RADIATION PROTECTION IN MEDICINE

Setting the Scene for the Next Decade

Proceedings of an International Conference
3–7 December 2012
Bonn, Germany

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International Atomic Energy Agency

RADIATION PROTECTION IN MEDICINE: SETTING THE SCENE FOR THE NEXT DECADE

The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world''.

PROCEEDINGS SERIES

RADIATION PROTECTION IN MEDICINE: SETTING THE SCENE FOR THE NEXT DECADE

PROCEEDINGS OF AN INTERNATIONAL CONFERENCE
ORGANIZED BY THE
INTERNATIONAL ATOMIC ENERGY AGENCY,
HOSTED BY THE GOVERNMENT OF GERMANY,
CO-SPONSORED BY THE WORLD HEALTH ORGANIZATION
AND HELD IN BONN, GERMANY, 3–7 DECEMBER 2012

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2015

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Marketing and Sales Unit, Publishing Section
International Atomic Energy Agency
Vienna International Centre
PO Box 100
1400 Vienna, Austria
fax: +43 1 2600 29302
tel.: +43 1 2600 22417
email: sales.publications@iaea.org
http://www.iaea.org/books

Printed by the IAEA in Austria
September 2015
STI/PUB/1663

IAEA Library Cataloguing in Publication Data

Radiation protection in medicine : setting the scene for the next decade : proceedings of an International Conference, Bonn, 3–7 December 2012. — Vienna : International Atomic Energy Agency, 2015.
p. ; 24 cm. — (Proceedings series, ISSN 0074–1884)
STI/PUB/1663
ISBN 978–92–0–103914–9
Includes bibliographical references.

1. Medical radiology — Safety measures — Congresses. 2. Radiation — Safety measures — Congresses. 3. Nuclear medicine — Safety measures — Congresses. I. International Atomic Energy Agency. II. Series.

IAEAL 15–00973

FOREWORD

The first international conference addressing radiation protection of patients triggered an International Action Plan that has since been guiding efforts in patient protection worldwide. The Málaga conference, held in March 2001, provided very broad international input on the status of radiation protection of patients at the time, and allowed accurate prediction of future trends. But recent years have witnessed significant increases in medical radiation uses, as well as developments in radiation protection, which need to be taken into account. For the first time in history, several countries are experiencing population doses from medical uses of radiation that exceed those from natural background radiation and have fully eclipsed those from other human sources.

There is no doubt that the application of ionizing radiation and radioactive substances in diagnostic, interventional and therapeutic procedures in medicine is beneficial for hundreds of millions of people each year. However, employing radiation in medicine has to involve carefully balancing the benefits of enhancing human health and welfare and the risks related to radiation exposure. There is a need for a holistic approach which includes partnership between national governments, civil society, international agencies, researchers, educators and professional associations aimed at identifying, implementing and advocating solutions; and leadership, harmonization and coordination of activities and procedures at an international level. Ionizing radiation in medicine involves the deliberate and direct exposure of humans, and there is a strong and continuing need to protect patients from unnecessary and unintended exposure, and also to protect medical staff, in particular, from incurring high doses.

Unnecessary exposure of patients can arise from medical procedures that are not justified for a specified objective, from the application of procedures to individuals whose condition does not warrant such intervention, and from medical exposures that are not appropriately optimized for the situation in which they are being used. Unintended exposure of patients and medical staff can arise from unsafe design or inappropriate use of medical technology. The number of occupationally exposed workers is much higher in medicine than in any other professional field, and individual occupational exposure varies widely among those involved in medical care.

Recent years have seen an increased recognition of the importance of communication with patients and patient organizations on medical radiation protection, as well as the value of openly sharing knowledge on adverse events involving medical radiation sources.

Considering these issues and taking account of current trends and developments, it became necessary to organize a conference to focus efforts

in this area for the next decade and to maximize the positive impact of future international work in radiation protection in medicine.

Thus, with the World Health Organization as co-sponsor, and the Government of Germany through the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety as host, the International Atomic Energy Agency organized the International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade. The conference was held in Bonn, 3–7 December 2012, and aimed, in particular, to:

- Indicate gaps in current approaches to radiation protection in medicine;
- Identify tools for improving radiation protection in medicine;
- Review advances, challenges and opportunities in the field of radiation protection in medicine;
- Assess the impact of the International Action Plan for the Radiation Protection of Patients, in order to prepare new international recommendations, taking into account newer developments.

The conference was attended by 536 participants and observers from 77 countries and 16 organizations. Eight topical sessions and four round table discussions were organized in a one-track programme that allowed all participants to follow all discussions. In addition, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the European Commission (EC) hosted lunchtime breakout sessions to address state of the art developments in their respective areas of expertise. The following organizations also contributed to the briefing session: the Pan American Health Organization (PAHO), the International Organization for Medical Physics (IOMP), the International Radiation Protection Association (IRPA), the International Society of Radiology (ISR) and the International Society of Radiographers and Radiological Technologists (ISRRT).

To maximize stakeholder participation, contributed papers were summarized by invited experts and presented for the respective sessions and round table discussions, and authors had the additional option to present their work as posters. This resulted in the acceptance of 224 contributed papers that described developments and the results of research being undertaken in all continents of the world. Invited papers were presented for each session and round table discussion to form part of the bases for the ensuing discussion among all participants. At the concluding session, summaries of all discussions were presented, together with insight into relevant requirements stated in Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (IAEA Safety Standards Series No. GSR Part 3) and perceptions of goals and challenges for the next decade.

An important outcome of the conference was the identification of responsibilities and proposal for priorities of stakeholders regarding radiation protection in medicine for the next decade. This is the Bonn Call for Action.

The aims of the Bonn Call for Action are: (a) to strengthen the radiation protection of patients and health workers overall; (b) to attain the highest benefit with the least possible risk to all patients by the appropriate use of ionizing radiation medicine; (c) to aid the full integration of radiation protection into health care systems; (d) to help improve the benefit–risk dialogue with patients and the public; and (e) to enhance the safety of technical operations in medicine.

The Bonn Call for Action highlights ten main actions, and related subactions, that were identified as being essential for the strengthening of radiation protection in medicine over the next decade. Action by all stakeholders is encouraged.

The IAEA gratefully acknowledges the support and generous hospitality extended to the conference participants by the German authorities. The IAEA officer responsible for this publication was O. Holmberg of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

The Proceedings have been edited by the editorial staff of the IAEA to the extent considered necessary for the reader's assistance. The views expressed remain, however, the responsibility of the named authors or participants. In addition, the views are not necessarily those of the governments of the nominating Member States or of the nominating organizations.

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BONN CALL FOR ACTION

The Bonn Call for Action highlights ten main actions, and related sub-actions, that were identified as being essential for the strengthening of radiation protection in medicine over the next decade. The actions are not listed in order of importance. Action by all stakeholders is encouraged.

Action 1: Enhance the implementation of the principle of justification

(a) Introduce and apply the 3As (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 (e.g. use of CT for individual health surveillance).

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 detailed 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 physical equipment and software and to make these available as default features rather than optional extra features;
(b) Support development of technical solutions for reduction of radiation exposure of patients, while maintaining clinical outcome, as well as of health workers;
(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 among these providers and 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

(a) 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;
(b) 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;
(c) 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;
(d) Explore the possibilities of identifying biological markers specific to ionizing radiation;
(e) Advance research in specialized areas of radiation effects, such as characterization of deterministic health effects, cardiovascular effects, and post-accident treatment of overexposed individuals;
(f) 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 improved global information on medical exposures and occupational exposures in medicine

(a) Improve collection of dose data and trends on medical exposures globally, and especially in low and middle income countries, by fostering international cooperation;
(b) Improve data collection on occupational exposures in medicine globally, also focusing on corresponding radiation protection measures taken in practice;
(c) 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

(a) Implement and support voluntary educational safety reporting systems for the purpose of learning from the return of experience of safety related events in medical uses of radiation;
(b) 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;
(c) 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;
(d) Implement prospective risk analysis methods to enhance safety in clinical practice;
(e) 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

(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 cooperation between radiation regulatory authorities, health authorities and professional societies;
(c) Foster closer cooperation 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.

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 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.

OPENING SESSION

Chairperson

M. PINAK
IAEA

OPENING ADDRESS

U. Heinen-Esser
Parliamentary State Secretary,
Federal Ministry for the Environment, Nature Conservation and Nuclear Safety,
Bonn, Germany

As the host of this conference in the former German capital, I would like to extend a warm welcome to you all, and to express my heartfelt thanks to you, **Mr. Flory** (Head of the Department of Nuclear Safety and Security), as representative of the IAEA, for accepting the German Government's offer to hold this important conference on Radiation Protection in Medicine here in Bonn, which is a great honour. At the same time, I would like to congratulate the IAEA on its excellent scientific preparation.

I would also like to welcome:

— **Mr. Matić** — the Acting Director of the World Health Organization European Centre for Environment and Health, who likewise supports this conference;
— **Mr. Nimptsch** — Mayor of the City of Bonn;
— **Mr. Faross** — of the European Commission;
— **Mr. Hendee** — Chair of the Programme Committee. Mr. Hendee, you have made a major contribution to the content and structure of this excellent, well balanced programme. Thank you very much for all your hard work.

There is one other person I would particularly like to thank at this point: **Mr. Weiss**, the President of this conference. Mr. Weiss, you may have officially retired from active working life in the summer, but you have been far from idle over the past few months. You have invested a huge amount of time and commitment, and this conference has benefited enormously from your wide ranging professional expertise. You have been instrumental in helping to ensure its success — thank you very much.

Ten years ago, the IAEA invited us to Malaga to discuss radiation protection in medicine. The outcome of that conference was the adoption of an Action Plan, which has guided international efforts on protecting patients from ionizing radiation ever since. Since then, developments in medicine have progressed at a rapid pace. New diagnosis and treatment techniques using ionizing radiation and radioactive substances have become well established. At the same time, there is also a growing awareness of both the benefits and risks of using ionizing radiation on humans.

In the face of such rapid progress, and all opportunities currently available for using ionizing radiation, we should continue to be guided by the following three pillars of radiation protection:

(1) Justification — weighing up the benefits and risks, i.e. the benefits of treatment must outweigh the risks. The increasing use of ionizing radiation in medicine worldwide (4 billion diagnostic procedures in 2008) is an indication of its benefits. However, it must benefit *all* countries. Radiation supported health services (e.g. for cancer diagnosis and treatment) must also be made accessible to developing countries. Conversely, with the wide range of diagnostic techniques using ionizing radiation, we must never lose sight of the associated risks. This is particularly true of early detection screening. Clear framework conditions on the admissibility of such screening must be drawn up.
(2) Optimization — achieving the treatment objectives with the lowest possible dose. Whichever diagnostic method or treatment is chosen, it should always be performed with the lowest possible radiation dose for both the patient and the medical personnel. We have a social and an ethical responsibility to control exposure appropriately. The protection and safe treatment of children is particularly key in this regard. Optimizing exposure is an ongoing challenge.
(3) Risk minimization — limiting the risk (for example, when setting limits). Apart from the obvious benefit of improving human health, it is very important to ensure the patient's safety, and increasingly, that of the medical personnel as well. This requires, firstly, the setting of standards and limits; and secondly, a good quality assurance regime (testing of equipment and procedures).

Modern high-tech diagnosis and treatment methods demand specialist knowledge and expertise at the highest level from physicians and medical personnel. A solid education and training in radiation medicine, therefore, offers the basis for effective radiation protection. In order to achieve this on a global scale, we must support developing countries, particularly via the transfer of expertise and training support.

The points I have touched on will be intensively discussed by you during the course of this conference. You will share your knowledge and expertise and rise to the great challenge of this IAEA conference — namely, to advance existing radiation protection standards and set new standards for the decade ahead. This is an important and honourable task: let us define uniform global standards for the justification and optimized use of ionizing radiation and radioactive substances, both to the benefit of the patient, and for the protection of medical personnel.

I would be delighted if we were to adopt a new action programme by the end of this week, and meet the shared objective of this conference: Setting the Scene for the Next Decade.

I wish you every success in pursuit of this goal.

OPENING ADDRESS

D. Flory
Deputy Director General,
Department of Nuclear Safety and Security,
International Atomic Energy Agency,
Vienna

Good morning and welcome to the IAEA's International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade.

I am pleased to have the opportunity to express the sincere gratitude of the IAEA to our host, the Government of Germany through the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, and to our co-sponsor, the World Health Organization, for making it possible to hold this valuable conference in this historical city of Bonn.

Being here today for me also means that there is life and work — important life and work — outside the scope of the lessons learned from last year's accident at Fukushima. Indeed, safety of nuclear power plants and contaminations following a nuclear accident have been, and still are, at the forefront of the concerns of governments and the public worldwide, but it is as well tremendously important to continue progressing in a field of safety which rarely makes the first page of newspapers: radiation protection in medicine.

Let me begin by stating that the use of ionizing radiation in medicine has brought humankind tremendous benefits since it was first used more than a hundred years ago. Over the years, the development of new technologies, new procedures and new uses has quickened its pace. This has resulted in medical radiation exposures becoming a very significant component of the total radiation exposure of humans. It is currently estimated that every single day, 10 million people receive diagnostic, therapeutic or interventional medical radiation procedures.

While the majority of these procedures are performed safely and appropriately, there are situations throughout the world where radiation safety is either lacking or deficient.

This is a central issue in your work, this week. More than 600 participants have registered for this conference, representing 88 Member States and 17 organizations. I say 'representing': I know that many more of our colleagues from all stakeholder groups would have liked very much to join our discussions this week.

You know that unintended exposure of patients and medical staff can arise from unsafe design or from inappropriate use of medical technology. There

have been a number of reports in recent years of accidents in several countries involving the use of ionizing radiation in medicine that caused either an over- or underdose to a large number of patients, which both may be detrimental to patients. The number of occupationally exposed workers is much higher in medicine than in any other professional field, and individual occupational exposure also varies widely among those involved in medical care.

The Malaga conference in 2001, which many of you may have attended, resulted in the International Action Plan on the Radiation Protection of Patients. This Action Plan has guided the international work of organizations, including the IAEA, in addressing the topic of achieving a culture of safety in the use of ionizing radiation in medicine.

As Deputy Director General of the IAEA, in charge of Nuclear Safety and Security, I can share with you some successful developments from recent years:

— The publication of safety standards, safety reports and guidance, as well as the development of a web site that provides information to patients and to the public, to health professionals and to specialized institutes among our Member States. This web site receives more than 1 million hits per month and is now also employing social media to increase its outreach.
— Electronic information sharing on safety related medical events in radiotherapy and interventional procedures, as well as on occupational exposure in medicine.
— Training courses and workshops have been delivered to many different groups of health professionals in our Member States, using approved standardized training material which has been developed over the years.

It has been possible to realize these successful developments only with the cooperation of our sister United Nations organizations, regional organizations such as the European Commission and the Pan American Health Organization, professional societies and, not least of all, the contributed expertise of renowned professionals such as yourselves. Together, we can ensure that the highest international radiation safety standards are developed and brought into force worldwide. Thank you to all of you for making this international progress possible.

But, observable and unmistakable trends stimulate the need to pursue further actions to improve safety for patients and health workers. Hence, our conference has the following objectives:

— To indicate gaps in current approaches to radiation protection in medicine;
— To identify tools for improving radiation protection in medicine;
— To review advances, challenges and opportunities in the field of radiation protection in medicine;

— To assess the impact of the International Action Plan for the Radiation Protection of Patients, in order to prepare new international recommendations, taking into account new developments.

The more than 200 submitted papers, 8 topical sessions and 4 round tables should provide fruitful discussions to guide our future work.

This is a single-track conference, which means that each of you is assured the possibility to follow *all* sessions and to participate in *all* discussions.

Together in this conference, we can arrive at a point which will guide our work in the next decade. It is for all of us, together, to formulate the call to action for the next decade.

Let us ensure that the work that we started in our respective institutes and organizations, and the focus of our discussions this week, will strongly contribute to instilling safety culture and promoting patient and worker safety in medicine.

But, in the same way as for reactor safety, understanding the issues and developing standards to answer them is not enough. Implementation is key. For safety culture in medicine to become an everyday reality, commensurate with the number of procedures delivered every day, we — you, must reach out to government and parliaments for a proper legislative and regulatory framework (we have relevant standards at the IAEA); we must also reach out to all professionals, particularly at the early stage of training. This is how my son, a cardiologist, became radiation conscious in his practice.

I wish you a productive conference. Thank you for your attention.

