nuclear weapons tests)	~0.005
Total artificial	**0.6 (~0–20+)**
Total	**3 (1–20+)**

[a] mSv: millisievert, a unit of measurement of effective dose
[b] The dose is much higher in some dwellings
[c] The dose is higher in some locations
[d] The dose increases with altitude
[e] 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.[1] 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%).

1. 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)[a]

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	**6.3**[b]	**43.2**[b]
Angiography and fluoroscopy-guided interventional procedures	< 1	6.1
Other X-ray medical imaging procedures	3	11
Dental procedures[c]	13	< 1

[a] Typical procedures and doses for paediatric patients are presented in **Table 3**

[b] 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

[c] 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[a]

Regions examined	Percentage of all the examinations of this type in each of these anatomical regions that are performed in children < 15 years
Radiography	
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%
CT Scans	
CT head	8%
CT abdomen	4%
CT thorax	5%
CT spine	3%

[a] 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).

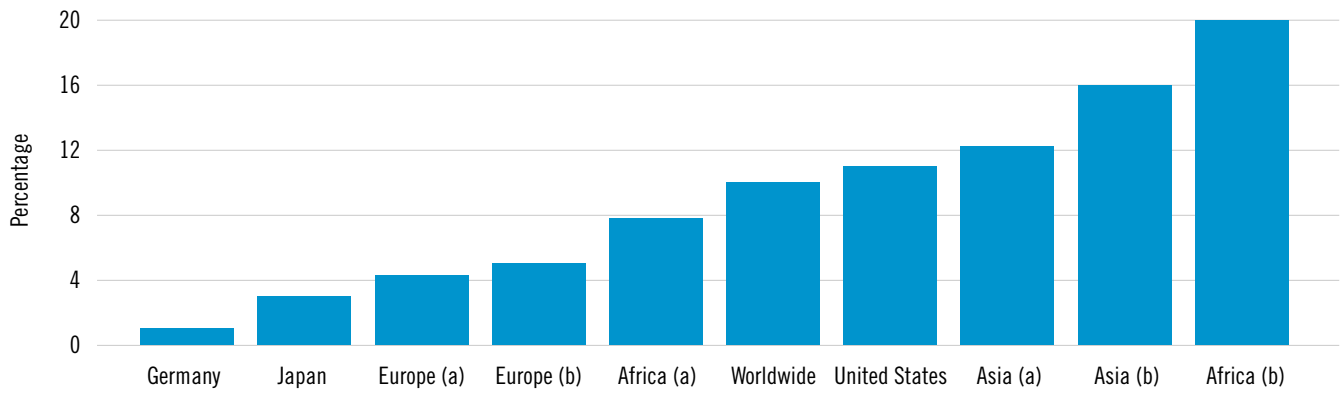
CT represented about 6% of all medical imaging procedures performed worldwide between 1997 and 2006, and accounted for the 43% of the total dose resulting from those procedures. The contribution of CT to the collective dose in 1991–1996 was 34% (UNSCEAR, 2010). Even though modern CT equipment has reduced 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

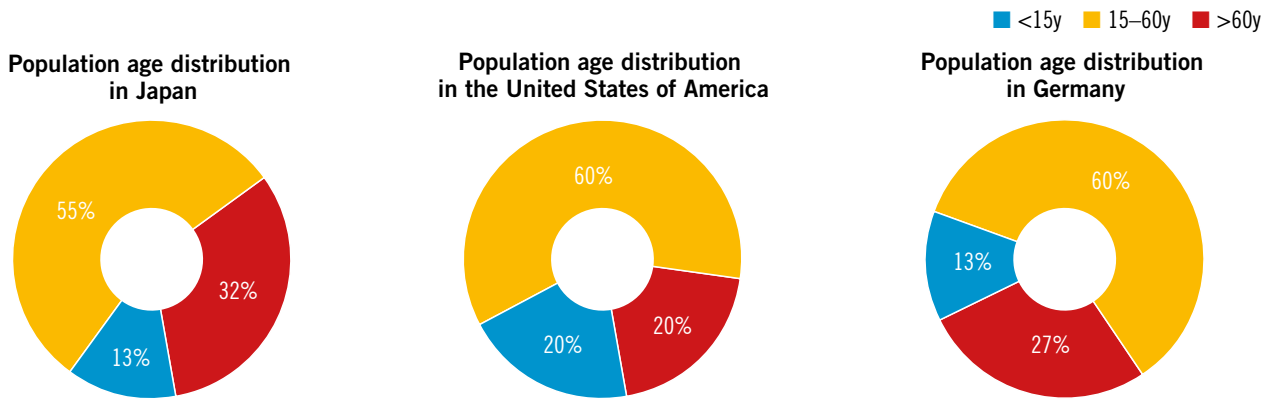
Figure 5: Percentage of the total CT scans which are performed in children in different regions of the world[a]



