Radiation Protection in Medicine

*The Bonn Call for Action*

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Ionizing radiation in health care
Ionizing radiation in health care today

The largest contributor to the exposure of the general population from artificial sources

Annually worldwide

3,600 million X-ray exams (> 300 million in children)

37 million nuclear medicine procedures

7.5 million radiation oncology treatments
Use of radiation in health care

- Benefits for patients gain recognition → the use of radiation in the diagnosis and treatment of human diseases increases.

- Development of modern health technology makes new applications safer.

- However, the inappropriate use can lead to **unnecessary** or **unintended** radiation exposures with potential **health hazards** for **patients and staff**.
The challenge in RP in health care

The wide use of radiation in medicine calls for a **public health** approach to control and minimize health **risks**, while maximizing the **benefits**.
Radiation protection: why?
Radiation effects (I)

- Radiation can induce cell killing, extensive enough to impair the function of the irradiated tissues or organs.

- These effects are clinically observable if the radiation dose exceeds a certain threshold.

- These are called 'tissue reactions' ("deterministic effects" in the past).

*Frequency and severity increase with the dose*

  e.g. cataract, skin damage, nausea, vomiting, sterility, epilation
Radiation effects (II)

- Radiation can also induce non-lethal transformation of a cell that still maintains its reproductive capacity.

- This might lead to cancer in the exposed individual after a latency period (years) or to heritable effects in the offspring.

- These are called 'stochastic effects'.

Their probability increases with the dose Linear Non-Threshold (LNT) hypothesis
Radiation exposure in early life

Growing children are in general more sensitive to radiation:
- physical, physiological, cognitive immaturity
- > proportion of proliferating cells
- new data on children risks (UNSCEAR 2013)

Children have a longer life-span to develop long-term radiation induced health effects like cancer.

Prenatal life has periods of exquisite sensitivity to the effects of radiation.
Radiation protection: what? how?
Radiation Protection: aim & principles

- To provide an **appropriate level of protection** for people and the environment against the detrimental effects of radiation exposure **without unduly limiting the benefits** that may be associated with such exposure.

- One individual-related RP principle: application of **dose limits**.

- Two source-related RP principles: **justification** of practices/procedures (to do more good than harm), **optimization** of protection (i.e. ALARA principle).
Radiation Protection in Medicine: scope

- Occupational exposures \((health\ workers)\)
- Public exposures
- Medical exposures
  - Patients;
  - Comforters and carers; and
  - Volunteers in biomedical research

World Health Organization
RP principles for medical exposures

- **Dose limits are not applied to medical exposures.** When used appropriately, IR is an essential tool that will cause more good than harm.

- **Justification:** a radiological medical procedure should always be justified *(generic and individual justification).*

- **Optimization:** the dose to the patient should be managed to ensure that it is commensurate with the medical purpose (i.e. the necessary dose *-neither more nor less*) to:
  - obtain the desired image, or
  - deliver an effective therapy
The benefit outweighs the risk when a radiological medical procedure is:

- appropriately prescribed
- properly performed.

This is not the case if there is no clinical indication or the radiation dose is higher than necessary for the clinical purpose (e.g. adult protocols used for imaging children)

- Do the right procedure!
- Do do the procedure right!
Appropriateness in imaging: "Best Test First!"

- When choosing a procedure utilizing ionizing radiation, the **benefit/risk** ratio must be carefully considered.

- There is **unnecessary** use of radiation when clinical evaluation or other imaging modalities could provide an accurate diagnosis (*e.g.* US, MRI).

- Cost, local expertise, available resources, accessibility and patient values have to be considered in addition to efficacy.
JUSTIFICACION

Asymptomatic individuals
Linking justification & optimization

Patient journey

Booking  Registration  Preparation  Examination  Report  Transcription  Validation  Delivery

QA / Error reduction

Justification  Optimization

Gate keeper

(adapted from Dr. L. Lau IRQN/ISR)
The initial DRLs are chosen as a percentile point on the observed distribution of doses to patients (e.g. percentile 75). The values are selected by professional bodies in conjunction with the health authority and the regulatory body, and reviewed at intervals that represent a compromise between the necessary stability and the long-term changes in dose distributions.
In radiotherapy (RT) there is a compromise between the dose to the **target volume** and the dose to **normal tissues**.

The main purpose of RT is to deliver the prescribed dose to the target volume while sparing healthy tissues, in order to **maximize tumor control and minimize risks** (i.e. radiation toxicity, second cancer).

Biological models in radiotherapy aim to predict the tumor control probability (**TCP**) as well as the normal tissue complication probability (**NTCP**) already at the stage of treatment planning, to optimize the treatment for the individual patient.
Tumor control probability and normal tissue complication probability

- The tumor control probability (TCP) as well as the normal tissue complication probability (NTCP) increase with increasing dose, and there is a dose range ("therapeutic window") where the probability for tumor control without complications receives its maximum.