OPENING ADDRESS

S. Matić
Acting Director,
WHO European Centre for Environment and Health,
World Health Organization,
Geneva

It is a great pleasure for me to welcome you on behalf of the World Health Organization (WHO) to this International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade. I congratulate the IAEA for organizing this meeting and for inviting the WHO as a co-sponsor. I particularly thank the Government of Germany for hosting this event through the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. I wish to commend the Conference President, as well as the Chairperson and members of the Programme Committee, for making today's event a reality by putting together the outstanding programme you will develop during the next five days.

Radiation protection in medicine is an essential component of good medical practice that has established itself as a subject of interest not only for radiation safety bodies and health authorities but also for policy makers, health care providers, researchers, manufacturers, patients and the general public. Your presence here today confirms this fact.

There is a global trend of a major increase in the number of radiological procedures, medical uses of ionizing radiation being the largest artificial source of radiation exposure today. Ionizing radiation has become one of the most important diagnostic tools and an essential component of cancer treatment. On the benefits side, new technologies, applications and equipment are constantly being developed to improve the safety and efficacy of procedures. At the same time, incorrect or inappropriate handling of these increasingly complex technologies can also introduce potential health hazards for patients and staff. This demands public health policies that both recognize the multiple health benefits that can be obtained, while addressing and minimizing health risks.

Management of such risks depends on two principles of radiation protection: justification for prescribing each procedure, and optimization of protection to manage the radiation dose commensurate with the medical purpose. When choosing the best medical imaging procedure for a given clinical condition, doctors have to take appropriate decisions, accounting for both benefits and risks. This is particularly important in paediatric health care, since

children are especially vulnerable to environmental threats and have a longer lifespan to develop long term radiation induced health effects such as cancer.

Primary prevention requires the improvement of radiation safety culture by health care providers. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reviewed the radiation accidents that occurred over more than 60 years (1945–2007). A large number of fatalities (46) and the highest number of cases of acute injuries (623 cases) were due to accidents occurring during the use of radiation in the medical field. It is likely that many more accidents occurred but were either not recognized or not reported.

The International Basic Safety Standards (BSS) represent the international benchmark for radiation safety. The BSS were recently revised and a substantial part of the new safety requirements refer to medical uses of ionizing radiation. The new BSS are co-sponsored by eight international organizations[1], several of which are represented at this conference. As a co-sponsor of the BSS, the WHO has been fully engaged in the revision process, completed the adoption of the new BSS in May 2012 and will foster the implementation of these safety standards in its 194 Member States.

A milestone in the history of radiation protection in medicine was the International Conference on Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy held in Malaga in 2001. One decade has passed since Malaga, and much progress has been made. However, the engagement of the health sector in the implementation of radiation safety standards in health care is still weak in many countries. Changing the culture of medical practice is crucial to ensure that patients benefit from the use of radiation in medical imaging. This will contribute to health systems strengthening, with a more cost effective allocation of health resources.

During the next five days, you will address challenges and opportunities to improve radiation protection in diagnostic radiology, imaging guided interventions, nuclear medicine and radiotherapy in the next decade. You will also have the chance to influence the way these are faced and other emerging challenges. This conference will give you a unique opportunity to enhance regional and international cooperation in this field. Your deliberations and conclusions can substantially contribute to improving the capacity for responding to these public health problems and to ensuring that the available tools are used in the most effective way. I wish you a productive and successful

[1] European Commission, Food and Agriculture Organization of the United Nations, IAEA, International Labour Organization, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environment Programme, and the WHO.

conference and an enjoyable stay in this wonderful place with such a long and distinguished history.

Thank you very much.

OPENING ADDRESS

P. Faross
Acting Deputy Director General,
Directorate-General for Energy,
European Commission,
Luxembourg

It is my pleasure to welcome you, on behalf of the European Commission and of Commissioner Oettinger to the International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade. We are honoured by the fact that a second event of this kind is taking place in Europe following the Malaga conference in 2001, and I would like to express my sincere gratitude to the IAEA and the World Health Organization (WHO) for taking the initiative for this meeting and to the Government of Germany and the city of Bonn for graciously hosting it.

I believe that everyone attending this conference is well aware of today's status of ionizing radiation as an indispensable tool in medicine — a tool used for diagnosis and treatment of patients suffering from medical conditions ranging from simple dental problems to life threatening cardiac diseases and cancer. The huge advances in medical technology and techniques utilizing ionizing radiation are well known, as are the challenges associated with these rapid developments. I am confident that the following week will help us prepare for the future developments and provide the impetus needed to deal with the associated challenges.

In the European Union, we are fortunate to have had a generation of scientists, medical professionals and policy makers who realized the need for radiation protection of patients early. The first European legislation in this area was passed in the 1980s and further elaborated in the 1990s. The European Framework Programme for Research and Innovation supported many projects on medical use of radiation, covering areas such as the transition to digital imaging and the implementation of breast cancer screening. The enlargement of the European Union in 2004 and 2007 helped to spread these achievements to an even larger population, now counting more than 500 million people in 27 countries.

Europe, in the past years, experienced several important developments in the wider area of nuclear energy and radiation protection. In 2009, the European Union adopted, for the first time, a legally binding instrument for nuclear safety and, in 2011, for radioactive waste management. Some European initiatives developed as a consequence of particular events: most importantly,

the ‘stress tests’ of the European reactors following the Fukushima accident have been finalized; more closely related to the present meeting is the recently established European Observatory on the supply of medical radioisotopes aimed at improving the reliability of technetium supply, affected by severe global shortages in the past years.

In May 2012, the European Commission adopted a proposal for a revised Euratom (European Atomic Energy Community) legal framework for radiation protection of workers, patients and the general public. The proposal is merging five existing legal instruments and bringing some important changes, including on protection of patients and medical workers. These changes will be discussed at a Breakout Session of this conference at lunchtime on Wednesday; I would like to invite everyone to take part in this discussion.

In 2010, the European Commission expressed its vision on the challenges and needs of the medical uses of ionizing radiation in a Communication to the European Parliament and the Council of the European Union. In the past years, the Directorate-General for Energy launched several important projects to address those needs. More detail about this will be given by Mr. Janssens in his presentation at the Briefing Session.

The European Commission cooperates with the IAEA on a broad range of issues, and radiation protection in medicine is certainly among our shared priorities; as examples of good cooperation, I would like to mention the European Commission’s involvement in the International Action Plan for the Radiation Protection of Patients and the jointly organized International Workshop on Justification of Medical Exposure in Diagnostic Imaging, held in Brussels in 2009. Last, but certainly not least, we are participating in the Global Initiative on Radiation Safety in Healthcare Settings of the WHO.

In conclusion, I would like to confirm the standing commitment of the European Commission and the Directorate-General for Energy to a high level of radiation protection for European citizens, as patients, workers or members of the general public. We can only achieve this if we learn from each other, talk to each other and help each other. I believe this conference is the right event at the right time for advancing on these goals and I wish all of you fruitful discussions.

OPENING ADDRESS

W. Weiss
President of the Conference
Germany

As you all know, there are three general categories of medical practices involving exposure to ionizing radiation: diagnostic radiology (including image guided interventional procedures), nuclear medicine and radiation therapy. In order to evaluate the level of medical exposures worldwide, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) regularly conducts global surveys of medical radiation usage and exposures. UNSCEAR bases its estimation of medical exposures on an analysis of the questionnaire returns and review of the published scientific literature. Most of the responses have been received from countries defined by the Committee as health care level I countries, which represent under a quarter of the world's population. The most recent results have been published in the 2008 UNSCEAR report: the levels of medical radiation exposure have been steadily increasing during the past decade all around the globe; to reach levels which — in some countries — are comparable to or even larger than the exposure of the population due to natural sources.

There is no doubt that the application of ionizing radiation and radioactive substances in diagnostic and therapeutic procedures is beneficial for hundreds of millions of people each year. On the other hand, the ability of ionizing radiation to penetrate tissues and to kill and transform tissue cells can make it hazardous to health. Employing radiation in medicine, therefore, has to carefully balance the benefits by enhancing human health and welfare, and the risk related to the overall radiation exposure of people in medical practices which should be kept as low as reasonably achievable, in order to minimize its deleterious effects. According to the International Commission on Radiological Protection, there is considerable scope for dose reduction in diagnostic radiology and simple, low cost measures are available for reducing doses without loss of diagnostic information. At the same time, while new diagnostic equipment and techniques are bringing new benefits, some of the procedures involve the delivery of relatively high radiation doses to patients.

While important work has been devoted to optimization over the past decades, less effort has been applied with respect to justification. Thus, recent efforts to strengthen the principle of justification and to discuss its implementation in clinical practice are, in particular, important and promising.

We have ambitious goals for this week, and we are going to address the full spectrum of topics related to the application of ionizing radiation in medicine, including the radiological protection of patients and staff, as well as the role of manufacturers in medical radiation protection. There are two main purposes of this conference: first, to foster information exchange in the area of patient protection; second, to formulate recommendations and findings regarding further international cooperation in this area.

The input will come from the large number of submitted papers, several topical sessions and round tables, and, more importantly, from you — the audience — as there will be enough time for discussion during this conference.

I would like to thank the IAEA as conference organizer and the World Health Organization as co-sponsoring organization, as well as the international organizations contributing to this important event. I would also like to express my gratitude to the Government of Germany and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety for their hospitality, and the organizing committee for all its hard work. Last but not least, I am particularly grateful to the members of the Programme Committee and its Chair; without their continuous engagement, this ambitious conference programme could not have been developed.

KEYNOTE ADDRESS

INSTILLING A CULTURE OF SAFETY

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Abstract

In its 1999 report, To Err is Human: Building a Safer Health System, the United States National Academy of Sciences recognized the necessity of establishing a culture of safety in any organization that wished to reduce patient morbidity and mortality caused by medical errors. The culture of an organization reflects its shared attitudes, values, goals and practices, and a safety culture requires that each employee accepts responsibility for improving patient and personnel safety, and that responsibility is shared and supported by the organization's administration. There are seven ingredients of a safety culture: leadership, evidence based practice, teamwork, accountability, communication, continuous learning and justice. These ingredients require thoughtful integration within an organizational strategy if they are to contribute collectively to improved safety of patients and personnel.

In 1999, the United States National Academy of Sciences issued a landmark publication on patient safety entitled To Err is Human: Building a Safer Health System [1]. The publication claimed that between 44 000 and 98 000 persons in the United States of America die each year because of medical errors, and that injuries from medical errors cost US $17–29 billion each year. The publication stated that: "The healthcare organization must develop a culture of safety such that an organization's design, process and workforce are focused on a clear goal — dramatic improvement in the reliability and safety of the care process."

A culture consists of the shared attitudes, values, goals and practices that characterize an organization, and a safety culture exists when each employee, regardless of his/her position, assumes an active role in error prevention and that role is supported by the organization [2, 3]. With regard to a health care organization, the questions are: (i) What are the drivers of a patient centered safety culture? (ii) What are the steps for instilling a safety culture in an organization? and (iii) How does one know when these steps have been achieved?

There are seven drivers of a patient centred safety culture. These drivers are: (i) leadership; (ii) evidence based practice; (iii) teamwork; (iv) accountability; (v) communication; (vi) continuous learning; and (vii) justice. Leadership is a critical element in any safety programme, and it must be both a top-down process, with committed organizational leaders, and a bottom-up process involving every member of the health care team. Leadership is not a delegable function, and must engage the interest and support of the administration, board of directors and others at the top of the organizational pyramid. In addition, it requires all members of the health care team to work together in an atmosphere of respect, support and appreciation.

Critical steps in instilling a safety culture within a health care organization include: (i) identifying strategic priorities for safety; (ii) engaging key stakeholders; (iii) communicating and building awareness; (iv) establishing system level objectives; (v) strengthening error reports/analysis; (vi) supporting staff and families impacted by errors; and (vii) aligning safety activities and incentives. Strategic priorities must encompass: (i) communicating patient safety as an organizational priority; (ii) adding safety to the job description of every employee; (iii) assessing the organization's current culture and enhancing the role of safety within it; (iv) establishing an open culture of trust for error transparency; and (v) supporting educational programmes on safety at all levels. Communicating the importance of patient and personnel safety includes safety focused management 'walk-rounds', safety briefings, error reporting without reprisal, and time-outs called when the safety of patients and personnel is not assured. Safety within an organization's culture can be enhanced by: (i) comparing quality/safety performance to benchmarks; (ii) employing error analysis methods such as root cause analysis and failure mode effects analysis; (iii) moving beyond benchmarks to highest attainable levels; (iv) measuring performance improvement over time; and (v) establishing 'recognition triggers' of potential/real errors.

Medical errors affect not only patients and their families, but also caregivers and the institutions in which care has been delivered. Health care is a complex, personnel intensive process, often functioning in a high intensity environment. Errors can happen because people are involved in the process, and the organization should make every effort, wherever possible, to establish mechanisms to prevent errors from adversely affecting patients. Still, errors cannot be prevented in their entirety, nor can patients be protected entirely from them. Consequently, some errors will harm patients, and the employees associated with that harm will undoubtedly feel terrible. An organization must have a process in place to support those employees and help them recover from the dismay accruing from the errors and resulting harm. This process should

function in parallel with a support process for patients and their families who are impacted by errors.

Some rules are available to align the safety activities and incentives of an organization. They include: (i) unification of strategic, quality improvement and financial plans towards an emphasis on patient and personnel safety; (ii) incorporation of safety and quality goals and measures into criteria for employee compensation and advancement; (iii) design of work processes to enhance safety; (iv) assurance that the right thing is the easy thing to do; (v) standardization of work processes to reduce variation; (vi) provide an emphasis on teamwork; (vii) trust and empower employees; and (viii) match work tasks to people's strengths.

An organization committed to patient and personnel safety should provide a management structure that follows a number of procedural guidelines, including: (i) responsibilities of individuals must be communicated clearly, and understanding of the responsibilities must be ensured; (ii) responsibilities entrusted to individuals must be within the scope of the individuals' education and ability; (iii) early warnings of risk must be present wherever possible; (iv) employees must be able to learn from the mistakes of others through a non-punitive error reporting process; (v) corrective actions to mitigate errors must be documented and communicated; (vi) periodic performance audits and peer review must be conducted; and (vii) when and where available, accreditation of specific health care facilities should be obtained.

A number of initiatives have been developed recently to help ensure the safety and appropriateness of medical imaging. An Image Gently campaign focused on paediatric radiology was launched in 2008 by the Alliance for Radiation Safety in Pediatric Imaging [4]. This campaign has had a major impact on reducing radiation dose to paediatric patients by 'right-sizing' imaging protocols to patient sizes. Within the Image Gently campaign, the Step Lightly Initiative focuses on the reduction of radiation dose in interventional radiologic procedures [5]. The Image Wisely campaign is modelled, in part, on the Image Gently campaign and is focused on appropriate and safe use of medical imaging for adult patients [6]. This initiative is a cooperative effort of the American College of Radiology, American Association of Physicists in Medicine, American Society of Radiologic Technologists, and the Radiological Society of North America. The Choosing Wisely programme is an effort by the American Board of Internal Medicine Foundation to encourage physicians to be better stewards of finite health care resources, including the use of imaging procedures [7].

Instilling a culture of safety in an organization encompasses several processes and steps, many of which are outlined in this paper. Foremost, it requires leadership from the top of the organization, and recognition by all employees that safety is everyone's responsibility.

REFERENCES

[1] COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, To Err is Human: Building a Safer Health System, National Academy Press, Washington, DC (1999).
[2] THOMPSON, E.M., Defining a culture of safety, OR Nurse **5** 1 (2011) 3.
[3] WIEGMANN, D.A., et al., A Synthesis of Safety Culture and Safety Climate Research, Technical Rep. ARL 02-3, FAA 02-2, Aviation Research Lab, Institute of Aviation, Illinois (2002).
[4] ALLIANCE FOR RADIATION SAFETY IN PEDIATRIC IMAGING, Image Gently, http://www.pedrad.org/associations/5364/ig/
[5] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Step Lightly, http://www.aapm.org/announcements/ImageGentlyStepLightly.asp
[6] AMERICAN COLLEGE OF RADIOLOGY, Image Wisely, http://imagewisely.org/
[7] ABIM FOUNDATION, Choosing Wisely, http://www.abimfoundation.org/Initiatives/Choosing-Wisely.aspx

BRIEFING SESSION

Chairpersons

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CHANGES IMPACTING ON RADIATION PROTECTION IN MEDICINE SINCE THE MALAGA CONFERENCE

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Millions of X ray examinations, both diagnostic and interventional, nuclear medicine procedures and radiotherapy treatments are performed annually worldwide. The radiation dose to the population of the United States of America from medical radiation is now almost equal to that of background radiation, and increased more than seven times in the 25 years from the early 1980s to 2006. The main reason is that modern medicine demands rapid diagnosis and treatment. Radiology is an essential component of patient management, as many patients have multiple investigations using ionizing radiation, particularly computed tomography (CT), and some go on to have X ray guided treatment or radiotherapy. There has been an inexorable rise in the range and numbers of minimally invasive interventional techniques being performed using fluoroscopy, and these techniques have offered enormous benefits to many patients who otherwise may not be candidates for more invasive surgery.

