WHO Workshop on Radiation Risk Assessment in Paediatric Health Care ALARA Issues Arising for the Safety and Security of Radiation Sources and Security Screening Devices: Summary and Recommendations

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WHO Workshop on Radiation Risk Assessment in Paediatric Health Care
National Institute of Radiological Sciences (NIRS), Chiba, Japan, 17 December 2009

The World Health Organization (WHO) conducted a Workshop on Radiation Risk Assessment in Paediatric Health Care to review current research on radiation risks following medical exposures early in life and to outline a strategy towards the development of a global research agenda. It was held in Chiba, Japan, on 17 December 2009, within the program of the third KIDS Workshop of the National Institute of Radiological Sciences (NIRS). Over 80 participants from 19 international and national agencies, international professional organizations, international and national research and scientific institutions, agreed to collaborate towards the common objective. This report summarises the presentations, discussions and collective views of the international group of experts, and does not necessarily represent the decisions or the stated policy of the WHO.

Dr Yoshiharu Yonekura, President of NIRS, welcomed participants highlighting the importance of children’s radiation protection. Chaired by Professor Shunichi Yamashita (Nagasaki University), the workshop consisted of four sessions. The first session, co-chaired by Dr Maria Pérez (WHO) was devoted to setting the scene of medical radiation exposure early in life. Professor Christian Streffer (Essen University) addressed the influence of the age on cancer risk following exposure to ionizing radiation. Epidemiological studies indicate a higher cancer risk in children, especially for thyroid, breast cancer and leukaemia, as observed in atomic bomb survivors (several cancer sites) and after the Chernobyl accident (thyroid cancer). Second malignant neoplasms (SMN), mainly breast and thyroid cancer, have been reported following paediatric radiotherapy after sufficiently long follow-up periods. Genetic predisposition, genomic instability, deficiencies in DNA repair, regulatory processes of cell proliferation and endocrine factors all seem to be involved in the age dependence of cancer risk following radiation exposure. In addition to the risk of developing cancer, fetal and early childhood exposure to ionizing radiation may affect the highly radiosensitive developing brain, leading to impaired learning ability.

Dr Richard Wakeford (Manchester University) provided an overview of the current knowledge on radiation risks after in utero exposure. Case-control studies showed a statistical association between fetal exposure during diagnostic imaging and childhood cancer, particularly leukaemia. However, further research is needed to conclusively support a cause-and-effect interpretation of this association. For young children exposed to radiation during the atomic bombings of Hiroshima and Nagasaki there is essentially an increased risk of childhood leukaemia and other cancers later in life, and the risk of childhood leukaemia is compatible with the data obtained from the case-control studies of antenatal diagnostic exposure. The atomic bomb survivors exposed in utero experienced an increased risk of childhood solid cancers and of cancers in adult life, although a longer follow-up is required to assess the level of lifetime risk. The status of cells from which childhood cancer originates and the particular radiosensitivity of the fetal haematopoietic system may account for these findings.

Dr Lawrence Lau (International Radiology Quality Network—IRQN) noted that inappropriate use of radiation in paediatric patients will lead to unnecessary, unintended or wasted exposures. The aim is to minimise the risks and to maximise benefits through appropriate medical use of radiation by doing the right exam (justification), using the right dose (optimization), and providing the right report (error minimization). Challenges and opportunities to promote appropriate use of radiation in the practice of paediatric imaging were discussed. An excellent example is the ‘Image Gently’ campaign which aims to change practice by promoting awareness of radiation protection and the opportunities of lower radiation dose when imaging children. Research on radiation risks provides evidence to inform decisions and underpin risk control. From a clinical perspective, an integrated research agenda for radiation risk assessment could include the reasons for inappropriate use of radiation and possible risk control measures.

The second session, co-chaired by Dr Yoshiya Shimada (NIRS) addressed children’s radiation doses resulting from radiological medical procedures, focusing on paediatric computed tomography (CT) and covering national and global perspectives. Dr Keiichi Akahane (NIRS) provided
One of the six core functions of WHO is to facilitate the mobilisation of the health sector towards a conscious management of the radiation dose and to communicate risks. The implementation of the ALARA (As Low As Reasonably Achievable) principle in radiation risk assessment is crucial for protecting the health of individuals and populations, particularly in children, where the risk of adverse health effects is higher.

Fetuses and children are particularly vulnerable to radiation exposure. The ALARA principle requires a systematic approach to risk assessment and management, including the use of advanced techniques such as automatic exposure control (AEC) and weight-based current settings in CT imaging. The combined use of AEC and weight-based current settings can significantly reduce organ doses in most cases.

In Japan, the NCCHD (National Children's Cancer Hospital and Development) uses three measures to reduce radiation doses in paediatric CT. These measures include the use of anthropomorphic 6-year-old bone marrow dosimetry, realistic phantoms of different ages, and an organ dose database. The dose variation among 14 facilities is due to different CT scanners, protocols, and effective mAs. The organ doses for chest and abdominal pelvic CT scans were significantly reduced in most cases.

The second session, co-chaired by Dr Maria Perez (WHO) and Dr Osamu Miyazaki (National Centre of Children Health and Development—NCCHD), focused on the generation, dissemination and applications of valuable knowledge. Within the WHO GI (Global Initiative) on Radiation Safety in Health Care Settings, the aim is to mobilise the health sector towards a conscious management of the radiation dose and to communicate risks.

Dr Kwang Pyo Kim (Kyung Hee University) presented a retrospective cohort study of almost 250,000 patients <22 years old, which is being conducted in the UK to determine cancer risks following paediatric and adolescent CT. A nested case-control study of leukaemia is also being conducted. Doses are estimated from electronic records and technical data. An organ dose database was developed using anatomically realistic phantoms of different ages to ensure better estimations of age-specific organ doses, including bone marrow dosimetry, which is relevant for leukaemia risk assessment.

Dr Osamu Miyazaki (National Centre of Children Health and Development—NCCHD) presented their experience in lowering doses in paediatric CT at the NCCHD. The increasing demand for paediatric CT in this centre reached its peak in 2007 and declined in 2009. It was suggested that this trend, also reported in other paediatric institutions in Japan and the US, might be due to increased awareness of radiation risks among other factors. Application of the ALARA principle in paediatric imaging requires a conscious management of the radiation dose to be commensurate with the medical purpose to avoid unnecessarily high dose/image quality.

The NCCHD uses three measures to reduce exposures: eliminating unnecessary multiphase protocols, using weight-based and colour-coded tube current settings, and employing AEC. The combined use of AEC and weight-based current settings delivered a better outcome than either technique alone.

Dr Maria Pérez (WHO) summarised the proposed strategy for risk assessment in paediatric health care within the WHO Global Initiative (GI) on Radiation Safety in Health Care Settings, aiming to mobilise the health sector towards a safer and effective use of radiation in medicine. Fetuses and children are particularly vulnerable to environmental threats and have a longer life-span to develop long-term health effects like cancer. While the benefits of justified and properly performed examinations outweigh the individual risks, unnecessary radiation exposure will result in unnecessary (and avoidable) risks.

One of the six core functions of WHO is shaping the global research agenda and stimulating the generation, dissemination and application of valuable knowledge. Within the WHO GI, radiation risks in children, young adults and pregnant women are considered a priority for the development of a strategic global research agenda on health effects of medical radiation exposures.

Ms Cynthia Cowling (International Society of Radiographers and Radiation Technologists—ISRRT) highlighted the role of the radiographer in the implementation of the ALARA principle when working with children. Immobilisation, use of verbal directions, role of parents and family, good communication skills and use of gonadal shielding have a special role in pediatric radiography.

Digital radiology is a major technological advance but carries a potential risk of abuse if the operators are unaware of the correct performance of the equipment. Radiographers can help to reduce dose in CT and intervention radiology by tailoring exposures to age and weight and customised to pathology. Radiographers’ organizations can promote the best practice through advocating policies to ensure justified and appropriately performed procedures.

The third session, co-chaired by Dr Rethy Chhem (International Atomic Energy Agency—IAEA) provided an overview of experimental and epidemiological ongoing research on radiation risks in children. Professor Shunichi Yamashita (Nagasaki University) presented a multi-disciplinary integrated approach for basic research on low dose radiation risks. The program for Radiation Health Risk Control of the Global Centre of Excellence (COE) has conducted medical research on descriptive and molecular epidemiology, especially in Nagasaki atomic bomb survivors and people living around Chernobyl.

The molecular genetics of radiation-induced thyroid cancer, particularly in children, has been a major research topic. Life science research and human science research should be integrated to improve understanding of radiation risks, to translate radiation research into policy and to narrow the gap between academic research and public risk perception. Basic science can contribute to a better understanding of the mechanisms involved in radiation-induced health effects, identify susceptible/resistant groups and improve knowledge on individual and population risk assessment.

Dr Yoshiya Shimada (NIRS) summarised current experimental research on the effects of radiation in children conducted by NIRS, including in vitro studies on human cells and in vivo studies on animal models. These studies evaluate the influence of dose, dose fractionation, radiation quality and age at exposure. The factors considered for the calculation of effective dose (Sv) from absorbed dose (Gy), i.e. tissue weighting factor...
(W T) and radiation weighting factor (W R), may be influenced by age at exposure. The target organs for radiation-induced effects also differ with age (age-related susceptibility windows). Radiation effects are modified by the dose fractionation, in which dose per fraction and interval between fractions are critical. The dose and dose-rate effectiveness factor (DDREF) might also be influenced by the age at exposure. Basic radiation research complements epidemiological research by providing scientific knowledge on health effects of paediatric medical exposures.

Dr Ausrele Kesminiene (International Agency for Research on Cancer—IARC) summarised the current epidemiological research conducted by IARC on the possible health effects of medical exposures early in life. The Gene-Rad-Risk study comprises two studies: a multinational case-control study nested in cohorts of women who survived first cancer or Hodgkin’s lymphoma before age of 35, and a cohort study of women who are BRCA1/2 mutation carriers. The studies aim at evaluating the joint roles of medical radiation and genetic predisposition in the risk of developing breast cancer. The Child-Med-Rad project was set up to assess the feasibility of establishing trans-national cohorts of children who have received substantial medical diagnostic exposures, in particular from CT. Epidemiological studies on diagnostic imaging have more relevance in terms of public health than radiotherapy studies because more people are involved. However, they are more difficult to conduct because very large populations with individual organ dose estimates are required. International cooperation and a multidisciplinary approach could overcome those limitations.

Dr Kazutaka Doi (NIRS) presented a meta-analysis of second malignant neoplasms (SMN) in childhood cancer survivors (CCS) following radiotherapy. Low risks are difficult to detect; multi-center collaborations and meta-analyses would ensure sufficient statistical power for such analyses. Due to the small number of publications, ERR estimations for SMN among CCS was suboptimal. A statistical methodology was developed to calculate an ERR based on other estimates. This meta-analysis technique was applied to 21 studies from the PubMed database from 1950 to 2008. The calculated ERRs ranged from 0.004 to 11.7 with an overall ERR of 0.45. This was significantly less than the ERR (1.7) obtained from the study on atomic bomb survivors.

Dr Junichiro Fujimoto (National Center for Child Health and Development—NCCHD) showed the results of the Japan CCS study. The number of CCS in Japan has significantly increased because the overall survival is higher. This is associated with an increase in late effects as CCS live longer. The aim of this study was to monitor the occurrence, understand the causes and prevent the late effects in CCS. In the preliminary survey, there were more than 100 SMN in about 7000 CCS.

Dr Quanfu Sun (National Institute for Radiological Protection—NIRP) gave an overview of NIRP activities in the field of radio-epidemiology. Medical exposures of the Chinese population have dramatically increased in recent years, with unequal distribution between urban and rural areas. CT is being increasingly used in children and about 500 000 cancer patients receive radiotherapy every year. However, radiation protection tools are not always available in hospitals. The Ministry of Health of China has established a Radiation Safety and Health Monitoring System of Medical Exposure. Dosimetry and epidemiology studies are being considered. There are plans and programs to improve QA/QC in radiotherapy, justification and optimization in diagnostic radiology.

Dr Ichiro Yamaguchi (National Institute of Public Health—NIPH) provided a public health perspective of how radiation risk assessment is handled in paediatric health care. The results of a web-based survey on CT exposures funded by a Health Labour Sciences Research Grant in 198 Japanese hospitals were discussed. The importance of pilot studies on diagnostic reference levels was highlighted. Radiation risk communication should provide trustworthy and evidence-based advice. For follow-up examinations, the cumulative dose could be significant. Therefore, this cumulative risk should be considered together with the benefit of all of the examinations. It could be difficult to detect a small risk from an individual study on radiation risk in paediatric health care. However, the study could ensure that the risks do not exceed an acceptable level and could also identify others which might be overlooked.

Dr Tetsurou Sei (Ministry of Health, Labour and Welfare—MoHLW) presented the survey of medical institutions conducted every three years by the MoHLW in Japan. The total number of radiological medical devices and radiological procedures have been monitored. However, no detailed information about modality and/or exposed site was collected. The MHLW is considering the development of a web-based system to monitor population medical radiation exposures modelled on JANIS (Japan Nosocomial Surveillance System). Implementation challenges include: access to dosimeters and measurement software, non-standardised dosimetry methodologies and workforce shortage on data collection, especially in smaller facilities.

During the last session, co-chaired by Professor Jolyon Hendry (International Commission on Radiological Protection—ICRP), the views of
Meeting reports

the stakeholders were summarised in a panel discussion. The session started with a presentation by Dr Malcolm Crick (United Nations Scientific Committee on the Effects of Atomic Radiation—UNSCEAR) and Dr Ferid Shannoun (WHO), who joined this session from Vienna, through a video conference. The structure and functions of UNSCEAR were summarised, including early warning, provision of scientific information and global knowledge management. UNSCEAR works in the collection, analysis, publication and dissemination of data on the levels, effects and risks of ionizing radiation. These scientific data assist the ICRP to develop recommendations on radiation protection, which in turn are considered by the relevant international and national organizations for the development of norms and standards. WHO will strengthen its cooperation with UNSCEAR within the Global Initiative (GI) on Radiation Safety in Health Care Settings to improve data collection on the frequency of radiological medical procedures and the resulting population dose distribution. The actions to assist the member states will include facilitating capacity building and providing technical support to conduct national surveys on medical exposures, including paediatric procedures. There was a discussion on the ways to promote and facilitate national surveys on medical exposures in children.

The discussion then focused on the actions proposed to shape and promote a strategic global research agenda on the health effects of medical radiation exposures occurring early in life. Major topics to be included in the research agenda were outlined and possible strategies to move forward were proposed. The key actions agreed include: to engage and collaborate with stakeholders; to encourage national medical exposure surveys in children; to develop a strategic global research agenda with WHO providing coordination and the GI serving as a platform for collaboration between the stakeholders; to adopt a research strategy guided by the principles of quality, impact and inclusiveness; to build national capacity and facilitate education and training; to promote awareness and strengthen advocacy. The publication of an interim report of this workshop would be the first step.

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ALARA Issues Arising for the Safety and Security of Radiation Sources and Security Screening Devices: Summary and Recommendations
12th European ALARA Network Workshop, Vienna, Austria, 21–23 October 2009

Workshop background, objectives and programme

Radiation protection has always included security-related provisions (for example to prevent the unauthorised use of sources), that have contributed to the overall system of radiation safety. In recent years, however, interest in security issues has dramatically increased and the challenge is to ensure that safety and security measures are designed and implemented in an integrated manner so that security measures do not compromise safety and vice versa.

The aim of the workshop was to consider how the implementation of ALARA, in terms of planned and emergency exposure situations involving worker and public doses, is affected by the introduction of security-related measures. In the case of new equipment and procedures, there is also the question of whether exposures arising from security screening devices can be justified and optimised. In addressing these issues, the workshop tried to consider how an optimum balance between protection, safety and security can be achieved.

As with previous workshops, half the programme time was devoted to presentations, and half to working group discussions and their findings. Participants had the opportunity to consider the findings of each group, contribute to discussions, and formulate the final conclusions and recommendations of the workshop. There were 56 participants from 16 different countries, and a total of 24 oral presentations and 2 posters, arranged under the following sessions:

• Introduction and scene-setting
• Security and safety measures
• Planned exposure situations
• Emergency situation management (especially due to malevolent acts)
• Justification and optimisation of doses in the use of security devices.

Two afternoon sessions were set aside for working group discussions, based on the following topic areas:

• Implementation of the Code of Conduct and HASS—ensuring ALARA
• Balancing security and safety—how to achieve an optimum solution
• Management of emergency exposure situations from an ALARA perspective
• Justification and optimisation in the use of security devices

On the final day, the reports from the groups were presented and discussed, and form the workshop conclusions and recommendations described later. Individual presentations (papers and slides) and the working group reports are available to download from the EAN website (http://www.eu-alara.net/).

Themes and issues arising

The introductory session focused on international developments, in particular from the European Commission (e.g. HASS), IAEA (e.g. the Code of Conduct on the Safety and Security of Radioactive Sources) and from ICRP recommendations (Publications 103, 109, and 111). The first two of these have largely been implemented successfully. It was noted that many security-related documents were originally issued as stand-alone documents, but the trend now was to integrate safety and security requirements, either into the same document, or at least into comparable document structures. Further integration is envisaged through the eventual harmonisation of HASS thresholds and IAEA D-values.

The new ICRP system of exposure situations was presented, which recommends that dose constraints (for planned exposure situations) and dose reference levels (for emergency and existing exposure situations) should be set as an upper bound on the optimisation process. The message from the workshop is that there is still much work to do in terms of implementing these recommendations in practice. For example, there are questions about when the different exposure situations apply, what the actual values of dose constraints and reference levels should be, and how to apply optimisation below these values. There is now the opportunity to provide feedback to international bodies on many of these issues, and it was suggested that EAN should help by collating comments from its members.