Optimization in RT requires a multidisciplinary team: radiological medical practitioner, medical physicist, radiation technologist...
The paradigm: science, recommendations, standards

Scientific basis
Effects, risks, sources, levels, trends, ...

Recommendations
System of RP
(philosophy, principles, dose criteria, ...)

Standards
(safety requirements, regulatory language, ..)

Medical settings
"What should I do to improve radiation safety in healthcare ????"

Need to bridge this gap
The BSS are the benchmark(*) for radiation safety requirements worldwide.  (*) not legally binding

Revision/update completed in 2011

Adoption by cosponsoring organizations completed in 2012

Current challenge: BSS implementation.
The Bonn Conference and its Call for Action
International Conference on RP in Medicine

- Organized by the IAEA, cosponsored by WHO, hosted by the Government of Germany.

- > 500 participants from 77 countries and 16 organizations reviewed advances, challenges and opportunities.

- Main outcome: **Bonn Call for Action** to improve RP in health care in the next decade.
Joint IAEA and WHO Position Statement on the Bonn Call-for-Action

The “International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade” was held 3-7 December 2012 in Bonn, Germany. It was organized by the International Atomic Energy Agency (IAEA), co-sponsored by the World Health Organization (WHO), and hosted by the Government of Germany through the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. The Conference had the specific purpose of identifying and addressing

Participants from 77 countries and 16 international organizations attended the Conference, and an important outcome was the identification of responsibilities and a proposal for priorities for stakeholders regarding radiation protection in medicine for the next decade. This specific outcome is the **Bonn Call for Action**. It is a statement that identifies the main actions considered to be essential for the strengthening of radiation protection in medicine. Participants and organizations who attended the Conference expressed the need for a joint statement to be issued by the IAEA and the WHO.
Bonn Call for Action

1. Enhancing implementation of justification of procedures
2. Enhancing implementation of optimization of protection and safety
3. Strengthening manufacturers’ contribution to radiation safety
4. Strengthening RP education and training of health professionals
5. Shaping & promoting a strategic research agenda for RP in medicine
6. Improving data collection on radiation exposures of patients and workers
7. Improving primary prevention of incidents and adverse events
8. Strengthening radiation safety culture in health care
9. Fostering an improved radiation benefit-risk-dialogue
10. Strengthening the implementation of safety requirements (BSS) globally

Action 1: Enhance the implementation of the principle of justification

a) Introduce and apply the 3A’s (awareness, appropriateness and audit), which are seen as tools that are likely to facilitate and enhance justification in practice;

b) Develop harmonized evidence-based criteria to strengthen the appropriateness of clinical imaging, including diagnostic nuclear medicine and non-ionizing radiation procedures, and involve all stakeholders in this development;

c) Implement clinical imaging referral guidelines globally, keeping local and regional variations in mind, and ensure regular updating, sustainability and availability of these guidelines;

d) Strengthen the application of clinical audit in relation to justification, ensuring that justification becomes an effective, transparent and accountable part of normal radiological practice;

e) Introduce information technology solutions, such as decision support tools in clinical imaging, and ensure that these are available and freely accessible at the point-of-care;

f) Further develop criteria for justification of health screening programmes for asymptomatic populations (e.g. mammography screening) and for medical imaging of asymptomatic individuals who are not participating in approved health screening programmes.
Action 2: Enhance the implementation of the principle of optimization of protection and safety

a) Ensure establishment, use of, and regular update of diagnostic reference levels for radiological procedures, including interventional procedures, in particular for children;

b) Strengthen the establishment of quality assurance programmes for medical exposures, as part of the application of comprehensive quality management systems;

c) Implement harmonized criteria for release of patients after radionuclide therapy, and develop further guidance as necessary;

d) Develop and apply technological solutions for patient exposure records, harmonize the dose data formats provided by imaging equipment, and increase utilization of electronic health records.
Action 3: Strengthen manufacturers’ role in contributing to the overall safety regime

a) Ensure **improved safety of medical devices** by enhancing the radiation protection features in the design of both equipment and software and to make them available as default rather than optional;

b) Support development of **technical solutions for reduction of radiation exposure** of patients and health workers, while maintaining clinical outcome;

c) Enhance the provision of tools and support in order to give **training for users** that is specific to the particular medical devices, taking into account radiation protection and safety aspects;

d) Reinforce the **conformance to applicable standards** of equipment with regard to performance, safety and dose parameters;

e) Address the special needs of **health care settings with limited infrastructure**, such as sustainability and performance of equipment, whether new or refurbished;

f) Strengthen **cooperation and communication between manufacturers and other stakeholders**, such as health professionals and professional societies;