The range of radionuclides that can be used in medicine has also increased and the types of specific radiotherapy have become more complex. Despite these huge benefits, health professionals have to accept that some procedures deliver high radiation doses to patients. Radiation injuries, in interventional radiology and cardiology, and accidental exposures in radiotherapy are fortunately not common compared to the number of procedures or treatments performed, but were increasingly reported in the 1990s and 2000s.

It is now 11 years since the International Conference on the Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy was held in March 2001, in Malaga, Spain. This landmark conference is now often referred to simply as the 'Malaga conference' among radiological protection professionals, which is a reflection of the significance of the event. The fact that many professional societies and organizations were involved in the conference demonstrated that the radiological protection of patients was perhaps the 'Cinderella' topic in the radiological

protection arena, i.e. had been overlooked and rather neglected. The conference resulted in the IAEA formulating an Action Plan for future work in collaboration with experts from other organizations.

Several key themes emerged from the Malaga conference. These included optimization with an emphasis on reducing doses and risks without compromising image quality or treatment effectiveness, recognition of high dose procedures, monitoring doses from multiple examinations, and the development of adequate infrastructures to support the safe use of ionizing radiation in medicine. The subsequent Action Plan addressed issues of education and training of health professionals; appropriate exchange of information, with wider dissemination of that related to protection of patients; and the provision of practice specific guidance documents in collaboration with professional bodies and international organizations.

Many national and international organizations have worked on initiatives to improve patient safety. Guidance on the use of appropriate imaging investigations for a wide range of clinical problems have been produced to aid clinicians and to reduce the unnecessary irradiation of patients. These include the American College of Radiology ACR Appropriateness Criteria [1] and the United Kingdom Royal College of Radiologists Referral Guidelines [2]. A learning, no blame culture has been encouraged by the establishment of databases, e.g. RADEV (International Database on Unusual Radiation Events), to provide a repository of information on radiation accidents, near misses or unusual events including medical exposures, and ROSIS (Radiation Oncology Safety Information System)[1] for the reporting of radiotherapy incidents.

Two campaigns in the United States of America have been established to raise awareness of radiation and to lower doses where possible. The Image Gently campaign[2] is an initiative of the Alliance for Radiation Safety in Pediatric Imaging aimed at lowering radiation dose in the imaging of children. Image Wisely[3] is a programme of several radiological societies in the USA with the objective of lowering the amount of radiation used in medically necessary imaging and eliminating unnecessary procedures in adults.

Diagnostic reference levels (DRLs) are useful as an optimization tool to compare the performance of imaging with other facilities locally, regionally or nationally by establishing a range of doses considered acceptable for different diagnostic examinations. Increasingly, particularly in Europe and the USA, the concept of a DRL is being extended to both radiological and cardiological

[1] http://www.rosis.info/

[2] http://www.pedrad.org/associations/5364/ig/

[3] http://imagewisely.org/

interventional procedures, where the range of doses is much wider, even for the same procedure.

Over the past 12 years, Committee 3 of the International Commission on Radiological Protection (ICRP) has produced 15 publications on different aspects of radiological protection in medicine. Even before the Malaga conference, the ICRP was aware of several of the issues raised, and during 2000 alone produced four publications: (i) Pregnancy and Medical Radiation [3]; (ii) Avoidance of Radiation Injuries from Medical Interventional Procedures [4]; (iii) Prevention of Accidents to Patients Undergoing Radiation Therapy [5]; and (iv) Managing Patient Dose in Computed Tomography [6].

The ICRP was one of the international organizations that participated in the conference and since then has worked on many of the aspects highlighted as a priority. Several subsequent publications have focused on providing guidance on specific topics, for example, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies [7], while others have been more general, for example, Radiological Protection in Medicine [8]. The ICRP also recognizes the importance of appropriate education and training, and has produced dedicated guidelines on Education and Training in Radiological Protection for Diagnostic and Interventional Procedures [9]. This training now needs to extend beyond those traditionally working in radiology departments as the number of non-radiological specialists using ionizing radiation is increasing, and this was addressed in Radiological Protection in Fluoroscopically Guided Procedures Performed outside the Imaging Department [10].

Continuing the theme of specific recommendations, the next two ICRP publications are Radiological Protection in Cardiology [11], including guidance on fluoroscopically guided procedures, cardiac CT and nuclear medicine, and Radiological Protection in Paediatric Diagnostic and Interventional Radiology [12].

Committee 3 has an extensive programme of ongoing work to take forward into the next term of the ICRP. Topics include the long standing task group on doses to patients from radiopharmaceuticals, and other task groups on radiological protection in ion beam radiotherapy, cone beam CT and second cancer risks in modern radiation oncology. Working parties are reviewing areas of justification and reference levels for both diagnostic and interventional imaging.

The ICRP has launched a strategic plan for 2011–2017 and recognizes that radiological protection in medicine is an important part of this. Technological developments in medicine continue at a great pace and it is a challenge to produce timely recommendations that deal with the associated radiological protection issues. In addition, there is an ongoing need to raise the awareness of radiological protection among the many health professionals who either use or request procedures involving ionizing radiation, often with little or no knowledge. The

objectives aim to improve the dissemination of the ICRP's recommendations to a wider audience and to extend the participation of the ICRP in medical conferences and other appropriate forums.

Significant progress has been made in the radiological protection of patients since the Malaga conference. This has been due to the considerable efforts of individuals and many organizations. Despite the achievements, there is no place for complacency and it is the responsibility of all radiological protection and health care professionals to continue to make improvements that enhance patient safety.

REFERENCES

[1] AMERICAN COLLEGE OF RADIOLOGY, ACR Appropriateness Criteria (2013), http://www.acr.org/Quality-Safety/Appropriateness-Criteria
[2] ROYAL COLLEGE OF RADIOLOGISTS, iRefer: Making the Best Use of Clinical Radiology, 7th edn, The Royal College of Radiologists, London (2012).
[3] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Pregnancy and Medical Radiation, Publication 84, Pergamon Press, Oxford and New York (2000).
[4] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Avoidance of Radiation Injuries from Medical Interventional Procedures, Publication 85, Pergamon Press, Oxford and New York (2000).
[5] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of Accidents to Patients Undergoing Radiation Therapy, Publication 86, Pergamon Press, Oxford and New York (2000).
[6] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Managing Patient Dose in Computed Tomography, Publication 87, Pergamon Press, Oxford and New York (2000).
[7] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, Publication 112, Elsevier (2009).
[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Medicine, Publication 105, Elsevier (2007).
[9] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Education and Training in Radiological Protection for Diagnostic and Interventional Procedures, Publication 113, Elsevier (2009).
[10] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Fluoroscopically Guided Procedures Performed outside the Imaging Department, Publication 117, Elsevier (2010).
[11] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Cardiology, Publication 120, Elsevier (2013).

[12] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Paediatric Diagnostic and Interventional Radiology, Publication 121, Elsevier (2013).

JUSTIFICATION IN THE USE OF RADIATION IN MEDICINE

(Session 1)

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INTRODUCTION TO JUSTIFICATION IN THE USE OF RADIATION IN MEDICINE

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The balance of benefit and risk from medical exposures is considered at three levels of justification (Fig 1.). Generic justification at International Commission on Radiological Protection (ICRP) level 2 [1] has been the focus of much work and interest globally, with a number of tools available to improve the process of justification by referring and radiological practitioners. This forms part of a larger move to improve the system of benefit–risk assessment, which takes in three key steps: awareness, appropriateness and audit (the 'three As').

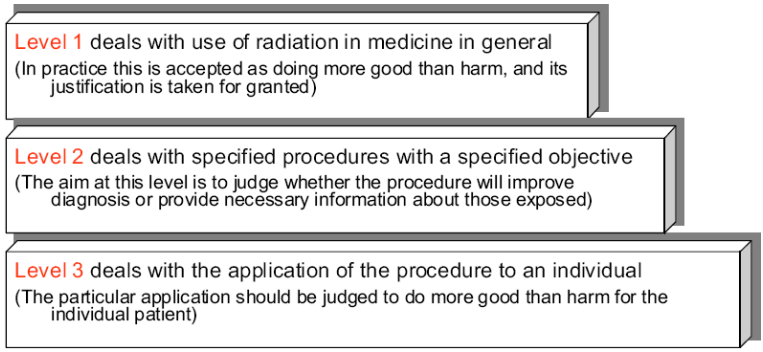

FIG. 1. Justification of medical exposures at three levels as identified by the International Commission on Radiological Protection (from Ref. [2]).

Awareness of this assessment is frequently portrayed in the media as a cost issue but health professionals correctly see the bigger picture of good medical practice and radiation safety as the two main criteria for selection of the best test first, before cost effectiveness. The balance of health benefit against radiation risk in a justified medical procedure is almost invariably in favour of the benefit. Radiological procedures can be life saving.

The need for better justification may be borne out by the substantial increase in the contribution of medical imaging to collective dose, which in the United States of America has risen from 15% to 48% in 25 years [3]. The per caput collective dose is not uniform, varying fivefold in Europe (Fig. 2) [4].

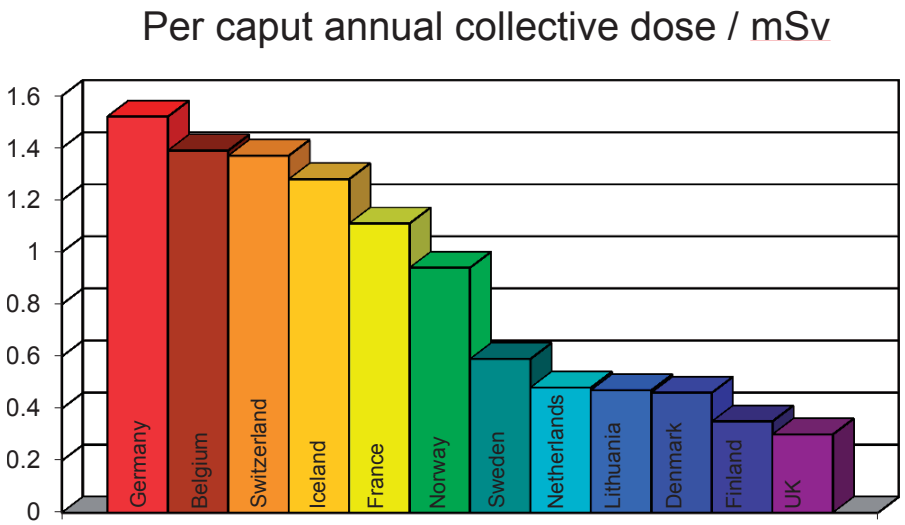

FIG. 2. Annual per caput collective dose in Europe [4].

Tools to support justification include educational initiatives such as the IAEA's Radiation Protection of Patients web site [5] and imaging referral guidelines/appropriateness criteria.

Imaging referral guidelines have been available for over 20 years in Europe and have been advocated through a European Commission Directive [6]. The Royal College of Radiologists (RCR) first published Making the Best Use of a Department of Clinical Radiology [7] in 1989. The Radiation Protection 118 Referral Guidelines for Imaging [8] were published in 2000 by the European Commission (based on the RCR 1998 publication Making the Best Use of a Department of Clinical Radiology: Guidelines for Doctors). The French Society of Radiology published imaging referral guidance in 2005 [9]. Rapid developments in imaging technology and new advances in medical imaging required an update of the guidelines by the European Commission in 2003.

The American College of Radiology's Appropriateness Criteria [10] and Western Australia's Diagnostic Imaging Pathways [11] provide evidence based guidance considering global evidence.

The value of evidence based guidelines for justification and reduction of unhelpful medical exposures was shown in early studies [12, 13]. Such guidance is also helpful to promote good medical practice and may improve cost effectiveness by facilitating the best and possibly only test first.

Guidelines are aimed to be used by:

— Referring practitioners: general practitioners, doctors-in-training and non-medically qualified health professionals.
— Radiology practitioners: ICRP level 2 justification.
— Patients: reinforcement of advice 'no decision about me without me'.
— Health care organizations/ministries of health: decision support, planning and provision.

Barriers to the use of guidelines are common globally and include:

— Overloaded knowledge base:
  • Medical and technical advances often take priority for medical education;
  • Competition for inclusion in curricula/continuing professional development;
— Time challenged agenda:
  • Erroneous belief that the fastest test with shortest waiting time is best.
— Mixed messages:
  • Different guidance from different sources confusing, leading to no guidance being used.
— Patient expectations:
  • Historical or geographical bias;
  • Unreliable, non-peer reviewed information from the Internet.

Suggested solutions to barriers are given in Fig. 3.

Education	Undergraduate, postgraduate and continuing professional development Communication of requests, not orders
Referral guidelines	Freely available from a trusted source Concordant with clinical guidelines +/– clinical decision support
Monitoring	Local internal audit (bottom up) External audit (top down)
External control	Legislation By payers/insurers

FIG. 3. Possible solutions for barriers to referral guideline use (adapted from Ref. [14]).

Other tools to support justification include clinical decision support systems, which are reaching maturity and acceptance in North America where there is 10 years of experience.

The role of clinical audit for monitoring guideline availability and use is promoted with advice on external audit [15] and suggestions of local internal audit [16]. Although there is potential for considerable quality improvement through clinical audit, this tool is still not uniformly used in all regions.

In the last four years, there has been considerable interest, effort and collaboration to increase awareness and appropriateness with a World Health Organization (WHO) Global Initiative [17] which began in 2008 and workshops on justification held by the IAEA and European Commission [18]. Regional and national efforts include a European Commission sponsored guidelines project, and valuable collaborative campaigns in North America such as Image Gently [19] and Image Wisely [20], which have become global in interest and distribution. Specific guidelines projects include the WHO's call for global guidelines [21] and the Canadian Association of Radiologists' Global Guidelines Symposium in 2010 [22].

Undoubtedly, the success of future initiatives lies in collaborative global efforts such as the Global Summit for Radiological Quality and Safety in 2013 where the barriers, needs and solutions of the radiological community in both developed and under-resourced countries will be considered.

In conclusion, justification is facilitated through imaging referral guidelines, implementation and uptake which may be enhanced with further tools such as clinical decision support systems. Future efforts for improved radiation safety through justification are aided by principles such as the three As: awareness, appropriateness and audit, with collaborative efforts for future success focused firmly on the 'three Rs': referrers, radiologists and regulators.

REFERENCES

[1] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103, ICRP, Elsevier (2008).

[2] HOLMBERG, O., MALONE, J., REHANI, M., et al., Current issues and actions in radiation protection of patients, Eur. J. Radiol. **76** 1 (2010) 15–19.

[3] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Ionizing Radiation Exposure of the Population of the United States, NCRP Report 160, NCRP, Bethesda, MD (2009).

[4] HART, D., WALL, B.F., HILLIER, M.C., SHRIMPTON, P.C., Frequency and Collective Dose for Medical and Dental X-ray Examinations in the UK, 2008, HPA-CRCE-012, Health Protection Agency, Chilton, Didcot (2010).
[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection of Patients (RPOP), http://rpop.iaea.org
[6] EUROPEAN COMMISSION, Council Directive 97/43/EURATOM of 30 June 1997: On Health Protection of Individuals against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/Euratom, Official Journal of the European Communities No. L 180/22-27, 9.7.1997.
[7] ROYAL COLLEGE OF RADIOLOGISTS, iRefer: Making the Best Use of Clinical Radiology, 7th edn, The Royal College of Radiologists, London (2012).
[8] EUROPEAN COMMISSION, Referral Guidelines for Imaging, Radiation Protection 118, Office for Official Publications of the European Communities, Luxembourg (2000).
[9] SOCIÉTÉ FRANÇAISE DE RADIOLOGIE, SOCIÉTÉ FRANÇAISE DE BIOPHYSIQUE ET DE MÉDECINE NUCLÉAIRE, Guide du bon usage des examens d'imagerie médicale (2005), http://www.irsn.fr/FR/professionnels_sante/documentation/Documents/guide_bon_usage_imagerie.pdf
[10] AMERICAN COLLEGE OF RADIOLOGY, ACR Appropriateness Criteria (2013), http://www.acr.org/Quality-Safety/Appropriateness-Criteria
[11] GOVERNMENT OF WESTERN AUSTRALIA, DEPARTMENT OF HEALTH, Diagnostic Imaging Pathways (2013), http://www.imagingpathways.health.wa.gov.au/
[12] OAKESHOTT, P., KERRY, S.M., WILLIAMS, J.E., Randomized controlled trial of the effect of the Royal College of Radiologists' guidelines on general practitioners' referrals for radiographic examination, Br. J. Gen. Pract. **44** 382 (1994) 427–428.
[13] ROYAL COLLEGE OF RADIOLOGISTS WORKING PARTY, Influence of Royal College of Radiologists' guidelines on referral from general practice, BMJ **306** 6870 (1993) 110–111.
[14] REMEDIOS, D., Justification: How to get referring physicians involved, Rad. Prot. Dosim. **147** 1–2 (2011) 47–51.
[15] EUROPEAN COMMISSION, European Commission Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy), Radiation Protection No. 159, Publications Office of the European Union, Luxembourg (2009).
[16] THE ROYAL COLLEGE OF RADIOLOGISTS, Academic Radiology and Audit, AuditLive, http://www.rcr.ac.uk/audittemplate.aspx?PageID=1016
[17] WORLD HEALTH ORGANIZATION, WHO Global Initiative on Radiation Safety in Healthcare Settings, http://www.who.int/ionizing_radiation/about/med_exposure/en/

[18] Justification of Medical Exposure in Diagnostic Imaging (Proc. Int. Workshop Brussels, 2009), IAEA, Vienna (2011).
[19] THE ALLIANCE FOR RADIATION SAFETY IN PEDRIATRIC IMAGING, Image Gently,
http://www.pedrad.org/associations/5364/ig/
[20] AMERICAN COLLEGE OF RADIOLOGY, RADIOLOGICAL SOCIETY OF NORTH AMERICA, AMERICAN ASSOCIATION OF PHYSICISTS IN MODERN MEDICINE, AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS, Image Wisely,
http://www.imagewisely.org/
[21] WORLD HEALTH ORGANIZATION, Medical Imaging Specialists Call for Global Referral Guidelines (2010),
http://www.who.int/ionizing_radiation/about/med_exposure/en/index2.html
[22] CANADIAN ASSOCIATION OF RADIOLOGISTS, 2010 CAR International Guidelines Symposium, Montreal,
http://www.car.ca/en/education/international-guidelines-symposium.aspx

STRATEGIES FOR IMPROVING JUSTIFICATION

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Abstract

Good practice in radiology relies on a core principle that each examination is justified for the patient involved. An international workshop organized by the IAEA and the European Commission concluded that: "There is a significant and systemic practice of inappropriate examination in radiology." Audit reveals that 20–50% of examinations are routinely not justified and the figure can be as high as 60–77% in particular cases (e.g. for lumbar spine examinations or cardiac angiography). Doctors/health professionals generally have poor awareness of the risks involved and consistently underestimate them. Knowledge of, and compliance with, guidelines for referral for common examinations is poor. The ethical background considerations to this situation are briefly reviewed and a strategy for improvement is proposed, i.e. the global 'three As' campaign of improving awareness, appropriateness and audit adopted by the IAEA.

1. INTRODUCTION

A joint IAEA/European Commission workshop identified the fact that there is a systemic failure of justification in medical radiology [1]. It is easy to overlook justification and risk–benefit analysis in busy, technically excellent departments, in which the scale of practice verges on the industrial. Such assessments involve a potent mix of values (ethics), science and medicine. Other international bodies, the World Health Organization, International Radiation Protection Association (IRPA) and Nuclear Energy Agency, simultaneously expressed concern or have taken related actions. The IAEA/European Commission joint workshop identified the three As as a viable and mature way forward. These are: awareness, appropriateness and audit. The approach is fundamentally based on ethical considerations although financial and health technology assessment issues are also important [2–4]. The Nordic countries have endorsed the three As approach and the heads of the European Regulatory Competent Authorities have also expressed support for the approach.

2. ETHICAL CONSIDERATIONS

Ethics as a discipline that helps nurture a moral sense and encourages us to examine our behaviour critically. It also brings to mind the assumptions underlying our behaviour. Thus, the role of ethics has been critically important in revisiting and rethinking the concept of justification in radiology [3]. It allows us to subject our assumptions to critical evaluation, and can provide an early warning system in respect of problems that might otherwise go undetected [3, 5, 6].

2.1. General considerations and core principles in medical ethics

The thinking behind the current framework for radiation protection in medicine is to be found in core publications of the International Commission on Radiological Protection from some decades ago. The core principles/values, which are still used, are justification, optimization and dose limitation [7, 8]. These principles/values have a low recognition in medicine. There is a disconnect between the way they are currently presented and prioritized for medicine/radiology, on one hand, and ordinary medical ethics, on the other [2, 3].

Work over several decades has identified a small core set of values/principles for medical ethics. These are presented in the first section of Table 1 and are discussed more fully elsewhere [2, 3, 9]. The three principles/values are found to be universally accepted and relatively culture independent. It is reasonable to assume that this can be transferred to radiology, which also requires a globally acceptable high recognition value system [2, 3].

There are additional problems in radiology, particularly those arising from communicating and managing the incomplete knowledge and uncertainty about risk we have in respect of both patients and the public. These also need to be addressed in the context of clear values with an ethical content. This gives rise to two additional values which are widely, but possibly not universally, subscribed to [3, 4]:

— The precautionary principle, often referred to as Pascal's wager;
— Openness, transparency and accountability.

The precautionary principle requires that we act prudently when we have to act out of incomplete knowledge, an approach that appears to be consistent with the wisdom literature of all cultures but at variance with medical radiation damage skeptics [3, 10].

TABLE 1. CORE PRINCIPLE FOR A SYSTEM OF ETHICS FOR CLINICAL RADIOLOGY

Core principles/values	Comment(s)
Three core values	
1. Autonomy and dignity of individual	
2. Non-maleficence (do no harm) and beneficence (do good)	Beauchamps and Childress [1, 9], Malone [3], Zölzer [2] and IRPA [4]
3. Justice, access, etc.	
Two additional values required	
4. Prudential/precautionary principle	Lochard at IRPA [4], Malone [1, 3]
5. Openness, transparency and accountability	
For asymptomatic patients	
6. Utilitarian principle	See text

There is a significant demand for radiological screening of asymptomatic patients for latent disease. Generally, when such programmes are formally approved by governments or by professional bodies, it is on the basis that more good than harm for the greatest number of people will result. This is most easily justified on the basis of the utilitarian principle, which seeks the greatest good for the greatest number of people [2, 3, 9]. Values 4–6, and particularly 5, are not as culture free as the three basic principles.

3. STRATEGIES FOR IMPROVING JUSTIFICATION

Three practical approaches to effective implementation of justification are identified in the formal conclusions to the joint IAEA/European Commission workshop [1, 6]. They are the means of ensuring that those referred for radiological examinations really need them, i.e. appropriateness; clinical audit of the effectiveness of the referral and related processes, i.e. audit; and finally, improving the effectiveness of communicating about radiation risk to patients, the public, physicians, surgeons, allied professionals, and of course the radiologists, i.e. awareness. These are briefly introduced here and the effectiveness of these interventions is discussed elsewhere [1, 6].

3.1. The three As: Appropriateness and referral guidelines

Referral guidelines for diagnostic and interventional radiology have been in existence for 20 years and have been published by the European Commission and in Australia; Canada; Hong Kong, China; New Zealand; the United Kingdom; the United States of America and elsewhere. Today's guidelines are increasingly evidence based, are intended to support decision making and are not prescriptive. They are also used in referral pathways and protocols. Guidelines will assist in avoiding: repeat investigations; investigations when results are unlikely to affect patient management; investigating too early; the wrong investigation; and over-investigation.

The effectiveness of guidelines can be greatly enhanced by involving the relevant stakeholders at all stages. It is essential to develop and disseminate guidelines suitable for global application, and regional/local adaptation; and to ensure resource or intellectual property issues do not unduly inhibit this. Including guidelines in information technology embedded order entry/decision support algorithms can be advantageous.

3.2. The three As: Audit (clinical)

Most countries seek to establish transparent, tangible procedures for managing quality in health care. A key element of this is clinical audit, which has been applied to many health care practices but has been slow to find its place in imaging. European Commission Directive 97/43/EURATOM [11], on radiation protection of the patient, introduced a mandatory requirement for audit of radiological practices. To assist States with implementation of these requirements, the European Commission prepared guidance on clinical audit in radiology [12]. The approach is flexible and will enable the Member States to adopt a form of clinical audit consistent with their national arrangements. Useful advice and practical recipes are available from bodies such as the IAEA and the Royal College of Radiologists.

Justification is a cornerstone of radiation protection and should be among the top priorities in the audit programme. The audit of the compliance with guidelines can be a simple and effective tool for improving justification, appropriateness and referral patterns.

3.3. The three As: Awareness and improved communication

It is obvious that awareness about radiation dose and risk is poor among physicians in all parts of the world, irrespective of specialty. A major obstacle to communication is that the formal language of these areas is arcane, esoteric and

has proved impenetrable to health professionals [1, 6, 13]. Simple, effective and scientifically more acceptable approaches have been proposed. These initiatives produce clear information on risk that acknowledges uncertainty and is readily accessible. For day-to-day use in clinical environments, a scale based on the equivalent number of chest X rays, or that state risk without citing dose, is likely to be adequate. Picano's graphical approach to dose and risk for different patient groups (including children, adult males, adult females and the elderly) has much to recommend it [1]. Finally, clear transparent public education programmes are essential, where imaging services are marketed directly to the public and to the worried well.

4. CONCLUSIONS

Since the Malaga Conference, thinking on the justification issue in radiation protection of patients has greatly advanced [14]. This conference devoted a full session to it and recognized it as a major area for attention during the coming decade. It is also treated more explicitly in the revised Basic Safety Standards [15]. The IAEA has adopted the three As approach to improving justification. The three As are sufficiently mature to be able to be implemented. The approach derives from an analysis of justification based on ethical considerations. However, the justification may also benefit from approaches that seek to reduce overutilization based on health economic or health technology assessment grounds.

ACKNOWLEDGEMENTS

The author is grateful for the ongoing support of the IAEA, and of the Trustees and Chairman of the Robert Boyle Foundation.

REFERENCES

[1] Justification of Medical Exposure in Diagnostic Imaging (Proc. Int. Workshop Brussels, 2009), IAEA, Vienna (2011).

[2] ZÖLZER, F., "A cross-cultural approach to radiation ethics", Social and Ethical Aspects of Radiation Risk Management (OUGHTON, D., HANSSON, S.O., Eds), Elsevier, Oxford and Amsterdam (2013).

[3] MALONE, J., "Ethical issues in clinical radiology", Social and Ethical Aspects of Radiation Risk Management (OUGHTON, D., HANSSON, S.O., Eds), Elsevier, Oxford and Amsterdam (2013).

[4] INTERNATIONAL RADIATION PROTECTION ASSOCIATION, Papers presented on relevant ethics issues by ZÖLZER, F., "A cross-cultural approach to questions of ethics in radiation protection"; LOCHARD, J., "The precautionary principle and the ethical foundation of the radiological protection system"; and COUSINS, C., "Ethics in medical radiological protection" (Int. Congr., Glasgow, 2012), Presentations available at http://www.irpa13glasgow.com/information/downloads/presentations/dochart/ (see Thursday).

[5] MALONE, J., "Justification and tools for change: Scene setting", Justification of Medical Exposure in Diagnostic Imaging (Proc. Int. Workshop Brussels, 2009), IAEA, Vienna (2011) 17–24.

[6] MALONE, J., et al., Justification of diagnostic medical exposures, some practical issues: Report of an International Atomic Energy Agency Consultation, Br. J. Radiol. **85** 1013 (2012) 523–538.

[7] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the ICRP, Publication 103, Elsevier (2008).

[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Medicine, Publication 105, Elsevier (2007).

[9] BEAUCHAMP, T.L., CHILDRESS, J.F., Principles of Biomedical Ethics, 7th edn, Oxford University Press, Oxford and New York (2012).

[10] SHAH, D.J., SACHS, R.K., WILSON, D.J., Radiation-induced cancer: A modern view, Br. J. Radiol. **85** 1020 (2012) e1166–1173.

[11] EUROPEAN COMMISSION, Council Directive 97/43/EURATOM of 30 June 1997: On Health Protection of Individuals against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/Euratom, Official Journal of the European Communities No. L 180/22-27, 9.7.1997.

[12] EUROPEAN COMMISSION, European Commission Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy), Radiation Protection No. 159, Publications Office of the European Union, Luxembourg (2009).

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Report of a consultation on justification of patient exposures in medical imaging, Radiat. Prot. Dosim. **135** 2 (2009) 137–144.

[14] Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy (Proc. Int. Conf. Malaga, 2001), IAEA, Vienna (2001).

[15] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

DEVELOPING AND IMPLEMENTING APPROPRIATENESS CRITERIA AND IMAGING REFERRAL GUIDELINES

Where are we and where are we going?

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There is currently a rapidly emerging consensus that there is a need for what are variously referred to as 'appropriateness criteria', 'imaging referral guidelines' or 'justification rules', to help in the utilization of imaging [1, 2]. There are several compelling reasons: first, it is universally accepted that a significant percentage of imaging worldwide is inappropriate, with both over- and underutilization. Estimates range from 20 to 50% inappropriate utilization. This leads to increased health care costs when imaging is overutilized and, in all likelihood, worsened quality of care with both over and under use. There is also an associated increase in radiation to patients. The effects of this remain unknown in individuals, but it is inarguable that unnecessary exposure to ionizing radiation should be avoided.

There are many reasons for inappropriate use. These include patient expectations and wishes, the expectation of health care providers that the use of imaging can protect them from malpractice accusations and litigation, financial conflict of interest, lack of specific guidance from imagers, and lack of sufficient knowledge on the part of referring health care providers. All of these are, to some extent, valid concerns. Patient expectations are clearly important, and they often have limited or incomplete understanding of the benefits and limitations of imaging, as well as of the costs. Also, they often, legitimately want something concrete done, even if there is no likely benefit. This occurs with the desire for an imaging study as well as in other settings, for example, with the desire for antibiotics for a simple cold.

Regarding litigation, in many countries litigation is increasing and anyone can, in fact, sue for anything, regardless of the reality of the medical situation and the outcome. Secondly, health care providers are worried about getting sued, and often do order imaging or laboratory studies or consultations that they believe are unnecessary but will protect them from litigation. In one study, the Massachusetts

Medical Society found that 83% of responding physicians believed that they practised defensive medicine and 28% felt that liability concerns had a major effect on how they cared for patients [3]. These findings have been confirmed in further studies that examined the behaviour of orthopaedists [4], neurosurgeons [5] and specialists in general [6], all in the United States of America. Even though litigation generally is settled in favour of the defendant doctors, and remains unusual, the fear of it has a significant impact on the use of imaging.

Inappropriate use of imaging is further complicated by the increasing complexity of modern medicine. Clearly, no health care provider can be fully knowledgeable about more than a small area, and best practice can change very quickly. This adds not only intellectual concerns, but also concern about delivering optimal care. This is further complicated by the increasing role that non-physicians, such as physician assistants and other 'physician extenders', play in the delivery of care. These factors taken together make a strong argument that imaging is not likely to be optimally utilized, and this has been shown in many studies. In one, for example, it was shown that a large percentage of patients with advanced cancer underwent screening for other cancer [7]. This screening was very likely to have no benefit in terms of longevity or altered treatment. In another, it was shown that increased availability of magnetic resonance imaging (MRI) scanners led to increased numbers of scans for low back pain; that is, the more available MRI units, the more scans were performed. In theory, this might indicate improved care, if the scans were done in more patients who needed them, but this study [8] indicated that a significant portion of the scans did not meet consensus criteria for MRI use for headache or low back pain.

Medical costs have increased dramatically over the last several decades, in many cases in concert with improved care, and it is clear that imaging has provided major advances in health care. Not all cost increases, however, are justified. High-tech procedures, such as computed tomography (CT), MRI and positron emission tomography (PET), tend to also be high cost ones, and the costs of all three have increased at a greater rate than conventional X ray. While in the USA imaging costs over the last several years are not growing as rapidly as other health care costs, and procedure volume has actually fallen, the overall cost of imaging, with the ageing population in many countries, continues to increase in absolute terms and as a percentage of gross domestic product [9].

Over the past few years, for a number of reasons, there has been increased concern about the exposure of populations and individuals to ionizing radiation. According to the National Council on Radiation Protection and Measurements Report 160 [10], for example, ionizing radiation in the USA led to an effective dose of 3.6 mSv per individual in the 1980s. This increased to 6.2 mSv in 2006. This increase was completely due to increased use of medical imaging, primarily CT, PET and image-guided intervention [11]. The effect of increased exposure

on individuals has been widely debated, with the Food and Drug Administration indicating a 1/2000 lifetime risk of a fatal cancer from a single 10 mSv study. It is essentially impossible to define the individual risks and population risks are also virtually impossible to define with precision. Recent studies, however, have suggested that limited exposure to ionizing radiation does measurably increase the cancer risk for populations [12, 13]. There are, in summary, two important basic concepts that must be kept in mind: first, there is potential risk of exposure to diagnostic level ionizing radiation, so any use should be based on a risk–benefit analysis, with the possible benefits to be gained through the imaging outweighing the theoretical risks of ionizing radiation. Secondly, the concern about the possible adverse effects of radiation can be used to help educate the lay public, to enable them to consider the risk:benefit ratio whenever imaging (particularly using ionizing radiation) is considered. This concern logically leads to the conclusion that there is need for ongoing education and specific guidance in the optimal use of imaging, and this is probably best achieved and most likely to be successful if it is based on methodologically sound, widely accepted guidelines for the use of imaging.

It follows, however, that imaging guidelines are likely to be very difficult to develop and deploy, given the complexity of modern medicine and the wide variations in disease patterns, availability of technology and treatments, and knowledge, but they are also necessary. There has been much discussion about how guidelines should be constructed, but there are several areas of wide consensus. First, clinical guidelines should be based to as large an extent as possible on high quality, peer reviewed literature. The available literature, however, is virtually never sufficient to provide data based guidance, except in very limited areas, so any guidelines must be data driven but supplemented by expert opinion. Guidelines must also be based on transparent, well defined, reproducible methodology that indicates how the literature is reviewed and synthesized, and how conclusions are reached. Guidelines must be updated regularly (e.g. every two years), must be widely accepted and must be readily available, ideally as part of an electronic health record. They must be developed and vetted by relevant experts, in this case imaging experts, as well as other health care providers, patients and even payers. This balance of multiple factors is very difficult to achieve. Guidelines are often focused on a single disease entity, e.g. low back pain or urinary tract infections, and address the entire spectrum of this disease, from initial presentation through treatment and outcome. They require specific expertise in the topic being addressed, as well as in methodology. They may take several years to produce, with an associated cost of over US $200 000. Imaging guidelines differ from most other guidelines in that the focus is confined to guiding the ordering health care provider in the best use of imaging. Most imaging guidelines, then, are relatively narrowly focused and

brief. They are, in a sense, horizontal, addressing all imaging, rather than vertical, addressing all aspects of a specific disease.

There are several, different, high quality clinical imaging guidelines available. The most comprehensive currently are the Appropriateness Criteria of the American College of Radiology (ACR) [14]. Other widely accepted ones include those from the Royal College of Radiology of the United Kingdom [15], the Canadian Association of Radiologists and the Diagnostic Imaging Pathways from Western Australia [16]. The entry level for the ACR Appropriateness Criteria is the question: In this specific clinical situation, if I as a clinician am considering an imaging study, which one, if any, is most likely to provide useful clinical information? Inherent in this is a consideration of the risk:benefit ratio of the imaging.

The ACR Appropriateness Criteria are created by ten diagnostic panels (based on body area, such as breast or musculoskeletal), one interventional and nine radiation oncology panels. Each panel has 8–20 members, with broad representation geographically and in modality expertise. Non-radiologist societies, such as the American College of Chest Physicians, the Society of Vascular Surgery and the American Society of Neurosurgery, have representatives on the panels. Currently, over 800 topics are addressed by specific appropriateness criteria and variants. Each topic is developed based on a perceived need, due to impact of disease, prevalence, cost implications and potential for impact on care and outcomes, as well as the availability of relevant peer reviewed studies in the published literature. Topics are developed by an assigned author who reviews, categorizes and selects and rates the relevant literature. An evidence table, consisting of the selected publications, is then created, which forms the basis for a narrative on the topic and presents and discusses all of the relevant imaging modalities. From this, an appropriateness table is developed for each variant of the topic. First, the panel chair and then the entire panel reviews all of this material, and then each modality in each variant is voted on for appropriateness. This is done using a modified Delphi approach, with three rounds of voting, one or two conference calls and consensus defined as 80% agreement of those voting. Rating is done on a scale of 1–9, with 1–3 defined as ‘usually not appropriate’, 7–9 as ‘usually appropriate’ and 4–6 as ‘may be appropriate’ (Fig. 1). There is a rarely used additional category of ‘no consensus’. Each panellist is instructed to base their votes to as great an extent as possible on data, not personal experience.

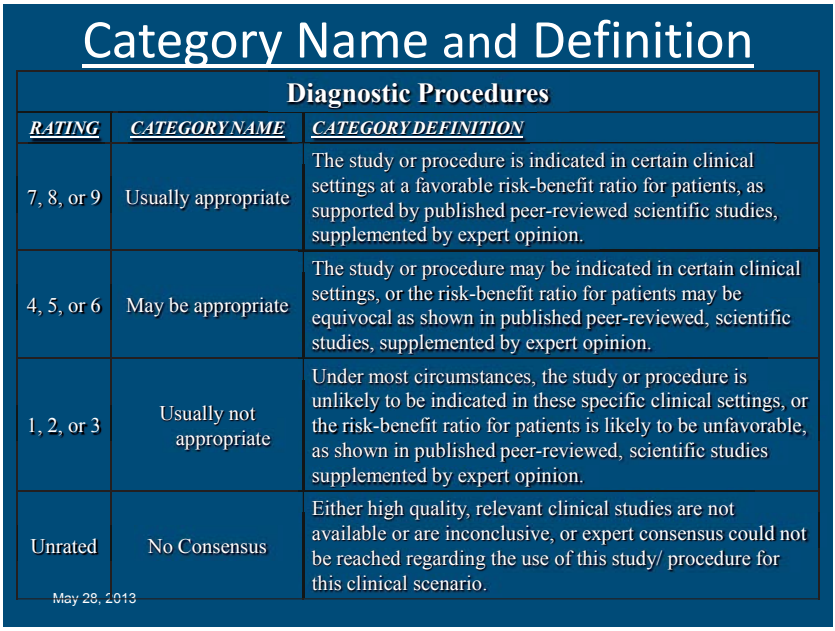
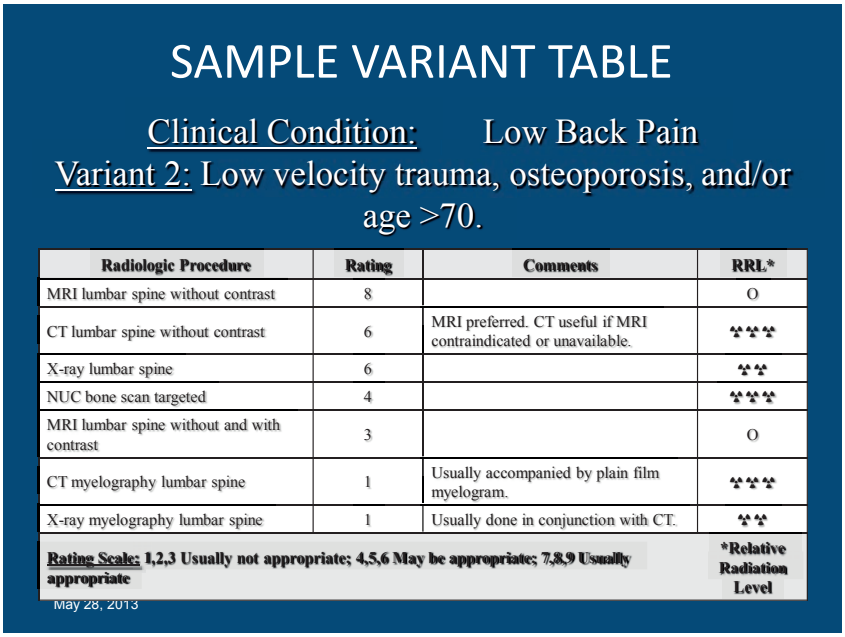


FIG. 1. American College of Radiology Appropriateness Criteria categories and definitions.

Additionally, a relative radiation level (RRL) rating is assigned for each modality in each variant, within one of five categories ranging from no radiation to >30 mSv. These ratings are developed by a separate committee of radiation physicists and radiologists, and these ratings too are revised every 1–2 years, revisited as needed in the interim and are based to as great an extent as possible on high quality published, peer reviewed reports. Figure 2 is an appropriateness criteria table for a single variant of the clinical condition ‘low back pain’, with the ratings as well as the RRLs and comments.

There are several major challenges to the use of guidelines. First, as noted, for guidelines to be valid, they must be based on sound methodology, be updated regularly and be widely accepted. All three of these present significant challenges. For example, there are areas covered by multiple guidelines, with differing recommendations, from different societies. Also, many doctors and payers, including insurance companies and regulatory agencies, would rather have direct control over the use of imaging, even if based on limited individual knowledge and experience. Finally, to really be useful, guidelines must cover most if not all clinical settings in which there is any question about the use of imaging, and they must be user friendly in terms of availability and utility. That is, useful and acceptable imaging guidelines must form a computer based decision support system.



SAMPLE VARIANT TABLE

Clinical Condition: Low Back Pain

Variant 2: Low velocity trauma, osteoporosis, and/or age >70.

Radiologic Procedure	Rating	Comments	RRL*
MRI lumbar spine without contrast	8		O
CT lumbar spine without contrast	6	MRI preferred. CT useful if MRI contraindicated or unavailable.	☢☢☢
X-ray lumbar spine	6		☢☢
NUC bone scan targeted	4		☢☢☢
MRI lumbar spine without and with contrast	3		O
CT myelography lumbar spine	1	Usually accompanied by plain film myelogram.	☢☢☢
X-ray myelography lumbar spine	1	Usually done in conjunction with CT.	☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

May 28, 2013

FIG. 2. Example of an appropriateness criteria table, for one of six variants of the topic 'low back pain', with ratings for modalities and relative radiation level.

The development of such a decision support system faces many challenges, including those of software development, hardware availability, system compatibility and interconnectivity, and availability of content with satisfactory breadth, depth and scientific validity. While extant guidelines, such as the ACR Appropriateness Criteria and the Diagnostic Imaging Pathways, are excellent educational tools, incorporation into clinical workflow has lagged due to the challenges noted in both information technology and in content. The ACR has developed an approach, through collaboration with a new commercial entity, to address these challenges. There are two major advantages to this: first, there is extensive prior experience with a clinical imaging decision support system which will help to inform the current effort. Second, the ACR Appropriateness Criteria, with their breadth and quality, form a valid, methodologically sound basis for decision support. Nonetheless, major challenges exist. For example, 'translating' the ACR Appropriateness Criteria variant from a pdf format to one that will work easily electronically is not straightforward. Also, there are a lot of concerns with utilization. Usual practice varies widely from region to region, and nation to nation, as does the availability of equipment and the prevalence of disease, all of which influence the recommendations from a decision support system. It is essentially impossible to cover all clinical

possibilities, and there can be disagreement among experts, so a systematic approach to incorporating questions and concerns from users is imperative. Nonetheless, given the recognized need for more effective use of imaging and more rational use of resources worldwide, and given the strength of the ACR Appropriateness Criteria and other high quality, methodologically sound clinical imaging guidelines/justification criteria, there is reason to be optimistic about the incorporation of such systems into wide clinical practice.

REFERENCES

[1] LIN, F.Y., et al., Impact of an automated multimodality point-of-order decision support tool on rates of appropriate testing and clinical decision making for individuals with suspected coronary artery disease: A prospective multicenter study, J. Am. Coll. Cardiol. **62** 4 (2013) 308–316.

[2] GIMBEL, R.W., et al., Radiation exposure and cost influence physician medical image decision making: A randomized controlled trial, Med. Care **51** 7 (2013) 628–632.

[3] MASSACHUSETTS MEDICAL SOCIETY, Report on Defensive Medicine (2008).

[4] SATHIYAKUMAR, V., et al., The prevalence and costs of defensive medicine among orthopaedic trauma surgeons: A national survey study, J. Orthop. Trauma **27** 10 (2013) 592–597.

[5] NAHED, B.V., BABU, M.A., SMITH, T.R., HEARY, R.F., Malpractice liability and defensive medicine: A national survey of neurosurgeons, PLoS One **7** 6 (2012) e39237.

[6] XU, X., SPURR, S.J., NAN, B., FENDRICK, A.M., The effect of medical malpractice liability on rate of referrals received by specialist physicians, Health Econ. Policy Law **8** 4 (2013) 453–475.

[7] SIMA, C.S., PANAGEAS, K.S., SCHRAG, D., Cancer screening among patients with advanced cancer, JAMA **304** 14 (2010) 1584–1591.

[8] EMERY, D.J., SHOJANIA, K.G., FORSTER, A.J., MOJAVERIAN, N., FEASBY, T.E., Overuse of magnetic resonance imaging, JAMA Intern. Med. **173** 9 (2013) 823–825.

[9] Cumulative Contribution of Aging and Excess Cost Growth to Medicare Spending Under OACT's Alternative Scenario, 2013–2035, Office of the Actuary, CMS (2013).

[10] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Ionizing Radiation Exposure of the Population of the United States, NCRP Report 160, NCRP, Bethesda, MD (2009).

[11] SCHAUER, D.A., LINTON, O.W., National Council on Radiation Protection and Measurements Report shows substantial medical exposure increase, Radiology **253** 2 (2009) 293–296.

[12] MATHEWS, J.D., et al., Cancer risk in 680 000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians, BMJ **346** (2013) f2360.

[13] PEARCE, M.S., et al., Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: A retrospective cohort study, Lancet **380** 9840 (2012) 499–505.
[14] AMERICAN COLLEGE OF RADIOLOGY, ACR Appropriateness Criteria, http://www.acr.org/Quality-Safety/Appropriateness-Criteria
[15] ROYAL COLLEGE OF RADIOLOGISTS, iRefer: Making the Best Use of Clinical Radiology, 7th edn, The Royal College of Radiologists, London (2012).
[16] GOVERNMENT OF WESTERN AUSTRALIA, DEPARTMENT OF HEALTH, Diagnostic Imaging Pathways (2013), http://www.imagingpathways.health.wa.gov.au/

JUSTIFICATION AND THE ROLE OF TECHNOLOGY AND ALGORITHMS

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Abstract

Justification of the use of ionizing radiation is one of the pillars of radiation protection, including in medical practice. While there are often clear justifications for performing diagnostic imaging examinations, there are many situations in which justification is more arguable. Determining what is justified is an extremely complicated aspect of medical practice as it potentially involves multiple health care providers, with varying levels of experience, anecdotal based decision making and a broad variety of other forces. It is beyond the intent of this paper to fully dissect this aspect of justification in medical imaging. However, there are tools that are becoming available for improving evidence based medicine, including decision rules, practice guidelines and appropriateness criteria, and point-of-care decision support. Many of these advancements are becoming embedded in electronic health care systems. The following material will present background information, define some of the terminology involved in 'algorithms' for improving justification, address the current status, provide some of the challenges in implementing models for improved justification of medical imaging, and present some of the current needs.

1. BACKGROUND

Globally, and certainly within the United States of America, the use of diagnostic imaging which employs ionizing radiation is certainly increasing. For example, the use of computed tomography (CT) in the USA over the past 30 years or so has increased nearly 600% [1]. This increased use of medical imaging has some associated potential health risks, but costs also include financial implications for health care delivery as well as utilization of often limited resources, such as equipment and medical personnel. With increased scrutiny on delivery of radiation, as well as some of these health care cost considerations, increased attention, particularly in more developed countries,

has recently been more focused on appropriateness of imaging. With respect to CT examinations, Hendee et al. [2] noted that 20–50% of examinations are potentially not justified. Similar comments of overutilization of 20–30% of imaging examinations are encountered elsewhere in the literature [3]. However, I would argue that overutilization is a very complicated topic and does not lend itself easily to the simplified percentage derivations of utilization. For example, utilization can be driven by evidence, or other accepted medical benefit, industry marketing, use by non-imaging experts (i.e. surgeons, neurologists, etc.) and self-referral. Evidence of self-referral is seen in Ref. [4], which demonstrates a substantial growth in CT utilization in 2001–2005 from about 200 000 to 800 000 in non-radiology facilities. Overall, comparing the use of the increased frequency of CT examinations performed by radiologists versus the non-radiologists in the same study showed significant differences, with lower rates of increase by radiologists. Once again, determining whether this is due to self-referral or other factors is extremely difficult. Other influences include reimbursement through government or private payers, legal forces, the media, and the expectation of patients and the public. All of the above can combine to give quite different perspectives on and decisions for what is appropriate and inappropriate in medical imaging for similar clinical circumstances for different patients. In addition, levels of training, overall expertise and experiential/anecdotal factors can drive imaging use. A few years ago, I had a conversation with a paediatric resident physician at my institution where the individual stated, "but I thought the emergency department was different than the clinic and we should order more CT examinations" (4 June 2008). This illustrates the fact that practice environments and landscapes might also drive utilization. Whatever the explanations, imaging has clearly increased. This is especially evident in the emergency care setting. For example, Broder et al. [5] noted that there was a 350–450% increase in cervical spine and chest CTs over a six year period (2000–2006). In addition, Larson et al. [6, 7] noted an increased utilization of CT examinations in the acute care setting.

Terms applied in discussions of utilization/justification include 'excessive', 'ineffective', 'unjustified', 'inappropriate' and 'overutilized' with respect to medical imaging. Often, these comments come from radiology sources and, whether directly or indirectly, imply that our clinical colleagues are 'ordering too many studies'. I find this very difficult to support; it conveys an antagonistic and confrontational (at best, judgemental) environment which serves little purpose in arriving at the requisite consensus strategies and solutions. In the setting of justification of medical imaging, I believe using the word 'inappropriate' is, with some irony, 'inappropriate'. We should be shaking hands instead of pointing fingers. Some of the steps to reducing the questionable utilization in imaging were nicely outlined by Hendee et al. [2]. These recommendations included

decision support at the point-of-care, evidence based appropriateness criteria, greater use of practice guidelines, education of stakeholders, accreditation of facilities, management of self-referral and defensive medicine, and payment reform. Note that the top of the list contained many items relevant to this current paper. In addition, J. Thrall, at the 2009 National Academies of Science Beebe Symposium [8], stated that:

> "imaging has transformed medical malpractice…[there is] better evidence and better methods… decision support…new technology and new protocol approaches offer promise…there is no low tech alternative in the US health system and we must do better in the stewardship of high technology medicine."

Of note, these exact same observations are pertinent now more than four years later.

2. DEFINITION OF TERMS

Relevant terms and phrases include 'justification', 'decision rule', 'algorithm'/'guideline' and 'decision support'. Justification will be dealt with in much greater detail in other aspects of this conference. A clinical decision rule, according to McGinn et al. [9], is: "a clinical tool that qualifies the individual contributions that various components of the history, physical examination, and basic laboratory results make toward the diagnosis, prognosis, or likely response to treatment in a patient". A decision rule provides probabilities. "Clinical decision rules have the potential to inform clinical judgment, to change clinical behavior, and reduce unnecessary costs while maintaining quality care and patient satisfaction" [9]. I see this as breaking down more simply to an equation:

If *A*, then the probability of *B* is…

Reilly and Evans [10] recently provided some of the strategies to overcome barriers to effective use of decision rules. The American College of Radiology (ACR) Appropriateness Criteria is a resource that helps with the establishment of clinical rules and guidelines:

> "Currently, the ACR Appropriateness Criteria are the most comprehensive evidence based [guidelines] for diagnostic imaging selection, radiotherapy protocols, and image-guided interventional

> procedures. They embody the best, current evidence for selecting appropriate diagnostic imaging and interventional procedures for numerous clinical conditions" [11].

As opposed to decision rules (equation above), appropriateness criteria connote:

If suspect *A*, then the appropriateness of using imaging *B* is…

As I see it, appropriateness criteria and these decision rules can then be built into guidelines, such as the Practice Guidelines and Technical Standards from the ACR [12].

If suspect *A*, then the pathway(s) to B to follow is/are…

Finally, decision support is information available at the point-of-care. Decision support, and the benefits and difficulties were recently outlined by Boland et al. [13]. In this publication, comments included that decision support must evolve through computer order entry systems, should alter behaviour, and improve utilization through evidence based medicine. The publication concluded noting that decision support is an added value for radiology. In past times, support was usually through person-to-person consultation with radiologists. In a contemporary setting, sending a question by email or using a cell phone has provided opportunities for point-of-care communication about imaging decision making. However, with current electronic health care information technology and computer order entry systems, this radiologist consultation can be built into the ordering mechanism. More simply:

If suspect *A* and are choosing to order exam *B* then here is information on why this may or may not be the best choice…

Thus, there is overlap between decision rule, appropriateness criteria, and guidelines/algorithms and decision support, and sometimes some terms are used interchangeably, but I believe these do have some distinct implications as discussed above.

3. CURRENT STATUS

One of the most fruitful applications of decision support has been reported at Massachusetts General Hospital. For example, Sistrom et al. [14] demonstrated with the application of appropriateness criteria at the point-of-care that increases

in imaging frequency levelled off. Blackmore et al. [15] concluded that 'just in time' (i.e. decision support) knowledge delivery decreased imaging rates especially for sinus CT, head magnetic resonance imaging (MRI) and lumbar MRI. These are just some examples in the USA. Other material presented at this conference will go over in much more detail referral guidelines, many of which have been well developed in Argentina, Australia, Canada, Europe and Hong Kong, China [16]. Other examples of appropriateness criteria and guidelines that could be built from international venues include work by Malone et al. [17], as well as information from the referral guidelines for imaging from the European Commission.

4. CHALLENGES

Some challenges include parallel, often independent, and potentially conflicting efforts. For example, appropriateness criteria for head injury from the ACR, the American Academy of Pediatrics and the European Commission provide some different management strategies and certainly different detail in guidelines. In addition, the sophistication of electronic health care varies greatly even within a country and embedded decision support is only one component of a potentially tremendously expensive and complex system of medical information technology improvement. In particular, to embed the ICD10 codes (tens of thousands) in decision support would be a daunting task. In addition, there are 2700 entries in the US National Clearinghouse. Additional challenges will be the responsibility not only for the development but also for the audit and maintenance and updates in decision support. For example, a recent publication by Williams et al. [18] developed a compendium of national guidelines for imaging of the paediatric patient. Even with this comprehensive review looking at multiple national and some international sources, this would need to be constantly updated and reviewed. In addition, expected benefits from this decision support might be different from the results. For example, a recent presentation at RSNA by S. Gupta [19] noted that about two thirds of examinations were still performed due to physician overriding of the decision support recommendation of an alternate study for low utility (less than 3 score on the ACR Appropriateness Criteria) scenarios. In addition, what are the metrics for success? What will be the impact analysis? Finally, and most challenging are: What are the potential penalties for not conforming to whatever established standards or decision support and utilization are established? Who will monitor this and what can be done?

5. NEEDS

Finally, decision support must include cumulative dose information as part of available information. Whether or not this will affect whether an examination is performed is somewhat debatable but it is incumbent upon the imaging community to be able to account for prior radiation delivered to a patient. Decision support must be in parallel with established guidelines, that are "standardized, [developed based on] need, accessible with a centralized repository, and be pluralistic (diverse community approach to guideline development)" [20]. The needs include accessing existing guidelines. Finally, according to Lau, with respect to global efforts for referral guidelines:

> "this is a major collaboration towards a more coherent, global approach to promote an appropriate use of medical imaging in interventional radiology procedures. The guidance we envision will provide direction to practices in both developed and developing countries that may or may not have the most up to date technologies" [16].

6. CONCLUSIONS

The use of medical imaging, including that using ionizing radiation is certainly increasing. This is due to a variety of factors, some of which are clearly recognized as a benefit for quality of care in the patient. However, there are multiple factors which drive imaging utilization and can contribute to what some consider substantial overutilization. Strategies to promote justified medical imaging include decision rules, appropriateness criteria, guidelines and algorithms for medical imaging. Whereas the traditional methods of direct consultation with radiologists could improve the appropriate utilization of medical imaging, given the complexities of contemporary practice, and the penetration of information technology, such as computer order entry systems, there is an opportunity to potentially help with this 'electronic consultation' through decision support. However, there are still challenges associated with this, particularly related to the cost of development, maintenance and assessment of impact. Despite these challenges, efforts should be directed at utilizing the electronic health care record and information technology, such as through decision support, to facilitate delivery of appropriate utilization of imaging, especially given the tremendous pressures on prompt and accurate health care, and expansive information.

REFERENCES

[1] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Ionizing Radiation Exposure of the Population of the United States, NCRP Report 160, NCRP, Bethesda, MD (2009).

[2] HENDEE, W.R., et al., Addressing overutilization in medical imaging, Radiology **257** 1 (2010) 240–245.

[3] CASCADE, P.N., WEBSTER, E.W., KAZEROONI, E.A., Ineffective use of radiology: the hidden cost, AJR Am. J. Roentgenol. **170** 3 (1998) 561–564.

[4] LEVIN, D.C., et al., Ownership or leasing of CT scanners by nonradiologist physicians: a rapidly growing trend that raises concern about self-referral, J. Am. Coll. Radiol. **5** 12 (2008) 1206–1209.

[5] BRODER, J., FORDHAM, L.A., WARSHAUER, D.M., Increasing utilization of computed tomography in the pediatric emergency department, 2000–2006, Emerg. Radiol. **14** 4 (2007) 227–232.

[6] LARSON, D.B., et al., Rising use of CT in child visits to the emergency department in the United States, 1995–2008, Radiology **259** 3 (2011) 793–801.

[7] LARSON, D.B., et al., National trends in CT use in the emergency department: 1995–2007, Radiology **258** 1 (2011) 164–173.

[8] THRALL, J.H., Evidence Based and Systems Based Best Practices for Management of Imaging Utilization, 2009 Bebee Symposium, http://dels.nas.edu/resources/static-assets/nrsb/miscellaneous/Thrall%20Presentation.pdf

[9] McGINN, T.G., et al., Users' guides to the medical literature: XXII: how to use articles about clinical decision rules. Evidence-Based Medicine Working Group, JAMA **284** 1 (2000) 79–84.

[10] REILLY, B.M., EVANS, A.T., Translating clinical research into clinical practice: impact of using prediction rules to make decisions, Ann. Intern. Med. **144** 3 (2006) 201–209.

[11] AMERICAN COLLEGE OF RADIOLOGY, ACR Appropriateness Criteria, http://www.acr.org/Quality-Safety/Appropriateness-Criteria

[12] AMERICAN COLLEGE OF RADIOLOGY, ACR Practice Guidelines and Technical Standards, http://www.acr.org/Quality-Safety/Standards-Guidelines

[13] BOLAND, G.W., et al., Decision support for radiologist report recommendations, J. Am. Coll. Radiol. **8** 12 (2011) 819–823.

[14] SISTROM, C.L., et al., Effect of computerized order entry with integrated decision support on the growth of outpatient procedure volumes: seven-year time series analysis, Radiology **251** 1 (2009) 147–155.

[15] BLACKMORE, C.C., MECKLENBURG, R.S., KAPLAN, G.S., Effectiveness of clinical decision support in controlling inappropriate imaging, J. Am. Coll. Radiol. **8** 1 (2011) 19–25.

[16] LAU, L.S., et al., Global quality imaging: Improvement actions, J. Am. Coll. Radiol. **8** 5 (2011) 330–334.

[17] MALONE, J., et al. Justification of diagnostic medical exposures, some practical issues. Report of an International Atomic Energy Agency Consultation, Br. J. Radiol. **85** 2013 (2012) 523–538.
[18] WILLIAMS, C.H., FRUSH, D.P., Compendium of national guidelines for imaging of the pediatric patient, Pediatr. Radiol. **42** 1 (2012) 82–94.
[19] GUPTA, S., personal communication, 2011.
[20] INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, Clinical Practice Guidelines We can Trust, http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx

RADIATION PROTECTION OF PATIENTS IN EXTERNAL BEAM RADIOTHERAPY

(Session 2)

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RADIATION PROTECTION OF PATIENTS IN EXTERNAL BEAM RADIOTHERAPY

Introduction of the topic

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Abstract

The benefits of radiotherapy can be summarized in the following statement: radiotherapy saves lives, prolongs lives and improves quality of life. On the other hand, to achieve these benefits, normal tissue often receives radiation doses that are on the upper edge of tolerable doses, as a result of which, accidental overdosage has sometimes had devastating consequences; in addition, underdosage, which may not always be detected timely, can also lead to severe consequences. A step-by-step approach is suggested for the prevention of accidental exposures in radiation therapy: (i) design and implementation of a quality and safety programme in accordance with safety standards and quality protocols; (ii) use of lessons from accidental exposures to test whether the quality and safety programme has some gaps or vulnerable aspects; and (iii) use of an anticipative approach to find other latent risks by posing the question 'What else could go wrong?' in all steps of the radiotherapy process and evaluating the list of potential events according to a combination of likelihood and severity of outcome. This rational approach facilitates focusing the efforts on a limited number of higher risk events.

1. INTRODUCING THE ISSUES

First, the benefits should be recognized: radiotherapy saves lives, prolongs lives and improves quality of life [1]. Some studies published in the last decade estimate that the proportion of new cancer patients in whom external beam radiotherapy is indicated should be 52% [2], according to the best available evidence. Radiotherapy plays an important role in the treatment of 40% of the patients who are cured of their cancer, and in palliation and symptom control in cases of advanced or recurrent cancer [1]. According to the United Nations Scientific Committee on the Effects of Atomic Radiation [3], in the period 1997–2007, the number of annual treatments with radiotherapy was 5.1 million,

of which 4.7 million were treatments with an external beam and 0.4 million with brachytherapy.

Since radiation is used to kill tumour cells, very high radiation absorbed doses are required; often, normal tissue receives radiation doses that are on the upper edge of tolerable doses, as a result of which, accidental overdosage has sometimes had devastating consequences; in addition, underdosage, which may not always be detected timely, can also lead to severe consequences. All of these features are unique for radiotherapy and pose high demands on quality and safety [4, 5].

With the advent of new technologies, it is possible to achieve dose distributions which conform more strictly to tumour tissue. A highly conformal dose distribution allows for dose escalation in the target volume without increasing the radiation dose to neighbouring normal tissues. These new technologies encompass the increased use of multileaf collimators, intensity modulated radiation therapy, volumetric modulated arc therapy, tomotherapy, image guided radiation therapy, respiratory gating, robotic systems, radiosurgery, newer and more complex treatment planning systems, virtual simulation and 'all-inclusive' electronic patient data management systems [5]. All of them have the principal aim of improving treatment outcome.

Most of these advances imply an ever increasing complexity of both equipment and treatment techniques, and the omnipresence of computers. Complexity may also increase the opportunities for accidental exposures, and 'common sense' and intuition may no longer be as effective a mechanism to perceive 'when something may be wrong' as it is with conventional radiation therapy [6]. The challenge is, therefore, to implement new technologies in conjunction with the appropriate means to ensure that they can and will be used safely [5].

2. WHICH RESOURCES ARE AVAILABLE?

A wealth of standards, guidance and information have been developed over the years that can be used to ensure quality and safety in external beam radiotherapy.

2.1. Standards and protocols for a programme of quality and safety

The first element is the design of a programme of quality and safety. International standards establish requirements on responsibility allocation, justification of treatments, optimization of protection in the techniques applied, traceable calibration, clinical dosimetry and quality assurance, as well

as the prevention and investigation of accidental exposures, and finding measures to avoid reoccurrences [7].

Protocols, usually prepared within national and international organizations and professional bodies, can be adopted or adapted in individual radiotherapy departments [8–10]. Some of the accidental exposures have occurred even in countries with a tradition in quality assurance, when some of the procedures or verifications were omitted. Thus, there is a need for continuous supervision to ensure that the programme remains effective over time and during any evolutionary change in the department.

2.2. Lessons from accidental exposures and near misses

Available lessons from accidental exposures with conventional technologies and techniques [4, 11–16] can be directly used to check whether the quality and safety programme is robust enough to withstand situations such as those found in reported accidental exposures and to find vulnerable areas needing attention. In addition, information on events that occurred with new technologies and techniques is also available [5]. Teaching case histories and their lessons to radiotherapy staff as part of their training is an effective tool to maintain awareness.

Not only can lessons from major past events be used, but also 'near misses' that happened to have no consequences, but may have severe consequences next time in another place can also be shared. Sharing near misses helps to address these types of error and to perform regular reviews, and, thus, is a tool for continuous improvement. Examples of systems for sharing near misses are ROSIS (Radiation Oncology Safety Information System)[1], and more recently, the SAFRON (Safety in Radiation Oncology)[2] system provided by the IAEA as a safety reporting and learning system for voluntary participation that aims to enable globally shared learning from safety related events and safety analysis in order to improve the safe planning and delivery of radiotherapy. Methods based on sharing information on past events are sometimes referred to as 'retrospective approaches'.

2.3. Anticipative methods

While the use of retrospective approaches is an important step, it has the limitation of being confined to reported events. In addition to the risks known

[1] http://www.rosis.info/index.php
[2] https://rpop.iaea.org/SAFRON

from published reports and from sharing information on near misses, there may be other latent risks that may not have surfaced. These risks will remain unaddressed unless a proactive search is performed to reveal them in a systematic, anticipative manner. These methods are often called 'proactive or prospective approaches'.

Some of these methods have already been applied to radiotherapy. They all have in common that the analysis is performed by a multidisciplinary group of radiotherapy staff and safety specialists. The first step consists of describing the radiotherapy process and breaking down the process into steps in a flow diagram. Then, the question 'what can go wrong?' is systematically asked and answered by the group for every step of the radiotherapy process.

Once potential events have been identified, the task becomes that of analysing the likelihood of an unacceptable event occurring, assessing the severity or consequences of the event should it occur, and assessing the likelihood that the event will not be detected during quality control checks and will, hence, have a negative impact on the patient's treatment.

Three prospective approaches have been applied so far to radiation therapy: (i) failure mode and effect analysis (FMEA) [17, 18]; (ii) probabilistic safety assessment [19]; and (iii) the risk matrix approach [20]. They are not totally independent, since FMEA has sometimes been performed as part of probabilistic safety assessment. The risk matrix approach is relatively straightforward and provides an opportunity for self-evaluation in individual hospitals.

3. WHAT COULD BE A STRATEGY FOR SAFE RADIOTHERAPY?

A rational strategy to preventing accidental exposure consists of three steps:

(a) Establishing a programme of safety and quality in compliance with safety standards and quality protocols;
(b) Obtaining confidence that this programme is robust enough to withstand situations such as those found in reported accidental exposures;
(c) Anticipating the unknown or unreported, screening the potential events by combining likelihood of occurrence with severity of outcome to sort the events in the order of level of risk and focusing on the most important ones.

REFERENCES

[1] WORLD HEALTH ORGANIZATION, Radiotherapy Risk Profile, Technical Manual, WHO/IER/PSP/2008.12, WHO, Geneva (2008).

[2] DELANEY, G., et al., The role of radiotherapy in cancer treatment: estimating optimal utilization from a review of evidence-based clinical guidelines, Cancer **104** 6 (2005) 1129–1137.
[3] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2008 Report to the General Assembly with Scientific Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).
[4] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of Accidental Exposure to Patients Undergoing Radiation Therapy, Publication 86, Pergamon Press, Oxford (2002).
[5] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, Publication 112, Elsevier (2009).
[6] ROSENWALD, J.C., Safety in radiotherapy: control of software and informatics systems, Cancer Radiother. **6** Suppl. 1 (2002) 180s–189s (in French).
[7] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
[8] WORLD HEALTH ORGANIZATION, INSTITUT FÜR STRAHLENHYGIENE DES BUNDESGESUNDHEITSAMTES, Quality Assurance in Radiotherapy: A Guide Prepared Following a Workshop Held at Schloss Reisensburg, Germany, WHO, Geneva (1988).
[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Setting up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects, IAEA, Vienna (2008).
[10] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Comprehensive QA for radiation oncology, report of AAPM Radiation Therapy Committee Task Group 40, Med. Phys. **21** 4 (1994) 581–618.
[11] ASH, D., BATES, T., Report on the clinical effects of inadvertent radiation underdosage in 1045 patients, Clin. Oncol. (R. Coll. Radiol.) **6** 4 (1994) 214–226.
[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Lessons Learned from Accidental Exposures in Radiotherapy, Safety Reports Series No. 17, IAEA, Vienna (2000).
[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica, IAEA, Vienna (1998).
[14] SOCIEDAD ESPAÑOLA DE FÍSICA MÉDICA, The Accident of the Linear Accelerator in the "Hospital Clínico de Zaragoza", SEFM, Madrid (1991).
[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Investigation of an Accidental Exposure of Radiotherapy Patients in Panama, IAEA, Vienna (2001).
[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in Bialystok, IAEA, Vienna (2004).

[17] STAMATIS, D.H., Failure Modes and Effects Analysis: FMEA from Theory to Execution, ASQC Quality Press, Milwaukee, WI (1995).
[18] FORD, E.C., et al., Evaluation of safety in a radiation oncology setting using failure mode and effects analysis, Int. J. Radiat. Oncol. Biol. Phys. **74** 3 (2009) 852–858.
[19] INTERNATIONAL ATOMIC ENERGY AGENCY, Análisis Probabilista de Seguridad de Tratamientos de Radioterapia con Acelerador Lineal, IAEA-TECDOC-1670S, IAEA, Vienna, (2012) (in Spanish).
[20] VILARAGUT, J.J., DUMÉNIGO, C., DELGADO, J.M., et al., Prevention of accidental exposure in radiotherapy: the risk matrix approach, Health Phys. **104** 2 (2013) 139–150.

IMPACT OF NEW TREATMENT TECHNOLOGY ON PATIENT PROTECTION IN RADIOTHERAPY

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Abstract

Introduction of new technologies in radiotherapy has improved patients' outcomes dramatically. Modern radiotherapy permits precise irradiation of tumours with minimum side effects. However, the methods are often associated with complex procedures with many steps, requiring careful adjustment and parameter setting in each individual patient. Rapid expansion of these new technologies in clinical practice may introduce increased risk of accidental exposure. Education and training for the personnel involved in the treatment procedure are essential for patient protection. These new technologies have successfully improved the dose distribution, resulting in a significant reduction of undesirable radiation to the outside target volume. However, the area which receives relatively low dose radiation may be increased, which might increase the risk of secondary cancer. Health care professionals should also be aware of the possible risk and consider the necessary procedures for patient protection when new technologies are introduced in clinical practice.

1. INTRODUCTION

Radiotherapy has made considerable progress in recent years in terms of increased applicability and enhanced therapeutic outcomes. In particular, high precision photon beam radiotherapy, such as intensity modulated radiotherapy and stereotactic radiotherapy, has been used effectively in clinical practice. The use of ion beams, such as proton and carbon, has also been rapidly advancing in recent years. Introduction of these new technologies in radiotherapy has successfully contributed to conquering cancer in many patients.

The advancement of modern radiotherapy is associated with complicated procedures, which require many experts with different professional skills. Thus, special arrangements are required for the construction of the facility, the management of the procedures and patients, and for education and training of the staff. The ability of precisely irradiating the target tumour region permits effective treatment with minimum biological effects in surrounding tissues [1]. Improved treatment outcomes result in longer survival of cancer patients after radiotherapy,

leading to a new question, the possible increase of secondary cancers at a later time. The impact of new treatment technology in radiotherapy is discussed from the viewpoint of patient protection.

2. NEW METHODS OF RADIOTHERAPY

The primary principle of radiotherapy relies on precise dose localization in the target, with minimal damage to the surrounding normal tissues. Dramatic progress in radiotherapy has been observed during the past century. Various new approaches have been proposed and some of them have demonstrated excellent outcomes in the treatment of cancer patients. Typical examples of these approaches developed in recent years are shown in Fig. 1: (a) irradiation from multiple directions to improve the target:non-target dose ratio; (b) ion beam treatment to maximize the target dose with minimum dose to the surrounding normal tissues; (c) brachytherapy using sealed sources; and (d) molecular target radiotherapy which can be applied to multiple scattered tumours.

New technology in radiotherapy focuses on improved physical dose to the target tumour and enhanced biological effect, either by using high linear energy transfer (LET) radiation or by applying a combination of radiation and molecular processes. Thus, the introduction of new methods in radiotherapy can be achieved by joint efforts of technology and biology. Considering the complicated properties of radiation and its biological effects, collaborative efforts among experts with different professional skills are required for the development of new technology towards safe and secure treatment in cancer patients.

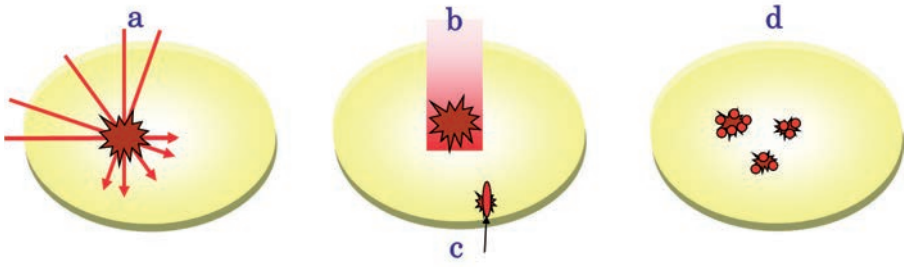

FIG. 1. Approaches to improving dose distribution in radiotherapy: (a) irradiation from multiple directions; (b) ion beam treatment; (c) brachytherapy; (d) molecular target radiotherapy.

3. NEW PROBLEMS AND SOLUTIONS

The significant advantage of new methods of radiotherapy can be obtained by careful preparation of the procedures. In order to provide the maximum benefit to the patient, each procedure must be optimized before the treatment.

3.1. Protection from accidental exposure

Appropriate dose delivery to the target tumour is the most important issue. Not only overexposure but also inappropriate or insufficient dose delivery to the target tumour could cause serious harm to the patient. New technologies have led to substantial improvements to radiotherapy, which is often achieved by complex procedures. There is an increased risk of human error and mistakes in equipment adjustment [2]. Education, sufficient knowledge and training of personnel involved in the treatment procedure are essential for patient protection.

3.2. Treatment planning and irradiation

Imaging technology plays a crucial role for precise localization of the target volume in radiotherapy. High precision radiotherapy is based on the assumption that the tumour boundary can be determined precisely. For this purpose, accurate diagnosis for the precise localization of a tumour is essential, and even a subtle error in diagnosis or misalignment of the tumour boundary could cause substantial harm to the patient.

Accurate dose delivery to the target tumour is based on the calculation of physical dose and the estimation of biological effects [3]. It is important to estimate the biological effects in a localized area. In addition to the calculation of physical dose, additional parameters of biological effects are required for high LET radiation [4]. Various models are proposed to estimate biological effects [5].

For high precision radiotherapy, the patient's position is important and is verified with orthogonal X ray radiographs in comparison with digital radiographs reconstructed from planning computed tomography images. Immobilization of the patient during the treatment is essential and care should be taken that the patient is comfortable. Respiratory gating is often used to minimize the movement effects of doses in tumours and surrounding organs.

Verification of dose delivery to the target volume should be based on experiment before or after treatment. Direct evidence of actual dose to each patient can be obtained only in ion beam treatment with protons or carbon ions, where nucleus reactions produce positron decayed nuclei such as ^{15}O and ^{11}C. By detecting coincidentally paired annihilation gamma rays from these nuclei, the dose distribution in the body can be verified by measurement of positron emission

tomography. However, significant washout of these radionuclides interferes with accurate estimation [6]. A more challenging approach is to observe the immediate molecular response of radiotherapy during or just after the treatment [7]. The combination of molecular imaging and the unique idea of new scanners provides exciting potential of integration of diagnosis and radiotherapy.

3.3. Late effects after the treatment

The worldwide spread of high precision radiotherapy has led to increased opportunity to treat a variety of cancers. The therapeutic outcome has improved for locally advanced cancers that were not curable with conventional methods. Many of these patients now survive for longer periods and, thus, more attention must be paid to radiation effects from a long term perspective [8].

In the past, radiation oncologists focused mainly on curing cancers with little consideration for secondary cancer. Recently, the situation has been changing; while high precision photon radiotherapy methods are superior to conventional radiotherapy in the dose distribution delivered to the tumour, a large volume of surrounding normal tissues may be exposed to low levels of dose. Ion beam radiotherapy with protons or carbon ions further contributes to localizing the dose to the tumour, and the extra dose received in surrounding normal tissues is further reduced. However, the possible risk of high LET radiation in the surrounding normal tissues may be of more general concern even though the absolute dose level is reduced [9].

The increasing use of radiation in young patients requires evidence of age dependent biological effects of radiation [10]. Children are generally more susceptible to radiation than adults [11]. Late deterministic effects after radiotherapy, such as retardation of growth, hormonal deficiencies, organ dysfunctions, and intellectual and cognitive functions are more severe in children than in adults. It should also be noted that children have distinctly different organ susceptibility from adults [12].

3.4. Protection of personnel

Protection of occupational staff can be achieved according to the general principles of radiation protection [13, 14]. Specific consideration should be given to the management of the treatment facility and devices for each method. The use of a high energy accelerator for ion beam radiotherapy requires a control of activated devices and air in the treatment room to avoid unnecessary radiation exposure of staff members. Exposure of patients' family members is also a concern, but is sufficiently low in ion beam radiotherapy [15].

4. CONCLUSION

The advantage of new radiotherapy is a significant improvement in patient outcome, providing longer survival and better quality of life. It is now expanding rapidly within the medical community, with significant benefits to patients. In addition to the general guidance for radiation protection of patients, unique problems specific to each treatment method have to be solved for the efficient and safe use of new technology in radiotherapy. Education, sufficient knowledge and training of personnel involved in the treatment procedure are essential for patient protection. Health care professionals should also be aware of the possible risks and consider the necessary procedures for patient protection when new technologies are introduced in clinical practice.

REFERENCES

[1] TSUJII, H., KAMADA, T., A review of update clinical results of carbon ion radiotherapy, Jpn. J. Clin. Oncol. **42** 8 (2012) 670–685.

[2] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, ICRP Publication 112, Elsevier (2009).

[3] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Relative Biological Effectiveness (RBE), Quality Factor (Q), and Radiation Weighting Factor (w_R), Publication 92, Pergamon Press, Oxford (2003).

[4] WAMBERSIE, A., et al., The RBE issues in ion-beam therapy: Conclusions of a joint IAEA/ICRU working group regarding quantities and units, Radiat. Prot. Dosimetry 122 1–4 (2006) 463–470.

[5] WAMBERSIE, A., et al., Isoeffective dose: A concept for biological weighting of absorbed dose in proton and heavier-ion therapies, Radiat. Prot. Dosimetry 143 2–4 (2012) 481–486.

[6] MIZUNO, H., et al., Washout measurement of radioisotope implanted by radioactive beams in the rabbit, Phys. Med. Biol. 48 15 (2003) 2269–2281.

[7] YAMAYA, T., et al., Simulation studies of a new 'OpenPET' geometry based on a quad unit of detector rings, Phys. Med. Biol. 54 5 (2009) 1223–1233.

[8] HALL, E.J., Intensity-modulated radiation therapy, protons, and the risk of second cancers, Int. J. Radiat. Oncol. Biol. Phys. **65** 1 (2006) 1–7.

[9] NEWHAUSER, W.D., DURANTE, M., Assessing the risk of second malignancies after modern radiotherapy, Nat. Rev. Cancer **11** 6 (2011) 438–448.

[10] IMAOKA, T., et al., Influence of age on the relative biological effectiveness of carbon ion radiation for induction of rat mammary carcinoma, Int. J. Radiat. Oncol. Biol. Phys. **85** 4 (2013) 1134–1140.

[11] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2008 Report to the General Assembly with Scientific Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).
[12] PRESTON, D.A., et al., Solid cancer incidence in atomic bomb survivors: 1958–1998, Radiat. Res. **168** 1 (2007) 1–64.
[13] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of Accidental Exposures to Patients Undergoing Radiation Therapy, Publication 86, Pergamon Press, Oxford (2000).
[14] INTERNATIONAL ATOMIC ENERGY AGENCY, Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 38, IAEA, Vienna (2006).
[15] TSUJII, H., et al., Research on radiation protection in the application of new technologies for proton and heavy ion radiotherapy, Jpn. J. Med. Phys. **28** 4 (2009) 172–206.

TOOLS NEEDED AND TOOLS AVAILABLE FOR SAFETY IMPROVEMENT IN RADIATION THERAPY

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1. INTRODUCTION

In this contribution, the safety hazards that exist within the radiotherapy process will be discussed and, in this context, the actions taken or tools needed to decrease the frequency and/or probability, or even eliminate risks. The discussion will cover the process from the decision to treat until the patient has completed the radiotherapy course.

2. THE RADIOTHERAPY PROCESS AND IDENTIFIED PITFALLS

First of all, a process map covering the above framework of radiotherapy is defined (Fig. 1), which will form the basis for the following discussion.

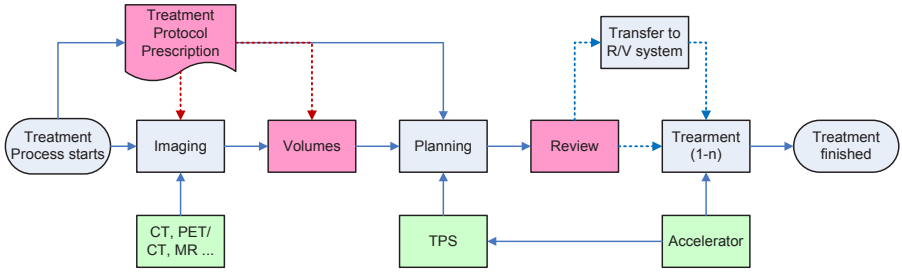

FIG. 1. A course process map describing the process of radiotherapy.

2.1. Prescription

The prescription is one of the most important steps in the process and should be one of the first substeps, and in this case it is shown in parallel with the imaging sessions. Sometimes, this is also what occurs in reality, i.e. the patient comes for a first visit to the radiotherapy department for a radiation oncology visit and a simulation/computed tomography (CT) scan session. Based on the information from previous steps in the health care process, and together with information that can be collected during the patient's visit, radiation oncologists have to decide according to the department's guidelines about which protocol the patient should be treated with. The guidelines and the protocol should include information about total dose, fractionation (dose per fraction, timing, e.g. number of fractions per day) and dose criteria for target volumes (GTV, CTV, PTV) and to critical tissues and organs (organs at risk). For today's high technology modalities, such as intensity modulated radiation therapy (IMRT) and its followers, e.g. volumetric modulated arc therapy (VMAT) (also called RapidArc in the Varian world), normal tissue should also be defined and connected to dose–volume criteria.

2.1.1. Tools

Guidelines and protocols should be evidence based when possible, and detailed to facilitate further development in the consecutive steps in the process. During the development of protocols, one must also include priorities for all these dose–volume criteria to facilitate the planning but especially the plan review process. In Table 1, an example of priorities is given for treatment of prostate cancer patients.

It is also advantageous if there is a consensus in the radiotherapy world regarding naming conventions. The Global Clinical Trials Quality Assurance of Radiation Therapy Harmonisation Group[1] has published a suggestion that would be favourable if it were adopted by professional organizations within radiation oncology, and if it were disseminated to all radiation oncologists, medical physicists, dosimetrists and radiation therapy technologists.

[1] http://rtqaharmonisation.org/Home.php

TABLE 1. PRIORITY, VOLUMES AND CONSTRAINTS FOR TREATMENT OF PROSTATE CANCER

Priority	Volume	Objective or constraint
1	CTV	$D_{min} \geq 95\%$, $D_{min} \geq 74$ Gy
2	PTV	V95% ≥ 95%, V74Gy ≥ 95%
3	Rectum	V90% ≤ 15%, V70Gy ≤ 15%
4	PTV	D99% ≥ 90%, D99% ≥ 70 Gy
5	Rectum	V75% ≤ 35%, V59Gy ≤ 35%
6	Femoral heads	$D_{max} \leq 70\%$, $D_{max} \leq 55$ Gy
7	Rectum	V65% ≤ 45%, V51Gy ≤ 45%
8	Body	$D_{max} \leq 105\%$, $D_{max} \leq 82$ Gy

2.2. Imaging

Imaging for radiation therapy used to be performed using a 'simulator' where two orthogonal X ray projections were produced. Together with other X ray examinations and anatomical atlases, a cross-section (sometimes several) was applied to construct typical target volumes and organs at risk. Today, a full spectrum of imaging devices is available, sometimes even at the radiotherapy department. The most common device today is the CT scanner, which gives information regarding geometry and density information for planning and dose calculation. To improve the volume definition, positron emission tomography (PET)/CT, magnetic resonance imaging (MRI), ultrasound, etc. are commonly used in combination with the planning CT dataset.

A classical orientation incident occurred in 2001 when a patient following a gamma knife treatment protocol was positioned in the MRI camera head first but the images were marked feet first, resulting in a stereotactic radiosurgery procedure that was delivered on the wrong side (gamma knife treatment to wrong side of brain; Event Notification Report 43746, United States Nuclear Regulatory Commission). This case is also discussed in the IAEA training set for prevention of accidental exposures in radiotherapy.

2.2.1. Tools

For this process step, imaging protocols are necessary to ensure correct reconstruction, and accuracy of the involved imaging systems regarding, for example, Hounsfield numbers (CT numbers which are converted to densities) but also geometric accuracy. The protocol should also ensure that the patient's position is correct both macroscopically, i.e. orientation (left–right, head first, etc.) as well as microscopically in the sense of immobilization.

In an environment where several imaging devices are available, the registration tools and methods must also be assured. This is a large task for a department, especially gaining an understanding of devices used in other departments. This probably leads to an increase in cooperation between imaging and therapy staff, e.g. imaging and radiation oncology physicists.

2.3. Treatment planning process

2.3.1. Volumes

The delineation of the volumes in radiotherapy that will be used for treatment planning and/or optimized intensity modulated radiotherapy is one of the most crucial steps in the whole radiotherapy process. The outcome of the individual treatment is directly correlated to this step. Several papers in the literature have shown the spread among radiation oncologist delineation of target volumes. For example, Steenbakkers et al. [1] showed that the GTV could vary by a factor of two for solid lung cancer tumours. In the same paper, it was also shown how functional imaging such as ^{18}FDG based PET/CT could improve the conformity among radiation oncologists.

2.3.2. Planning

Many hazards exist in planning; thus, thorough protocols and guidelines must exist that describe the process for most of the treatments given at the department. The quality of the treatment plan is strongly dependent on the information given at the prescription, which has to be combined with the planning directives present in the guidelines. Several incidents and accidents have been reported in the literature, e.g. the Panama accident where a workaround was introduced to facilitate the use of an increased number of shielding blocks. The first physicist did it correctly, but his colleague did it slightly differently, resulting in severe overdosing [2].

Other hazards in planning include the selection of normalization methods; for example, the International Commission on Radiation Units and

Measurements (ICRU) has defined criteria for the selection of a single point for reporting radiotherapy, however, the mean or average dose to the volume is often more related to tumour response. Other popular measures for tumour dose have been suggested, e.g. the median dose. Unfortunately, there is no direct correlation between different measures; an example between the ICRU reference point and the median dose is presented in Fig. 2.

Experience is, of course, an important parameter when creating robust and accurate treatment plans, and combining inexperienced dosimetrists with ambiguous guidelines and a lack of experienced supervisors will lead to unsafe conditions in the treatment planning process. The Glasgow accident, in which a young girl was overdosed, was partly a consequence of a situation of this sort.

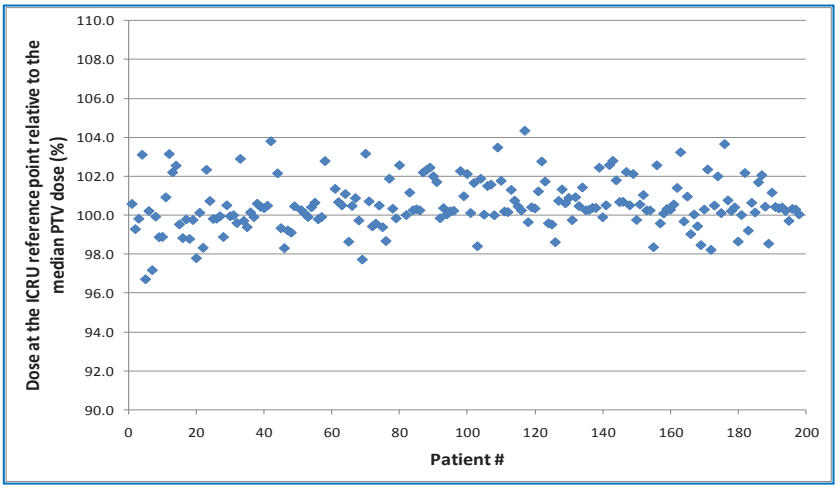

FIG. 2. Dose to the ICRU reference point relative to the median dose within the PTV (courtesy of P. Nilsson, Skåne University Hospital, Sweden).

2.3.3. Review and evaluation of plans

For the clinical user, there is a great need for tools to evaluate and compare the relative merits of all different IMRT modalities, i.e. static or dynamic multileaf collimator techniques or rotational techniques such as VMAT or RapidArc. Specific delivery systems increase the number of modalities with Tomotherapy and Cyberknife (both from Accuray), and lately the VERO system (Brainlab). Tools are needed to select the proper treatment plan for an individual patient, but also at a higher level to ensure that the resources (staff and equipment) are utilized in an efficient manner, without compromising treatment quality and

patient safety. For all purposes, it is important that the results of such comparisons are not biased due to limitations or uncertainties of the evaluation method itself or by the individuals involved.

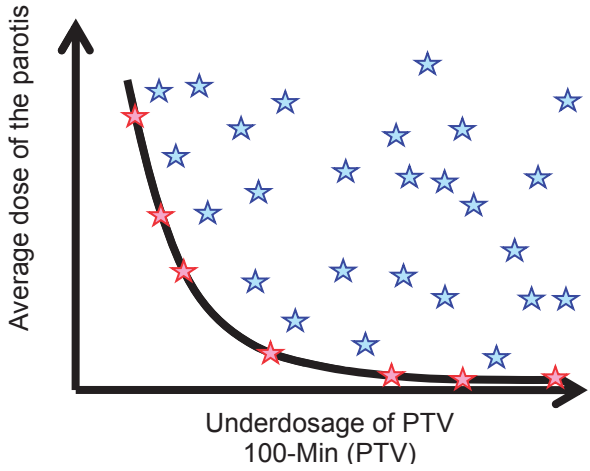

FIG. 3. Dose plans with two criteria: (i) underdosage of the PTV and (ii) dose to the parotis. The blue stars represent any plan with a certain underdosage of the PTV and a certain average dose to the parotis. The red stars represent plans for which one cannot improve any of the two criteria without diminishing the other. Those points or plans follow the Pareto front.

It is observed that a radiation treatment prescription commonly contains multiple, mutually conflicting objectives. In general, the goal of full target coverage is set against the need to spare healthy tissues and organs at risk. The relative weighting of these different treatment objectives represents a trade-off that is seldom expressed specifically in the prescription. Instead, this trade-off is usually explored by investigating multiple treatment plans, either from a pre-calculated database or, more often, in an iterative process.

The Pareto evaluation concept is based on a set of Pareto optimal solutions/treatment plans. The definition of a Pareto optimal solution, in this context, is the fact that one objective cannot be improved without worsening another objective (see Fig. 3). The plans can be Pareto optimal from a mathematical or from a clinical point of view. The mathematical Pareto front is often used in the optimization to find the best solution. The clinical method is used to compare different techniques for the same patient or to visualize the trade-off between contradicting organs and tumours. Since individual dosimetrists will approach an optimization problem in different ways (due to, for

example, experience and/or lack of planning protocols), different Pareto fronts may be produced (see Fig. 4). Further information regarding plan evaluation and the uncertainties in this sub-process are described in Refs [3, 4].

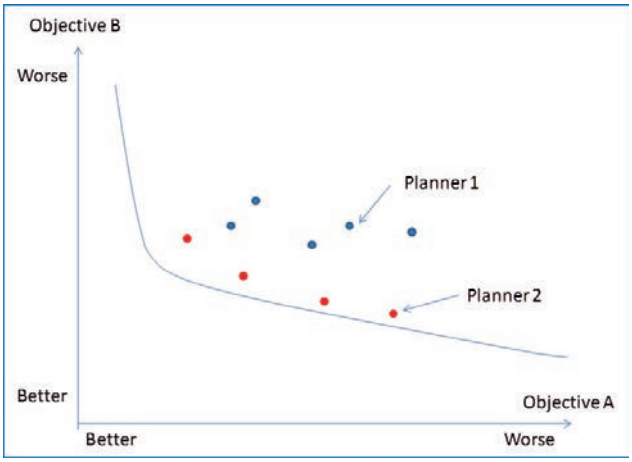

FIG. 4. Do different planners deliver the same plan quality?

2.3.4. Tools

Delineation conformity can be achieved by consensus discussion with groups of radiation oncologists locally within a department. However, it can be more advantageous if, for example, several hospitals in a region perform such tasks together. For participants in clinical trials, this is of the utmost importance. One way of improving one's skills in this could be to participate in the educational programme made available by the European Society for Radiotherapy and Oncology (ESTRO) called FALCON[2]. This programme offers live, hands-on delineation workshops at the annual ESTRO meetings, with interaction with worldwide experts as well as on-line/virtual delineation workshops. The opportunity for individual professionals to validate their daily contouring practice on-line, by comparing it with delineation by experts and the ESTRO guidelines, is of high importance for improving delineation quality. An interesting paper was recently published from Canada regarding plan quality and the relationship with the experience of the radiation oncologist [5]. One should remember that rounds offer a great opportunity for education of all participants.

[2] http://estro-education.org/Pages/Default.aspx

Other tools that have to be explored are how to produce and select the best plan for the individual patient regarding required plan quality, as well as delivery quality. Especially the latter may be of importance for the individual patient concerning positioning accuracy, intra- and inter movements, etc.

2.4. Transfer of data

In this case, only the transfer from an approved treatment plan to the control or record and verify system is discussed. Two different technologies exist today: integrated environment or not. In the first case, the information is kept within the same vendor's environment and for the user it appears as though all the information is available from the same source. The opposite solution is having data within different systems which requires that information has to be exported from one system and then imported to the next system through a process which requires certain quality controls to ensure correct data transfer. The first solution should, in principle, be the safest method from a patient's view; however, accidents have occurred where information was lost between treatment planning and delivery systems in such an environment (cf. the IMRT accident in New York where the control points in the plan were lost [6]). Other problems that have also been reported are when an old method for data transfer still exists after the introduction of new systems (see Glasgow accident [7, 8]).

2.4.1. Tools

The important tools here can be divided into hard and soft solutions. The hard or technical solutions can be watch-dogs or independent dose calculation (included in the linac/control system asking the operator whether they really want to deliver this dose to the patient), and, in many cases, an integrated environment will improve safety. This has the opportunity to offer a safer environment.

The soft solutions include awareness, training, knowledge and understanding, and not forgetting communication among all staff involved in radiation oncology. These skills can never be emphasized enough.

2.5. Linear accelerator

2.5.1. Commissioning

The commissioning part of a medical device, such as a linear accelerator with the capabilities of delivering high doses within a very short time period, is one of the most critical steps in radiation oncology. The medical physicists who are involved in these steps have the huge responsibility of performing

many measurements, taking decisions, etc. during this process that will have an impact on the future usage of the device. Errors made at this stage will give rise to systematic deviations for the lifetime of the equipment. Such errors have occurred repeatedly; a couple of examples are given:

(a) Exeter (1988): error during calibration of a replaced ^{60}Co source, measurements performed at 0.8 min, and during calculation it was assumed it was measured for 1.0 min. This led to a 25% error in dose for several years [9].
(b) Ottawa (2008): after re-localization of an orthovoltage machine, a new commissioning process was initiated. The physicist managed it as a linear accelerator but for calculation of output factors for field limiting cones other than 10 × 10 cm^2 the backscatter factor was missing, leading to dose differences of up to 10% in specific cases; most patients were undertreated [10].

It should be noted that in these accidents, as well as in others, only a single physicist performed the duties, and neither double-checking appears to have occurred nor any internal or external audit. In the Exeter case, it was the national audit in the United Kingdom that discovered the problem.

2.5.2. Quality control

One can easily imagine that quality control (QC) in the radiotherapy process may be error prone and, in the worst case, also introduce errors into the process. For example, in Copenhagen, a repaired ion chamber used for periodic QC had been re-calibrated after a repair and this new calibration factor was not implemented correctly, resulting in an erroneous output (5%) of the linac. A classical contributing factor in this case was also that the physicist performing the QC was working alone and the work was not double-checked.

Lack of a communication system led to an incident because the staff performing the treatment arrived at the linac after the morning check-out and believed that everything was correct and put the machine back into clinical mode, set up a patient and were going to treat the patient when the physicist returned and stopped them as the machine had not yet been cleared for clinical use.

Finding the balance between production and QC in radiotherapy is a big problem. Moving into an environment where more than 50% of treatments are complex, i.e. RapidArc and VMAT, where and how is the patient specific quality assurance/QC scheduled? Should it be incorporated into the daily programme or should it be a parallel track performed by the physics group out of hours? For a modern and efficient department, this should be one of the subprocesses that are considered in the whole package.

2.5.3. Tools

One of the most important tools to avoid systematic errors or deviations during these steps is to use audits or second opinions. