Summary of the IAEA Technical Meeting on Radiation Protection of Paediatric and Pregnant Patients

27 February - 1 March 2023

Motivation for the meeting

The rapid advance of medical radiation technology has opened new opportunities for improved diagnosis and treatment of cancer and other disorders. As a result, the use of all medical imaging and therapeutic procedures, including those that depend on ionizing radiation, has continued to increase, in both children and adults. Owing to the higher radiosensitivity of children and issues with the combination of fetal and maternal exposure in pregnant patients, these populations may have unique requirements to ensure a balance is achieved between the medical benefits and risks.

The International Basic Safety Standards, published in the IAEA Safety Standards Series No. GSR Part 3, require special consideration with respect to justification and optimization of radiation protection for paediatric patients or those who are pregnant or breast-feeding. Guidance for practical implementation is provided in the IAEA Specific Safety Guide SSG-46, Safety Report Series No. 71, and further resources, including training and information material, are provided by the IAEA through the specialized website on Radiation Protection of Patients. Other international organizations and professional bodies also provide guidance and training resources for radiation protection of the paediatric and pregnant patients.

The Bonn Call for Action by the IAEA and WHO, calls for a holistic approach and international cooperation aiming at identifying and implementing solutions to address existing and emerging challenges, and highlighted ten main actions and related sub-actions for the strengthening of radiation protection in medicine over the next decade. These actions have a special emphasis given to the need to strengthen investigations in low-dose health effects and radiological risks from external and internal exposures, especially in children and pregnant women (Action 5), and to ensure establishment, use of, and regular update of diagnostic reference levels for radiological procedures, including interventional procedures across all ages (Action 2).

Considering that a decade has passed since the release of the Bonn Call for Action, and owing to the rapid advance of medical practices and the importance of the radiation protection for the most sensitive groups, the IAEA convened this Technical Meeting.

Objectives

The Technical Meeting had the following objectives:

- To review the current state of knowledge on (1) the radiation effects in the embryo, fetus and children relevant to medical uses of ionizing radiation, and (2) medical radiation technology and clinical advances and other aspects to promote the appropriate balancing of benefits and risks in medical uses of ionizing radiation for paediatric and pregnant patients, as well as for breastfed children and their mothers from radiopharmaceutical procedures.
- To provide a platform for sharing information from the Member States and professional bodies about the successes and challenges in the practical implementation of the principles of justification and optimization of radiation protection for these special groups, including tools such

as referral guidelines for imaging, diagnostic reference levels, clinical protocols tailored to the specific patient needs, and use of patient shielding.

- To identify the needs for the development of guidance and other tools for ensuring the radiation protection of paediatric and pregnant patients undergoing diagnostic and therapeutic medical radiation exposures, and patients undergoing nuclear medicine procedure while breastfeeding.

Attendance

The meeting was attended by 91 participants and experts (68 in person and 23 online) representing 45 Member States, as well as 17 international organizations and professional bodies presented in Annex 1. Meeting participants represented a wide spectrum of specialties including epidemiologists, paediatric radiologists, radiation oncologists, nuclear medicine physicians, physicians performing interventional procedures, medical physicists, technologists/ radiographers, radiation protection specialists, ethicists, and regulators.

Agenda

The meeting agenda is in Annex 2.

Updates on the medical exposure in pregnancy and childhood and associated radiation risks (summary of session 2)

Medical exposures remain the largest contributor to radiation exposure of the population from artificial sources, as noted in the latest report relating to medical exposure to ionizing radiation of the United Nations Committee on the Effects of Atomic Radiation (UNSCEAR). Although the frequency varies significantly among countries and modalities, it is estimated that approximately 3-10% of all radiological procedures are performed on children. **International collaboration in collecting information on medical exposures is essential**.

