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).

How the experts perceive risk

Hazard x exposure x susceptibility



How the public perceive risk

Hazard + [fear, anger, outrage]

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).

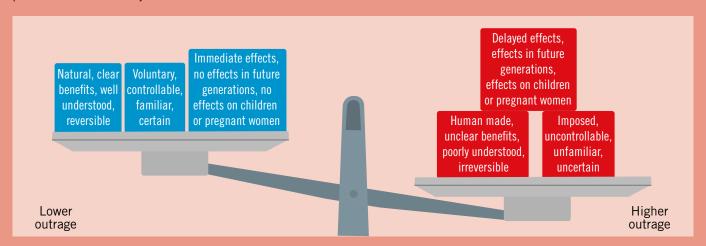


Fig. B. Factors influencing risk perception

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.

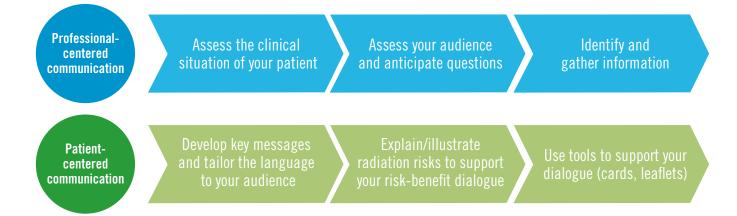
Preparing for patient-centred communication

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 μ 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	
"Why are you recommending this radiological examination?"	"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."	
"Are there any risks of this radiological examination?"	"One concern is the possibility of cancer resulting from the radiation from this examination."	
"How great is this risk?"	"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."	
"How does the risk from this radiological examination compare to the risk of [my child's presenting condition]?"	 "I have considered your current situation carefully, taking into account many factors." Depending on the circumstances: "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." "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." 	
"When will these risks occur?"	"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).	
"What is the safest course of action?"	"Comparing the potential risks of this radiological examination against the risk of your child's condition, the safest course is"	
"What are my options?"	"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 <u>long-term effects</u> 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%).¹ 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.

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.

I) 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 Gently²) 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 scan³ 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.⁴
- 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.

^{2.} http://www.imagegently.org/

^{3.} In some countries people are more familiar with the term "CAT" to informally refer to computed tomography

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.5
- 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.

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. 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 medicine⁷ 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.

^{6.} 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"

^{7.} 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.8

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).9
- 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!

^{8.} 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, Parisis & Treves, 2011; Lassmann et al. 2007; Lassmann et al., 2008)

^{9.} 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 professionals¹⁰ 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.

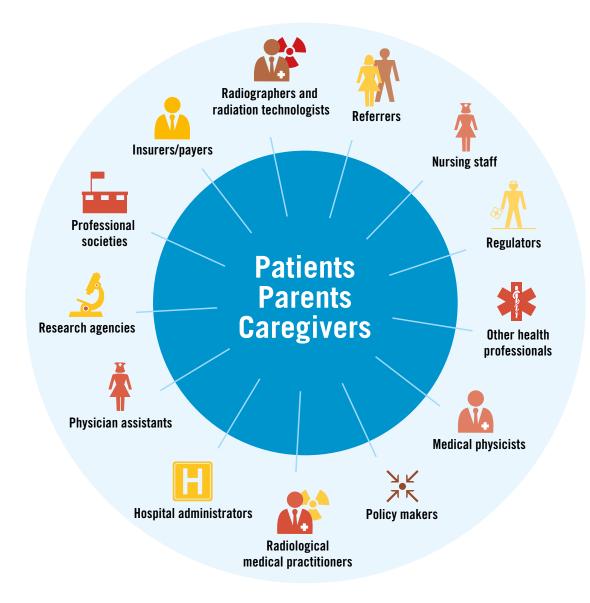
3.3.2 Dialogue between referrers and radiological medical practitioners

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

^{10.} 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.