[a] Different data from Europe, Africa and Asia are shown: (a) from Vassileva et al. (2012) and (b) from Muhogora et al. (2010)

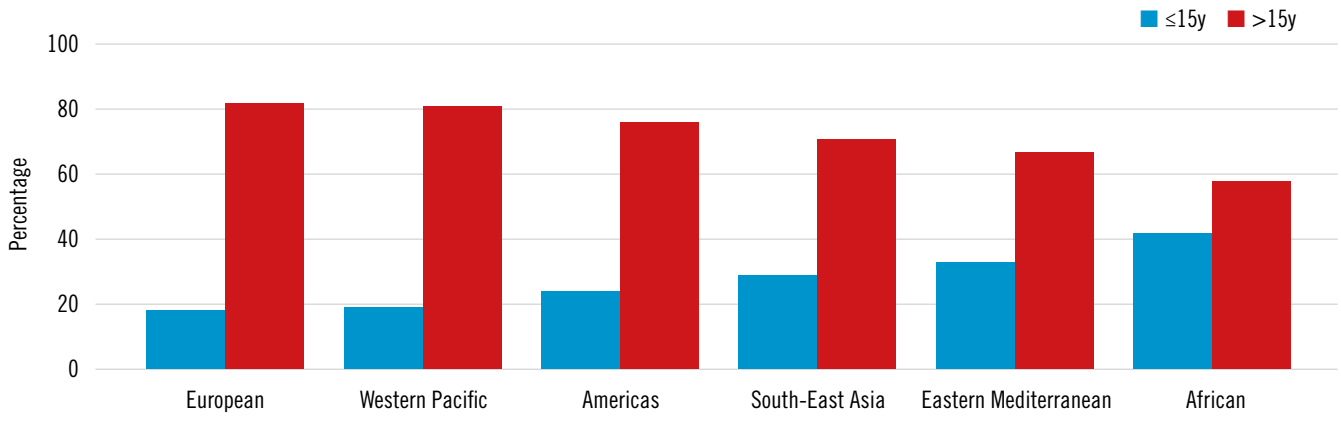
Source: Based on data published in (UNSCEAR, 2010). (Galanski, Nagel & Stamm, 2006). Vassileva et al. (2012) and Muhogora et al. (2010)

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[a]

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

[a] 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.
[b] Based on a worldwide average of 2.4 mSv/year
[c] Mettler et al. (2008)
[d] From the Image Gently website (http://www.imagegently.org/)
[e] Rather than actual age, this refers to phantoms equivalent to a reference child of typical physical dimensions for that age
[f] Johnson et al. (2014)
[g] Rather than actual age, this refers to phantoms equivalent to a reference child of typical physical dimensions for that age
[h] European Commission (2012)
[i] Bacher et al. (2005)
[j] 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.[2]

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).