Overall, children are more sensitive to radiation effects than adults, but this varies within both stochastic effects and tissue reactions. UNSCEAR 2013 report shows that children are more sensitive than adults to a number of tissue reactions (neurocognitive, growth, cardiovascular and thyroid effects, among others) following moderate and high acute doses, and most age-at-exposure sensitivity effects are not apparent at acute doses under 0.5 Gy. There is clear increased risk for exposure in childhood vs adulthood for leukemia and thyroid, breast, skin and brain cancers (~25% of cancers), similar risk for 15% of cancers (e.g., bladder), while others (~10%, e.g., lung) have a lower risk, with the remaining percentage uncertain. Accurate estimation of risks requires data derived from observations of exposed children and not just generalizations from observations of adults: **development of radiation dose databases for all ages and both sexes that can be combined and tracked long term are recommended.**

Although medically exposed groups offer a valuable complement to evidence derived from the Japanese atomic-bomb survivors, care in interpretation is required, as exposure occurs because of known or suspected disease and this may bias the risk estimates obtained from medical studies, and accurate dose estimates are often lacking. The EPI-CT cohort study concluded a significant linear dose-response relationship for brain cancer of 1.27 ERR per 100 mGy, meaning that for every 10 000 children who received a head CT, about one radiation-induced brain cancer is predicted to occur during a 5–15 years following the examination. Further follow-up of this cohort, and the other ongoing epidemiological studies should provide more detailed information about patterns of risk.

Radiation risk from the exposure of the gravid uterus depends on the stage (eg., conceptus, embryo and fetus age) of pregnancy at the time of irradiation, and on the resultant absorbed dose. Irradiation with moderate and high doses above a certain threshold produce abortion, malformations, growth restriction or cognitive deficits. An association between a low dose of X rays to the fetus and risk of

most types of childhood cancer has been reported. Higher doses may produce a raised risk of childhood solid cancers, but not leukemia. There is also evidence of cancer risk from prenatal exposure extending into adult life.

Managing medical exposure during pregnancy and breastfeeding (summary of sessions 3 and 4)

For most diagnostic radiology examinations and nuclear medicine procedures with short-lived radionuclides (such as ^{99m}Tc or ^{18}F) radiation risk to fetus is minimal. In addition to adherence to the principles of justification and optimization, technological developments also contribute to dose reduction. In diagnostic nuclear medicine imaging, fetal dose can be additionally reduced by encouraging frequent urinary voiding, such as by drinking water.

Pregnancy screening is a key action to avoid accidental exposure of the fetus.

Scientific data show that contact shielding is not required during well optimized medical imaging procedures in pregnancy, but use may be appropriate in certain settings which should be addressed in practice policies/procedures, and implementation of shielding during pregnancy should include proper education and communication procedures for advantages and disadvantages for the patients.

Radioiodine (such as ^{131}I) may cause significant fetal thyroid harm and is contraindicated in pregnancy. If pregnancy is discovered early after the administration, giving stable iodine reduces dose.

Current guidelines (eg: SSG-46) provide recommendations on avoidance of pregnancy following radionuclide therapy. Various guidelines (e.g. ICRP128 annex D, IAEA safety guide SSG-46, EANM) advise cessation of breastfeeding after nuclear medicine procedure, periods varying depending on the type of radiopharmaceutical. **More data on the newer radiopharmaceuticals and their effect would be very useful, as well as harmonized recommendations on this topic.**

When needed, fetal dose in diagnostic imaging can be estimated using various methods, among which dedicated software packages or estimation based on normalized data are practically applicable to the everyday clinical practice. Wide variation of fetal dose estimation suggested a need to identify factors affecting this variation and guidance on limitation of each calculation method. **Artificial intelligence (AI) plays a role, but research is needed to better understand the value.**

In rare situations where radiotherapy is needed for a pregnant patient, it is essential to be able to calculate the patient specific fetal dose according to each situation (prescribed dose, tumor location, stage of pregnancy, evolution of the size of the fetus during treatment and treatment type) rather than generalize the results for all patients. Out-of-field dosimetry in proton and photon radiotherapy in pregnancy is a topic of further research. **There is a need to increase knowledge on how to optimize fetal doses considering treatment planning parameters (treatment technique) and the quality of the patient treatment plan vs fetal dose reduction.**

Dose assessment and dose monitoring in paediatric imaging (summary of session 5)

The latest developments and challenges in patient dose assessment for different modalities, including setting and using diagnostic reference levels (DRLs) for optimization were discussed in this session. The need was highlighted for improving access to adequate and calibrated dosimetry equipment, dose documentation in the appropriate format (accuracy vs availability), verification of dose indices provided by the x-ray systems, and uncertainty assessment. Proper dosimetry requires involvement of clinically qualified imaging medical physics that is a challenge for many countries.

Dose data collection for establishing paediatric DRLs requires proper planning and involvement of different parties. Challenges exist in the following: 1) cohort characterization (e.g. PiDRL study in Europe suggested weight for body and age for head CT examinations, and the proposed USA

paediatric DRLs are size- and age-based); 2) classification of examinations (DRLs based on clinical indications have some advantages compared to anatomy-based DRLs); and 3) small sample size due to a low frequency of paediatric exams. Possible solutions for overcoming challenges include establishing regional DRLs involving several countries, and the DRL-curve approach on experience of Nordic countries. Automatic dose monitoring systems facilitate data collection and should be further promoted along with the data verification and curation.

The proper use of DRLs to benchmark local practices and objectively guide optimization process is linked to dissemination of information and promotion, education and training, and involvement of all professional groups, including regulators.

Radiation protection optimization in paediatric diagnostic imaging: best practice and challenges (summary of session 6)

The session focused on technology and clinical advances with resultant leverage improving the balancing between benefits and risks. The need for on-going education and guidance with technological and scientific advances continue to be a priority, particularly for pediatric applications where adoption maybe be delayed, for example out of an abundance of caution.

As a best practice for radiation protection of children, before performing any ionizing radiation examination, the justification (i.e., value) of the examination is to be acknowledged, and may require discussion with the referrer and/ or the patient/ caregiver. For all imaging examinations, best practices include the need for patient positioning and immobilization, and age or size appropriate technical adjustments for the examination.

The technological advances in CT include dual energy CT, adaptive bow-tie filters, or most currently photon counting CT, and artificial intelligence (AI)/deep learning (DL) post-processing. More simply, adherence to existing recommendations for consistent pediatric imaging are needed. Studies found variable (250%) patient dose between and within facilities, with dedicated pediatric facilities outperforming adult facilities. Minor dose savings have been shown (~10%) for tube current modulation (TCM) and organ based TCM. A challenge is that the 16 cm collimators used in axial mode create large dose depositions. **AI/DL is not being developed for pediatrics at the same rate as adults in the medical imaging domain; clarification of appropriateness for children in existing applications, pediatric-conscious development, and advocacy are needed.**

The use of cone beam CT (CBCT) in dentistry continue to grow, with over 50 various systems on the market with many protocol options, variable geometry of exposure in relation to the radiosensitive organs, resulting in variable doses. There is a need of As Low as Diagnostically Acceptable, indication-oriented and patient-specific dose optimization of protocols for children.

Patient contact shielding in pediatric imaging was discussed, and a need identified to further education for imaging professionals and patients, parents, and caregivers. Involvement of radiation protection authorities and regulatory bodies is found to be important, to reduce conflicts between recommendations and legislation. **The recommendation by the participants was that the IAEA develop an international guidance document on this topic.**

Radiation protection optimization in paediatric nuclear medicine and radiotherapy: best practice and challenges (summary of session 7)

Optimization in paediatric practice requires dedicated well-trained and empathetic staff, a friendly and comfortable environment, informational material for parents and children, and access to pediatric appropriate equipment and optimized protocols. This is linked to team work and safety culture.

In nuclear medicine, the EANM paediatric dosage card is widely used to optimize administered activity for children. Advances in PET technology calls for updates of the pediatric dosage card, depending on the technology used.

In radiotherapy, the major concern for paediatric patients is to characterize and develop dosimetry systems for the assessment of out-of-field doses and the related risks of second cancer following radiotherapy. Proton Pencil Beam Scanning (PBS) radiotherapy reduce out of field doses up to two orders of magnitude in comparison with earlier techniques such as Three-Dimensional Conformal Radiation Therapy (3DCRT), Intensity-Modulated Radiation Therapy (IMRT) or Gamma-Knife. The main dosimetric challenges remain for neutrons in proton PBS. There is a need to further promote research on out-of-field doses in pediatric and pregnant patients for different RT techniques, their prediction and inclusion in the treatment planning optimization for pediatric patients. Frequency of CBCT imaging during the course of RT of children needs careful consideration.

