WHO’s Global Initiative on Radiation Safety in Health Care Settings

Maria del Rosario Pérez*, Ferid Shannoun¹, Zhanat Carr¹, Pablo Jiménez², Steffen Groth³, Douglas Noble⁴, Andreas Ullrich⁵, Ausrele Kesminiene⁶, Isabelle Thierry-Chef⁶, Elisabeth Cardis⁷, Emilie van Deventer¹ and Maria Neira¹

¹Department of Public Health and Environment, World Health Organization, 20 Avenue Appia, Geneva-27, CH-1211 Switzerland
²Area of Technology, Health Care and Research, Pan American Health Organization, Washington USA
³Department of Essential Health Technologies, World Health Organization
⁴World Alliance for Patient Safety, World Health Organization
⁵Noncommunicable Diseases and Mental Health Department, World Health Organization
⁶Radiation and Cancer Group, International Agency for Research on Cancer, Lyon, France
⁷Center for Research in Environmental Epidemiology, Municipal Institute of Medical Research and CIBER Epidemiology and Public Health, Barcelona, Spain

Abstract. Advances in medical radiation technology have resulted in significant gains in the diagnosis and treatment of human diseases. Medical use of ionizing radiation has become by far the largest artificial source of radiation exposure. Although individual cancer risk associated with diagnostic exposures is low, overall exposure is becoming a public health concern due to the widespread use of radiation in health care settings, which is foreseen to continue rising. According to its global health mandate, WHO has an important role to play in preventing unjustified exposures while promoting and ensuring safe use of radiation in medicine. In order to underscore its commitment to this field, WHO started a global initiative on Radiation Safety in Health Care Settings to support Member States in the implementation of the international radiation safety standards in medicine. This new initiative will bring together key stakeholders, including international organizations, professional and scientific societies, health authorities and policy makers. Actions of the initiative will focus on public health aspects related to risks and benefits of diagnostic radiology, image guided interventions, radiotherapy and nuclear medicine. Based on a scientific evidence, special consideration will be given to critical sub-populations (e.g. children and pregnant women), to high dose procedures and to unintended exposures. Practical materials focusing on the justification and optimization principles of radiation protection will be developed and disseminated, such as evidence-based good practice manuals. In addition, advocacy and communication tools will be produced and made available widely. Contribution to the development of education and training programs will be also considered.

KEYWORDS: radiation protection, public health, health care settings.

1. Introduction

Medical use of ionizing radiation (IR) is by far the largest contributor to the exposure of the general population from artificial sources. The use of radiation in medicine produces major benefits in terms of the diagnosis and treatment of human diseases. The availability of new medical technology and the increasing resources being put into health care systems indicate that the frequency of medical procedures involving use of IR will significantly increase, particularly in industrialized countries and emerging economies. Although the individual cancer risk associated with diagnostic exposures is low, overall medical exposure is becoming a public health concern due to the widespread use of radiation in health care settings.

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS)¹ specifically address radiation protection in medical exposures. Currently under a process of revision, the BSS are the international benchmark for radiation safety requirements.

* Presenting author, E-mail: Perezm@who.int
¹ The current BSS were published in 1996, co-sponsored by International Atomic Energy Agency (IAEA), Food and Agriculture Organization (FAO), International Labor Office (ILO), Nuclear Energy Agency (NEA), Pan American Health Organization (PAHO) and World Health Organization (WHO).
However, there is a need to raise awareness and to improve BSS implementation in health care facilities.

As the global public health leading agency, WHO has an important role to play in preventing unjustified radiation exposures while promoting safe use of radiation in medicine. Therefore, WHO is launching a global initiative on Radiation Safety in Health Care Settings to mobilize the health sector towards safe use of IR in medicine. This initiative will complement the international Action Plan for Radiation Protection of Patients (Action Plan), established by the IAEA in 2002 to coordinate international efforts and to provide guidance with the overall objective of making progress in radiation protection of patients.

2. WHO functions and vision

The World Health Organization (WHO) is the coordinating authority for health within the United Nations (UN) system, with specific mandate on public health. In addition to the headquarters, there are six WHO Regional Offices \(^2\) and 145 country offices that cover 159 Member States. This decentralized structure provides WHO diverse opportunities and optimal conditions for working with the health authorities of its 193 Member States (MS).

WHO is responsible for providing leadership in matters of public health through six core functions:
1. providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
2. shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
3. setting norms and standards and promoting and monitoring their implementation;
4. articulating ethical and evidence-based policy options;
5. providing technical support, catalysing change, and building sustainable institutional capacity; and
6. monitoring the health situation and assessing health trends.

WHO functions regarding radiation protection and health include the development and promotion of evidence-based public health policy for MS to protect health and reduce radiation risks and the provision of technical support and capacity building on radiation protection and health. According to its global health's mandate, WHO has an important role to play in radiation safety in health care settings and this commitment can be underscored by promoting radiation safety culture in the medical community, health authorities and health policy makers. WHO's vision is the appropriate use of radiation in medicine through good practice promotion.

3. Objectives and scope

This initiative aims to support MS in the implementation of radiation safety standards in health care settings by promoting safe use of radiation in medicine and preventing unjustified radiation exposures. In order to mobilize the health sector, the initiative will be addressed to users of IR in medicine, professionals who prescribe medical procedures involving use of IR, policy makers and health authorities. Key stakeholders will be involved and partnership will be established with international organizations, specialized institutions, professional bodies, scientific societies and academic institutions. Actions will be focused on public health aspects related to the risks and benefits of the use of radiation in medicine, including diagnostic radiology, interventional radiology, radiotherapy and nuclear medicine with special consideration for critical sub-populations (e.g. children and pregnant women), high dose procedures and prevention of unintended medical exposures.

\(^2\) WHO Regional Office (RO) for Africa (AFRO), the Americas (AMRO), the Eastern Mediterranean (EMRO), Europe (EURO), South-East Asia (SEARO) and the Western Pacific (WPRO).
4. Focus and proposed actions

The focus and proposed actions are presented in a dual approach:
- common needs and topics identified across all disciplines involving the use of IR for medical purposes (cross-cutting issues);
- some other topics particularly identified in certain disciplines (diagnostic radiology, interventional radiology, radiotherapy and/or nuclear medicine).

4.1 Cross cutting issues

Justification of medical exposures is a major topic to be addressed under the global initiative, by providing practical tools for its implementation and raising awareness throughout the medical community. Referral guidelines and appropriateness criteria are the main tools for applying the principle of justification, intended to guide radiologists and referring physicians in making initial decisions. They exist and are used in some countries for preventing unnecessary radiation exposures and optimizing costs to the health care system. However, they are not available in many countries and global harmonization is still needed. Promoting evidence-based medicine, the global initiative will provide a platform for harmonizing referral criteria and making them available for other MS. Efforts will be concentrated on critical groups (i.e. children), addressing both generic and individual justification. Opportunistic screening\(^3\) and self-referral will be particularly considered. Clinical audit of radiological practices is critical for promoting of good medical practice (GMP). There is a need for guidance on how to implement clinical audits in MS combining assessment of clinical efficiency with radiation safety aspects.

Critical groups will be in the focus of the initiative, including children, young adults, pregnant women, breastfeeding mothers and patients with chronic diseases. Children are especially vulnerable due to a higher sensitivity and longer life-span to express radiation-related risks. Premature babies are often subjected to long hospitalization and frequent medical procedures involving radiation exposure. The approach to address pregnant and breastfeeding women will be mainly based on advocacy tools to raise awareness of risks and provision of basic recommendations (booklets) considering two different situations:
- If the pregnancy is known, decisions will be based on justification. If the clinical condition justifies the procedure, then optimization should be implemented;
- When dealing with women in childbearing age, appropriate measures should be put in place in the respective departments of the hospital to avoid unintended exposure during pregnancy (questionnaires, warning, biological tests, informed consent).

There is a need for guidance on how long following the administration of radiopharmaceuticals patients should avoid pregnancy. Guidance for breastfeeding mothers undergoing nuclear medicine procedures is also needed.

Assessment of population exposures resulting from medical uses of IR is mainly available in industrialized countries, particularly within the EC in the context of the implementation of the Directive 97/43 EURATOM. UNSCEAR reports constitute the most comprehensive source of compiled information in this area. The global initiative will provide a platform to assist MS to conduct this type of surveys at national level (frequency of procedures, patient doses). By mobilizing the health sector, the global initiative can contribute to a broader and more effective participation of MS in international surveys.

Global health workforce is inequitably distributed throughout the world, with severe imbalances between industrialized and developing countries, even worse in rural areas compared to urban settings. This shortage is particularly evident with regard to staffing in medical facilities dealing with IR.

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\(^3\) Opportunistic screening: screening of asymptomatic people outside of organized screening programmes
Staffing is closely related to education and training of health workforce. Under the umbrella of the global initiative it is envisaged:

- to raise awareness on this issue, strengthening the role of medical and health physicists, radiopharmacists, radiographers and technologists in health care settings.
- to advocate for the inclusion of radiation protection topics in the basic curricula of both medical and dental schools.
- to contribute to education and training programs based on existing materials (considering developing/adapting training packages if necessary).

In addition to the cross-cutting issues applicable to all medical disciplines involving the use of IR, the global initiative will address specific topics related to radiodiagnosis (focused on computed tomography), interventional radiology, radiotherapy and nuclear medicine.

