Improving radiation protection in medicine

The Bonn Call for Action

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The function of the World Health Organization (WHO)

WHO is the directing and coordinating authority for health within the United Nations system.
The WHO's objective

“Attainment by all peoples of the highest possible level of health”
WHO is conducting a Global Initiative on Radiation Safety in Health Care Settings

Diagnostic radiology
Interventional radiology
Radiotherapy
Nuclear Medicine

To promote safe and appropriate use of radiation in health care
To support the implementation of the recommendations of the Bonn Conference

Bonn Call for Action

10 actions to improve radiation protection in medicine in the next decade

http://www.who.int/ionizing_radiation/about/med_exposure/en/
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.
Global collaboration to improve justification: imaging referral guidelines

- Insufficient **access at the point of care** is a major cause of lack of adherence of physicians to referral guidelines (RGs).

- Computerized decision support systems facilitate **integration of imaging RGs into the daily workflow**, but there is a need to consider **local conditions** for feasible and sustainable implementation.

- Need to complement RGs with other strategies (**awareness, audit, education**)
Medical Imaging of Asymptomatic People for Individual Health Assessment (IHA)

- Expert consultation **Justification of the use of CT for individual health assessment (IHA) of asymptomatic people** Munich, Oct. 2014

- Report of this consultation as a **paper** for submission to a peer-reviewed journal

- **Stakeholders workshop** in 2016

- Final report: a framework with key factors in the **process of justification**
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.
Optimization in medical exposures

- The dose to the patient to be commensurate with the medical purpose.

- In medical imaging the goal is to use the suitable dose to obtain the desired image ("diagnostic quality image") i.e. "not more nor less" dose.

- Diagnostic reference levels (DRLs)
Optimization of protection and safety

- Collaboration with Image Gently and its International Outreach Committee, contribution (Advisory Group) to the EC Project PiDRL (paediatric DRLs)

- Side Event at the next WHA68 proposed by the MS & NGOs
  - "Imaging to Save Kids- the inside story of patient safety in paediatric radiology" Initiative of the ISR, co-organized with 4 Member States and other NGOs in Official Relations with WHO: ISRRT, IOMP, ICRP, ICNIRP, WFUMB, DITTA, RAD-AID and WONCA
**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.
Engagement of manufacturers: DITTA

- Represents and unites the medical imaging industry to address global issues.
- DITTA just became an NGO in Official Relations with the WHO
- DITTA’s membership: COCIR (Europe), JIRA (Japan), ITAC (Canada), MEDEC (Canada), MITA (United States), THAIMED (Thailand), IMEDA (Russia), CAMDI (China), ABIMED (Brazil) and KMDICA (Korea).
- DITTA was represented at the 1st Regional Workshop on RP Culture in Medicine co-organized by IRPA-WHO-IOMP (Buenos Aires, 11th April 2015) and supports a side event at the next Work Health Assembly on RP in paediatric imaging
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.
Global collaboration to develop guidance on RP education and training of health workers

- ICRP report 113 "Education and Training in Radiological Protection for Diagnostic and Interventional Procedures"

- EC Radiation Protection N° 175 Guidelines on RP education and training of medical professionals in the EU