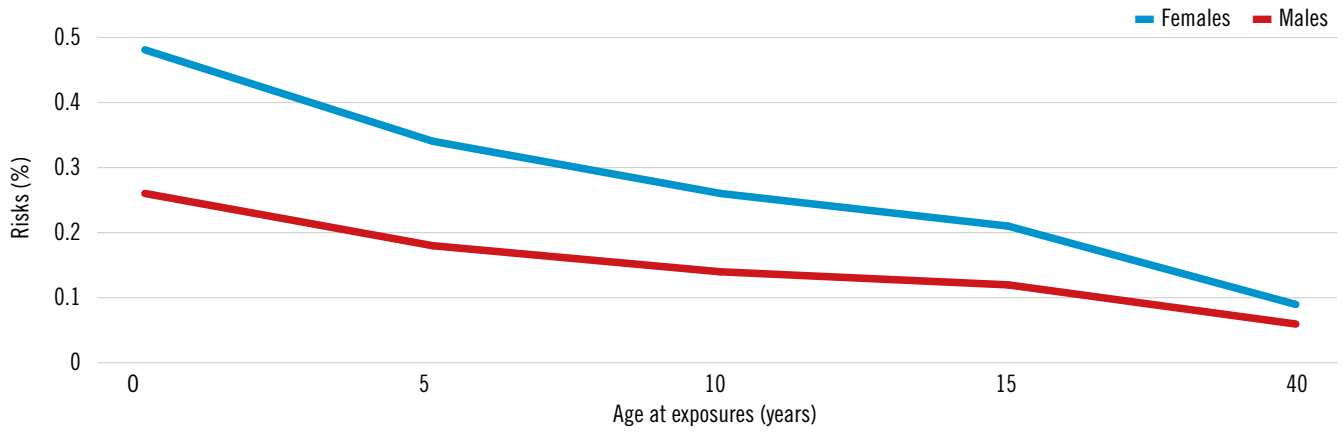
Despite robust DNA repair mechanisms within the body, radiation exposure can also induce non-lethal transformation of cells. The transformed cells that are not removed may become malignant after a long latency period (several years to decades). Effects of this nature are termed "stochastic effects". 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;

2. 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.[3] 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.

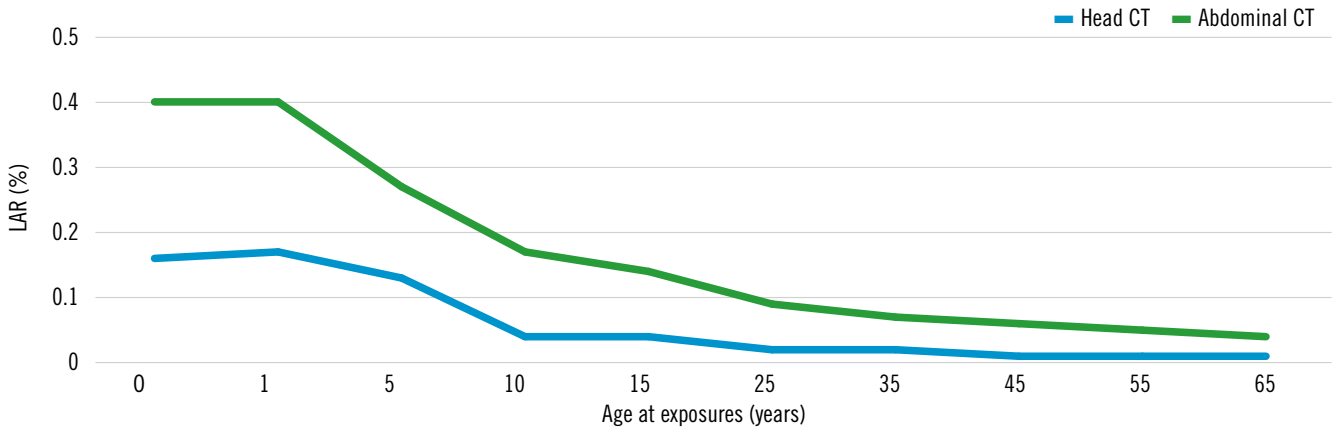
Everybody has a chance of having a cancer (incidence) and/or dying from cancer (mortality) over the course of her/his lifetime. This is the so-called "lifetime baseline risk" (LBR). The additional risk of premature incidence or mortality from a cancer attributable to radiation exposure is called the "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

3. 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[4] (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[5]), 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,

4. 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).

5. 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)[a]	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

[a] 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)[a]	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

[a] 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[a]
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

[a] 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.[6]

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.

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6. 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).