### 4.2 Diagnostic radiology

During the past decades, computed tomography (CT) has found fast and widespread use in diagnostic radiology. Justification of the use of CT, particularly in children and young adults, will be the main focus of the global initiative. CT became the most important source of IR in diagnosis. New technology has been developed, from the conventional CT to spiral CT and multi-slice CT with a resulting increased patient throughput (higher frequency) and wider scan volumes (higher patient dose per scan). Radionuclide-tracer techniques such as positron-emission tomography (PET) and single-photon emission computed tomography (SPECT) can now be fused with CT combining good image quality with functional information, but also implying new challenges for radiation safety in medical imaging. Harmonized evidence-based good practice guidelines on pediatric CT, including its combination with other imaging techniques (e.g. magnet-resonance imaging), could be helpful tools to implement the principle of justification in this discipline.

### 4.3 Interventional radiology

The number of percutaneous interventional procedures fluoroscopically-guided has increased significantly world-wide and remains in continuous expansion. Benefits are really big, since now it is possible to treat with minimally invasive techniques some medical conditions that once required very complex surgery. However, radiation doses delivered in interventional radiology can be high enough to go beyond the threshold for deterministic effects.

Local radiation injuries (e.g. skin burns) are observed rather often in patients undergoing interventional fluoroscopy, some of them with severe consequences for health. However, no formal system for reporting such events is still in place. Dose to health professionals working in interventional radiology may be high, and deterministic effects could be observed if no appropriate radiation protection measures are implemented (e.g. lens opacities).

Radiation protection of patients in interventional radiology will be included in the global initiative (advocacy for prevention of deterministic effects, collaboration on reporting system and database). Radiation protection of workers will be also addressed under the umbrella of the initiative. This will contribute to the WHO global plan of action on worker's health and to the international action plan on occupational radiation protection.

### 4.4. Radiotherapy

A number of unintended exposures have occurred in patients undergoing radiotherapy. Some of them resulted in severe health consequences and even death, causing increasing concerns amongst health authorities, regulatory bodies, the medical community, patients and the general public. The WHO

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World Alliance for Patient Safety recently convened an expert consensus group to improve radiation safety in radiotherapy by mapping the process of health care, identifying risks and suggesting actions to reduce risk at each stage. This work is shortly to be published by WHO as a Technical Manual which is hoped to be an important adjunct to overall Quality Assurance.

Systematic reporting of adverse events will enhance patient safety by learning from failures of the health care system. There is a need for harmonization of reporting criteria, avoiding allocation of blame and leading to a constructive response. Under the global initiative harmonization of error reporting systems will be addressed (e.g. guidance on reporting criteria) and international cooperation regarding development and maintenance of databases of incidents and accidents will be promoted.

4.5 Nuclear Medicine

High-resolution molecular imaging technology, like PET and SPECT may imply high doses to staff. A new concept of biological target volume is now applied for radiotherapy multimodal planning, involving fused technology (SPECT/CT or PET/CT). The use of nuclear medicine for therapeutic purposes is no more limited to the treatment of thyroid diseases and bone metastases. In the last years, therapeutic radiopharmaceuticals have expanded their potential applications and new tumor targeting methods have been developed. Although benefits are enormous, the use of new technology implies new challenges for radiation safety in nuclear medicine.

Justification of procedures and optimization of radiation protection in nuclear medicine is particularly critical in children and this will be the focus of the global initiative, including good practice guidance on diagnostic reference levels for administered activity in children, according to age and weight.

5. Current status and next steps

The strategy of the global initiative was determined in a sequential approach. As a first step, possible internal synergisms between different groups working in related areas in IARC, PAHO and WHO were explored. An internal consultation was convened to present and discuss the proposal, agree on the overall strategy and consider interactions with external partners.

Then, WHO convened an international consultancy to identify MS priority needs for ensuring radiation safety in health care settings; and to determine the expected role of WHO to assist countries in meeting those needs. A panel of experts from 21 countries, FORO and IAEA identified numerous issues to be addressed under the umbrella of the global initiative. This consultation was useful in identifying needs and priorities, defining key players and roles and mapping out MS capacities. Fruitful discussion focused on how the global initiative can complement the Action Plan and other regional and/or national actions.

Taking into account the conclusions and recommendations provided by the expert panel, the global strategy was outlined. Based on the major issues identified, working groups were defined to address specific topics and a coordinating task group was established. In addition to national competent authorities, other outstanding partners were identified and collaboration is being expanded to involve relevant international organizations, professional bodies, scientific societies and academic institutions.

A number of stakeholders worldwide are actively working in the field of radiation protection in medicine, making successful coordination, synergy and integration among players a challenge. It is

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6 IARC: International Agency for Research on Cancer
7 PAHO: Pan American Health Organization
8 Argentina, Australia, Bahrain, Belgium, Czech Republic, China, Finland, Argentina, France, Germany, Greece, Ireland, Japan, Norway, Qatar, South Korea, Spain, Sweden, Switzerland, United Kingdom, and United States.
9 FORO is the Iberian-American Forum of Regulatory Bodies of Argentina, Brazil, Chile, Cuba, Mexico, Spain and Uruguay.
envisioned that this new WHO initiative will contribute to strengthening international cooperation and promoting a radiation safety culture in medical practice.

6. References

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