g) Support usage of **platforms for interaction** between manufacturers and health and radiation regulatory authorities and their representative organizations.
Action 4: Strengthen radiation protection education and training of health professionals

a) Prioritize radiation protection education and training for health professionals globally, targeting professionals using radiation in all medical and dental areas;

b) Further develop the use of newer platforms such as specific training applications on the Internet for reaching larger groups for training purposes;

c) Integrate radiation protection into the curricula of medical and dental schools, ensuring the establishment of a core competency in these areas;

d) Strengthen collaboration in relation to education and training among education providers in health care settings with limited infrastructure as well as with international organizations and professional societies;

e) Pay particular attention to the training of health professionals in situations of implementing new technology.
Action 5: Shape and promote a strategic research agenda for radiation protection in medicine

- Explore the **re-balancing of radiation research budgets** in recognition of the fact that an overwhelmingly percentage of human exposure to man-made sources is medical;

- Strengthen investigations in **low-dose health effects and radiological risks** from external and internal exposures, especially in **children and pregnant women**, with an aim to reduce uncertainties in risk estimates at low doses;

- Study the occurrence of and mechanisms for individual differences in **radiosensitivity and hypersensitivity to ionizing radiation**, and their potential impact on the radiation protection system and practices;

- Explore the possibilities of identifying **biological markers specific to ionizing radiation**;

- **Advance research in specialized areas of radiation effects**, such as characterization of deterministic health effects, cardiovascular effects, and post-accident treatment of overexposed **Individuals**

- Promote research to improve methods for **organ dose assessment**, including patient dosimetry when using unsealed radioactive sources, as well as external beam small-field dosimetry.
Action 6: Increase availability of global information on medical and occupational exposures in medicine

- Improve collection of dose data and trends on medical exposures globally, and especially in low- and middle-income countries, by fostering international co-operation;

- Improve data collection on occupational exposures in medicine globally, also focusing on corresponding radiation protection measures taken in practice;

- Make the data available as a tool for quality management and for trend analysis, decision making and resource allocation.
Action 7: Improve prevention of medical radiation incidents and accidents

- Implement and support voluntary **safety reporting systems** for the purpose of learning from the return of experience of safety related events in medical uses of radiation;

- **Harmonize taxonomy** in relation to medical radiation incidents and accidents, as well as related communication tools such as severity scales, and consider **harmonization with safety taxonomy in other medical areas**;

- Work towards inclusion of **all modalities** of medical usage of ionizing radiation in voluntary safety reporting, with an emphasis on brachytherapy, interventional radiology, and therapeutic nuclear medicine in addition to external beam radiotherapy;

- Implement **prospective risk analysis** methods to enhance safety in clinical practice;

- Ensure prioritization of **independent verification of safety** at critical steps, as an essential component of safety measures in medical uses of radiation.
Action 8: Strengthen radiation safety culture in health care

- Establish **patient safety** as a strategic priority in medical uses of ionizing radiation, and recognize leadership as a critical element of strengthening radiation safety culture;

- Foster closer **co-operation between radiation regulatory authorities, health authorities and professional societies**;

- Foster closer **co-operation on radiation protection between different disciplines** of medical radiation applications as well as between **different areas of radiation protection** overall, including professional societies and patient associations;

- Learn about **best practices** for **instilling a safety culture from other areas**, such as the nuclear power industry and the aviation industry;

- Support integration of **radiation protection aspects in health technology assessment**;

- Work towards recognition of **medical physics** as an independent profession in health care, with **radiation protection responsibilities**;

- Enhance information exchange among peers on radiation protection and safety-related issues, utilizing **advances in information technology**.
Action 9: Foster an improved radiation benefit-risk dialogue

a) Increase **awareness** about radiation benefits and risks among health professionals, patients and the public;

b) Support **improvement of risk communication skills** of health care providers and radiation protection professionals – involve both technical and communication experts, in collaboration with patient associations, in a concerted action to develop clear **messages tailored to specific target groups**;

c) Work towards an **active informed decision making process for patients**.
Action 10: Strengthen the implementation of safety requirements globally

a) Develop practical guidance to provide for the implementation of the International Basic Safety Standards (BSS) in health care globally;

b) Further the establishment of sufficient legislative and administrative framework for the protection of patients, workers and the public at national level, including enforcing requirements for radiation protection education and training of health professionals, and performing on-site inspections to identify deficits in the application of the requirements of this framework.
Improving RP in medicine

A number of actions from international organizations, professional societies, scientific institutions, regulators, others…

Bridge gaps
Respond to needs
Avoid duplication
Foster cooperation between regulators and health authorities
Co-operate, coordinate, interact, concert actions
Build partnership, engage stakeholders.
Thank you very much for your attention

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