### MEDRAPET guidance (EC RP N°175)

#### Table 3.1: Learning outcomes in radiation protection for referrers

<table>
<thead>
<tr>
<th>Knowledge (facts, principles, theories, practices)</th>
<th>Skills (cognitive and practical)</th>
<th>Competence (responsibility and autonomy)</th>
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</thead>
<tbody>
<tr>
<td>K1. Explain the principle of justification and its application at different levels including for asymptomatic individuals and on a case by case basis.</td>
<td>S1. Apply the principle of justification to specific groups of patients and individuals including the exposure of asymptomatic Individuals, comforters and carers.</td>
<td>C1. Take responsibility for justification in accordance with requirements in European and national legislation and guidelines of professional bodies.</td>
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<tr>
<td>K2. List the diagnostic and therapeutic practices that are formally approved through legislative or administrative acts at the national or state level.</td>
<td>S2. Identify situations in which the use of ionising radiation is justified in the case of pregnant women, women of reproductive age, children or breast feeding mothers.</td>
<td>C2. Implement published appropriateness criteria in own practice.</td>
</tr>
<tr>
<td>K3. Explain why certain groups are more susceptible to harmful effects of ionising radiation (e.g. children, pregnant patients)</td>
<td>S3. Assess the cumulative effective dose for a series of exams for a given individual patient.</td>
<td>C3. Provide necessary information in referral for imaging facility to aid in optimisation of an examination.</td>
</tr>
<tr>
<td>K4. Explain the joint responsibility of referrers and imaging specialists in the justification process of a radiological examination as specified by European and national legislation.</td>
<td>S4. Carry out a review of the literature to aid justification in cases for which appropriateness criteria are not yet available.</td>
<td>C4. Advise actions in case of inadvertent radiation exposure of a pregnant patient.</td>
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<tr>
<td>K5. List approximate values of radiation doses for common diagnostic examinations.</td>
<td>S5. Explain benefits and risks of particular procedures to specific patients.</td>
<td>C5. Be competent to diagnose radiation induced skin injury and other potential radiation effects in a patient or a worker in a radiation facility and avoid unnecessary referral.</td>
</tr>
<tr>
<td>K6. Explain the importance of the utilisation of clinical and radiological information from previous examinations in the process of justification.</td>
<td>S6. Inform patients of their health problems and the planned procedure.</td>
<td>C6. Act as a role model for junior colleagues to support the processes of justification and optimisation of radiation protection.</td>
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<tr>
<td>K7. Discuss some clinical situations where a test with non-ionising radiation is better than one using ionising radiation.</td>
<td>S7. Communicate the radiation risk to the patient at an understandable level, whenever there is a significant deterministic or stochastic risk, or when the patient has a question.</td>
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<tr>
<td>K8. List and describe available appropriateness criteria and guidelines applicable in your area of practice.</td>
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<tr>
<td>K9. Discuss the information to be provided to patients with respect to benefits and radiation risk and risk of procedures in own area of practice.</td>
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<tr>
<td>K10. Explain principles governing the use of ionising radiation in woman of child-bearing age.</td>
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<td>K11. Discuss the pros and cons of an examination involving the use of a radiopharmaceutical for breastfeeding women and action warranted to protect the child.</td>
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<tr>
<td>K12. Explain circumstances in your practice where use of ionising radiation on a child is justified.</td>
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</tbody>
</table>
Training Package on Justification of Medical Imaging and Use of Referral Guidelines

- **Train referrers** on the use of medical imaging referral guidelines.
- Enable participants to subsequently deliver effective local training on medical imaging referral guidelines using the WHO-ISR curriculum ("train-the-trainers").
- Apply a “Locally-Championed and Globally-Supported” model to help build a sustainable approach for training in various local environments.
Training of Referrers on Justification and Use of Imaging Referral Guidelines

- Pilot testing of a training package in Dubai, Sept 2014
- Collaboration with WONCA and European Academy of Teachers in General Practice and Family Medicine (EURACT), to adapt/pilot the training material to family doctors (2015-2016)

Dubai, UAE, Sept. 2014
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 overwhelming 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 hyper-sensitivity 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.
Research for health: priority setting

• Shaping and promoting a global research agenda for radiation protection in medicine

• Collaboration with EC Open Project for the European Radiation Research Area (OPERRA)

• Strategic Research Agenda (SRA) on RP in Medicine
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 cooperation;

- 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.
Workshops on **Data Collection in Medical Exposures** jointly organized by UNSCEAR-WHO-IRPA during the regional IRPA Congresses:

1. **Asian** Workshop in Kuala Lumpur, May 2014
2. **European** Workshop in Geneva, June 2014
3. **African** Workshop in Rabat, September 2014
4. **Latin American** Workshop, Buenos Aires, April 2015

This platform is supported to stimulate international organizations to provide national and regional data on the use of radiation in medical diagnosis and treatment for the next UNSCEAR Global Survey of Medical Radiation Usage and Exposures from 2005 onwards.

National focal persons (NFP) are invited to register here to be able to access the protected area before they can download the questionnaires for official data submission. Additional national experts can be registered to support the NFPs.