The 2nd session raised a number of interesting issues on the balancing of safety and security measures. Although both can be said to share a common goal—protecting people from harm—there is a difference in approach. Safety mostly focuses on the control of the source, whereas security is concerned with controlling the actions of (certain) people. These differences have practical implications; for example, safety relies on sharing information and mutual trust, whereas security may require the opposite. The workshop contained a number of presentations on the security measures being applied to different practices. Most of these described source-related controls (e.g. physical security measures), for which there would seem to be a good synergy between safety and security, even though the approach does have to be tailored to different sectors.

In contrast, people-related controls (e.g. security checks and surveillance) were not discussed in any detail, and this may well be an area where there is more potential for conflicting requirements.

The session on planned exposure situations encompassed both normal operations (i.e. in which measures are taken to counter security threats) and the recovery of orphan sources. Examples were given of training programmes for staff involved in both these activities. Such programmes can involve large numbers of people and require much greater resources than have traditionally been devoted to radiation safety training—perhaps a reflection of the societal importance assigned to security issues.

Dose constraints for security-related staff were mentioned several times, with the consensus being that 1 mSv per year was appropriate in most cases. There was less information on dose constraints for recovery staff; further developments and exchanges of information in this area would be useful.

The same issues—staff training and dose reference levels—were raised in the 4th session in relation to emergency situation management. In this context, training is important not only for radiation protection purposes but also to ensure that the emergency response is proportionate, and that the level of risk (especially to the public) is communicated in a consistent manner. More generally, as recommended in ICRP Publication 109, the national authorities should prepare plans for all types of emergency exposure situations, and relevant stakeholders should be consulted during this process. Dose reference levels for emergency responders are beginning to emerge—these are within the range of values recommended by ICRP, although there are significant differences in the values being proposed in different countries. There is also an operational need for derived reference levels, in terms of dose rate and contamination levels, to help guide the optimisation process on the ground. Again, further developments and information exchange in these areas would be useful.

The final oral session considered radiation sources used for security purposes, which continue to increase in type and number. In many cases, these new practices can be managed through the normal requirements for planned exposure situations, although there are some reservations in relation to the safe use of certain types of portable equipment. Special attention was given to the introduction of x-ray security screening devices (‘body
scanners’ at airports and other locations. The consensus was that such devices must still be subject to controls, even if the dose per scan is extremely low (e.g. as is the case with backscatter scanners). Furthermore, novel uses of such devices should be subject to the justification principle, to prevent widespread and indiscriminate scanning of the public.

Workshop conclusions and recommendations

As mentioned before, the working group reports, containing details of the discussions, conclusions and recommendations, are available at http://www.eu-alara.net/. A brief summary of these is given below.

Implementation of the Code of Conduct and HASS—ensuring ALARA

- EAN should assist on compiling feedback for the EC on the practical implementation of the HASS directive.
- Better cooperation and information exchange between EU regulatory authorities on the movement of sources between member states is necessary.
- EC Regulation 1493/93 should be reviewed to ensure that it is consistent with IAEA guidance on import/export of radioactive sources.

Balancing security and safety—how to achieve an optimum solution

- The justification of a practice is a safety judgement, but security should be considered as an integral part of the licensing and inspection process.
- Safety and security can be integrated and made to work in practice, and both should be proportionate based on realistic assessments of the credible risks, both due to accidents and malevolent acts.
- As experience is gained, more could be done to establish harmonised international security levels and controls for different categories of sources.

Management of emergency exposure situations from an ALARA perspective

- The potential radiation exposures to different persons (responders, public etc) from different emergency scenarios should be assessed in order that a proportionate response, including practical protection and communication strategies, can be planned.
- Plans must be flexible. In the event of an emergency it is important for the actual radiological conditions to be assessed as soon as possible, to help direct the response and facilitate information exchange between the agencies involved.
- Training of responders is essential and, where possible, should be harmonised so as to develop a ’common language’ of protection.

Justification and optimisation in the use of security devices

- The use of ionizing radiation for security purpose should not be trivialised. Thus, even when individual doses are low, the use of security screening devices should still be subject to regulatory control, with different types of use subject to specific justification.
- Public doses should be below the 0.3 mSv/y dose constraint, with a requirement for further optimisation below this dose. In practical terms this requires much lower reference doses for individual scans, with further optimisation applied through the correct setting up, operation and quality assurance of scanning systems. To this end, draft IEC standard 62463 should be agreed and adopted.
- Where practicable, persons should be informed prior to being scanned, and an alternative to x-ray scanning should be available upon request.

The next EAN Workshop, on ‘ALARA in the Medical Sector’, is planned for 7–10 June 2011, in Norway. Details will be announced on the EAN website.

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