Despite the growth of AI-based studies in the scientific literature, only a few AI-based models have been deployed in the RT clinic so far. The concerns are related to the risks of unintended and negative consequences, lack of standardization and harmonization of data used to develop and train the AI-based models, challenges in their implementation and quality assurance, legal and ethical issues, and lack of specific education and training of radiation medicine and medical physics professionals. A multidisciplinary approach to AI-based tools is needed for safe and effective clinical implementation of AI. **The IAEA has a specific role to provide recommendations and support Member States by identifying roles and responsibilities of clinically qualified medical physicists and other health professionals involved with AI, education and training requirements, providing guidelines and advice as requested.**

Justification for medical imaging: challenges with children (summary of session 8)

The objective of the session was to understand, based on current guidance, what are successes and challenges for appropriate use of imaging for children. It was highlighted that there is still low awareness of radiation doses and variations in imaging pathways for children in clinical practice that contribute to debates about imaging appropriateness. Justification as a radiation protection principle as applied to medical applications is not a binary yes/no judgement (although this can be the perception). Justification involves assigning a reasonable level of value based on all available information to select the most appropriate examination for the individual needs of each patient. This is a shared responsibility between clinician and radiologist – radiologists are not in the trenches and must be understanding of the multitude of factors that contribute to the value of an examination by referring clinicians. A challenge is when professional clinical experience differs from evidence-based imaging guidelines, which may often be generic and not patient-centered. The view from the imaging specialist over perceived value and that from the provider may not be mutually recognized. Input from referrers is essential when developing imaging guidelines as is reciprocal education by imaging experts for referrers that affords more informed understanding of the benefits for imaging. Availability of these more consensus imaging guidelines offers audits to be performed with comparison to standards, and mindful of the complexities with “justification” from the referrer standpoint.

Further trusted information resources would help increase awareness among physicians, patients and parents and help reduce unjustified examinations.

Radiation risk-benefit communication in paeditric healthcare (summary of session 9)

The objective of the session was to discuss the role of different stakeholders in fostering risk-benefit dialogue. The session was built on the information about the WHO project on Communicating radiation risks in paediatric imaging. The medical radiation practitioners have a responsibility to communicate risks and benefits of medical imaging; the document targeted this line of communication with medical providers although there can be situations in which input from imaging

professionals with patients and families may be necessary. Communication should be considered as a dialogue, not a monologue. The WHO guidance for medical practitioners provides the model of message mapping for consistency in delivering the message.

There are four key principles for ethical decision-making in health care: autonomy, beneficence, non-maleficence and justice. Informed consent is a vital element in the healthcare, medical professionals have the duty to disclose risk, preferably from the patient's perspective.

Communication among professionals is key, especially when change of practice is foreseen. A lesson learned from the topic of discontinuing patient contact shielding is that consensus should be built among professionals and communication strategies and tactics developed, before any change in practice for patients and caregivers.

Public and representatives of all possible stakeholders need to be involved in developing strategies for communication. Communication needs skills and training, with due consideration of cultural aspects. Communication strategy should consider development of outreach material and multiple platforms specifically designed for patients and caregivers. **Further efforts are needed to better involve referring physicians and develop approaches and resources for improving their awareness and knowledge on radiation doses and risks along with the clinical value of various medical imaging modalities.**

Conclusions and recommendations

Even though the use of diagnostic imaging including nuclear medicine, and radiation therapy in pregnancy and childhood occur across the globe, comparable approaches to these practices are still not global. Further effort is needed on developing a more human-centered narrative with the patient in focus, including shared decision making; this can reduce anxiety by better informing on the value and potential risks of medical imaging and radiation therapy, leading to improved individual patient care. This approach also requires a commitment to provider education and shared dialogue regarding medical imaging, especially justification/value which can also enhance their essential role in the shared decision-making process.

Developments in pediatric health care and related radiation protection should continue to be driven by the evidence-based science and technological developments. Taking advantage of the easier access to information and data, researchers, practitioners, and regulators need to join efforts in ensuring access to up-to-date guidance and tools to best inform the decision-making process that are based on holistic benefits and risks. As people, rather than guidelines, make decisions, more focus is needed on improving the education, training and communication through developing effective approaches and tools adapted to the current realities of medical care. International cooperation will continue to play important role.