UNSCEAR is grateful to the World Health Organization for the arrangement for cooperation established which resulted in developing a common medical questionnaire for this survey and the European Commission for permitting the use of the outcomes of the DoseDataMed II project.
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.
Minimal Information Model for Adverse Event Reporting in Health Care

- Patient Safety
- Injection Safety
- Blood Safety
- Pharmacovigilance
- Radiation Safety
- Human-derived
- Safety in surgery
- Safety in vaccination
- Technovigilance

Collaboration with IAEA to promote use of **SAFRON, SEVRRA**
**Action 8: Strengthen radiation safety culture in health care**

a) 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;

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

c) 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;

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

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

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

g) Enhance information exchange among peers on radiation protection and safety-related issues, utilizing **advances in information technology**.
Guiding principles to establish safety culture in health care

- IRPA-IOMP-WHO project
- Regional workshops to be held 2015-2016
  - Latin America: Buenos Aires, 11\textsuperscript{th} April 2015
  - Europe: Geneva, 30\textsuperscript{th} Nov to 2\textsuperscript{nd} December 2015
  - Africa, Asia, … TBC

Radiation Protection Culture in Medicine

Regional Workshop
11 April 2015
Buenos Aires, Argentina
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.
Tools to support risk-benefit dialogue

Dialogue Seminar to test the tool followed by a Kids' Workshop jointly organized by WHO and NIRS

(Chiba, Japan, 7-9 December 2014)
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.
Radiation basic safety standards (BSS)

- The new **international BSS** cosponsored by 8 international organizations including WHO, have expanded the requirements for medical exposures.

- Through the Global Initiative in RSHCS, **WHO is working to support the BSS implementation in the health sector**
WHO continued working with BSS cosponsors to support BSS implementation. WHO is a member of the Inter-Agency Committee on Radiation Safety (IACRS), a forum for collaboration in matters of radiation safety, to promote consistency and co-ordination of policies with respect to areas of common interest.

IACRS created a **Task Group on BSS Implementation** with a strategic plan including safety guides, regional and national BSS workshops, update of training packages, development of information materials (e.g. brochures, posters, leaflets).
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 for 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

Disseminating the Bonn Call for Action

- Dissemination of the Bonn Call for Action at regional IRPA Congresses 2014
- Presentation at a WHO-Asian Pacific Symposium KSR, October 2014
- Presentation at IAEA–WHO Workshop on BSS in China (July 2014) and IAEA-WHO African Workshop Medical Physics role in Tanzania Nov 2014
- PACORI and launching of AFROSAFE, Kenya, February 2015
Global networking: cross fertilization and positive impact

- 2007 **Image Gently**: radiation safety in paediatric imaging, followed by **Image Wisely**: radiation safety in adult medical imaging (started in USA, expanded later)

- 2014: **Eurosafe Imaging**: holistic approach to improve safety and quality in medical imaging in Europe

- 2015: **AfroSafe**: multistakeholders campaign to improve safety and quality in medical uses of radiation in Africa
PAN AFRICAN CONGRESS OF RADIOLOGY AND IMAGING
BIENNIAL SCIENTIFIC CONGRESS
Held at Laico Regncy Hotel, Nairobi, 17th - 20th February, 2015

THEME: BEYOND MDGS: RADIOLoGY TOWARDS SUSTAINABLE QUALITY HEALTH CARE
WS for Portuguese speaking countries

- Workshop on RP in medicine for **Portuguese speaking countries**
  - Plans to hold it in Lisbon, Portugal (September 2015)
  - Jointly organized by Portugal and Brazil, in cooperation with WHO
  - Cooperation with IAEA
  - To Involve other Portuguese-speaking countries
Portuguese speaking countries involved in WHO's e-Portuguese network

- Angola
- Brazil
- Cape Verde
- Guinea-Bissau
- Equatorial Guinea (new)
- Mozambique
- Portugal
- Sao Tome and Principe
- Timor-Leste
CONFERENCIA IBEROAMERICANA SOBRE PROTECCIÓN RADIOLÓGICA EN MEDICINA

MADRID, 18, 19 y 20 de octubre 2016

Casa de América, (Palacio de Linares), Madrid
Thank you!
Gracias!
Obrigada!
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