ANNEX 1. Represented international organizations and professional bodies (in alphabetical order)

American College of Radiology (ACR)
American Association of Physicists in Medicine (AAPM)
European Association of Nuclear Medicine (EANM)
European Federation of Organizations for Medical Physics (EFOMP)
European Federation of Radiographer Societies (EFRS)
European Radiation Dosimetry Group (EURADOS)
European Society of Radiology (ESR)
Heads of the European Radiological Protection Competent Authorities (HERCA)
Image Gently Alliance for Radiation Safety in Pediatric Imaging
International Association of DentoMaxillofacial Radiology (IADMFR)
International Commission on Radiological Protection (ICRP)
International Organization for Medical Physics (IOMP)
International Society of Radiographers and Radiological Technologists (ISRRT)
International Society of Radiology (ISR)
United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)
World Federation of Paediatric Imaging (WFPI)
World Health Organization (WHO) **ANNEX 2. AGENDA of the Technical Meeting**

Monday, 27 February 2023

8:00 – 9:30	Registration at the UN Pass Office	
9:30 – 10:00	**Session 1: Opening session** ***Objective:*** *Introductions, welcome, and logistics* Opening Introductions Expectations from the meeting, scope and program	 IAEA All J. Vassileva, Scientific secretary
10:00 – 12:30	**Session 2: Setting the scene** ***Objective:*** *Identifying the background information about medical exposure in pregnancy and childhood and associated radiation risks*	Session Chair: D. Frush Rapporteur: M. Mahesh
15’	Overview of the topic by the Meeting Chair	D. Frush
15’	WHO perspective	E. Van Deventer
15’	IAEA activities and resources on radiation protection of paediatric and pregnant patients	O. Holmberg
10:45 – 11:15	*Coffee break and Group photograph*	
20’	Updated data from UNSCEAR reports on medical exposure of children and health effects	F. Shannoun
20’	Risks to health from exposure to ionizing radiation in utero and in childhood	R. Wakeford (online)
20’	Update from epidemiology on cancer effects: EPI-CT cohort study and HARMONIC project	I. Thierry-Chef

15’	Discussion	Open discussion
12:30 – 13:30	*Lunch break*	
13:30 – 15:00	**Session 3: Medical exposure in pregnancy: X-ray imaging** ***Objective:*** *Review the current understanding of use of radiation in pregnancy and associated challenges for radiation protection*	Session chair: J. Damilakis Rapporteur: N. Pongnapang
15’	Diagnostic and interventional radiology procedures of pregnant patients: when and how?	J. Kasznia-Brown
15’	Estimation of fetal doses from X-ray imaging: an update	J. Damilakis
15’	Fetal dosimetry in diagnostic and interventional radiology procedures: update from EURADOS WG 12	G. Simantirakis
30’	Approaches to optimization of X-ray imaging procedures in pregnancy, and communication with patients and providers	Panel: speakers, plus K. Applegate (ICRP) M. Mahesh (IOMP, ACR) P. Gilligan (EFOMP) N. Pongnapang (ISRRT) N. Kirk (EFRS)
15’	Discussion	Open discussion
15:00 – 15:30	*Coffee break*	
15:30 – 17:00	**Session 4: Medical exposure in pregnancy and breastfeeding: nuclear medicine and radiotherapy** ***Objective:*** *Review the current understanding including challenges in the use of nuclear medicine and radiotherapy procedures during pregnancy and breast feeding*	Session chair: R. Bly Rapporteur: S. Somanesan
20’	Managing pregnant and breastfeeding patients in nuclear medicine	S. Holm
10’	IAEA recommendations for avoidance of pregnancy following radiopharmaceutical therapy and for cessation of breast-feeding following administration of radiopharmaceuticals	J. Vassileva
15’	Out-of-field dosimetry in radiotherapy in pregnancy (update from EURADOS)	M. De Saint-Hubert
10’	Fetal dose assessment for pregnant women with cancer treated by external radiotherapy – toward recommendations on treatment planning (France)	M. Edouard
35’	Managing nuclear medicine and radiotherapy procedures during pregnancy and breastfeeding	Open discussion

Tuesday, 28 February 2023

9:00 – 10:30	**Session 5: Dose assessment and dose monitoring in paediatric imaging** ***Objective:*** *Review the latest developments and challenges in patient dose assessment for different modalities, including setting and using DRLs*	Session chair: D. Frush Rapporteur: O. Ciraj-Bjelac
15’	Introduction to the discussion on paediatric imaging	D. Frush
15’	Dosimetry in diagnostic radiology for paediatric patients: IAEA activities and resources	O. Ciraj-Bjelac
15’	Challenges with DRLs for paediatric patients	J. Damilakis
25’	Case stories from Member States	USA: S. McKenney Sweden: A. Almen OPRIPALC Project: C. Ubeda Uruguay: N. Nobile Gonzalez
30’	Challenges with patient dosimetry in paediatric radiology	Open discussion
10:30 – 11:00	*Coffee break*	
11:00 – 12:30	**Session 6: Radiation protection optimization in paediatric diagnostic imaging: good practice and challenges** ***Objective:*** *Review the recent advances and remaining needs*	Session chair: M. Mahesh Rapporteur: S. McKenney
15’	Diagnostic radiography/ fluoroscopy	J. Kasznia-Brown
15’	Computed tomography	S. McKenney
15’	Dental imaging	M. Hedesiu
15’	Relevance of patient shielding	C. Granata
30’	Optimization in diagnostic imaging and use of patient shielding	Open discussion
12:30 – 13.30	*Lunch break*	
13:30 – 15:00	**Session 7: Radiation protection optimization in paediatric nuclear medicine and radiotherapy: good practice and challenges** ***Objective:*** *Review the recent advances and remaining needs*	Session chair: I. Thierry-Chef Rapporteur: D. Faj
20’	Nuclear medicine	S. Holm
10’	Out-of field dosimetry in radiotherapy of children (update from EURADOS)	M. De Saint-Hubert
10‘	Role of AI in paediatric imaging	J. Damilakis
10‘	Role of AI in radiotherapy	E. Titovich, M. Carrara

20‘	Case stories from Member States ((5-7 min each)	Singapore: S. Somanesan Serbia: V. Artico
10‘	Perspective of regulators	R. Bly
10‘	Discussion	Open discussion
15:00 – 15:30	*Coffee Break*	
15:30 – 17:00	**Session 8: Justification for medical imaging: challenges with children** ***Objective:*** *Based on current guidance, what are successes and challenges for appropriate use of imaging for children?*	Session chair: J. Kasznia-Brown Rapporteur: T. Cain
30’	Perspectives of international organisations	Panel: O. Pellet (IAEA) E. Van Deventer (WHO) C. Granata (ISR/ESR) A. Garcia Bayce (WFPI) D. Frush (Image Gently) M. Hedesiu (IADMFR) N. Pongnapang (ISRRT)
60’	Challenges with justification for children: panel discussion followed by an open discussion	Panel: N. Macedonia: J. Chabukovska Radulovska Latvia: I. Alpine Zambia: V. Sichiziya Australia: T. Cain Uruguay: A. Garcia Bayce

Wednesday, 1 March 2023

9:00 – 10:30	**Session 9: Radiation risk-benefit communication in paeditric healthcare** ***Objective:*** *Discuss the role of different stakeholders in fostering risk-benefit dialogue*	Session chair: M. Perez Rapporteur: V. Gershan
15’	WHO project on Communicating radiation risks in paediatric imaging	M. Perez
15’	Fostering risk-benefit dialogue: ethical considerations	M. Kirwan
15’	Importance of communication between professions (lessons learned from the discussions on discontinuing patient shielding)	Panel: D. Frush S. McKenney (AAPM) C. Granata (ISR/ESR) P. Gilligan (EFOMP) N. Kirk (EFRS) N. Pongnapang (ISRRT)

30’	Role of different stakeholders: health professionals, societies, patients, referrers, regulators, manufacturers	Panel: all above + M. Kirwan, K. Applegate (ICRP), M. Mahesh (ACR) T. Cain (WFPI)
30’	Strategies, tactics, resources for messaging topics covered in this technical meeting	Open discussion
10:30-10:50	*Coffee Break*	
10:50- 12:30	**Session 10: Closing session** ***Objective:*** *Meeting report, summary, closing*	Session chair: D. Frush
40-50’	Reports from sessions 2-9	Session rapporteurs: M. Mahesh N. Pongnapang S. Somanesan O. Ciraj-Bjelac S. McKenney D. Faj T. Cain V. Gershan
20-30’	Meeting summary	D. Frush
10’	Summary and closing	IAEA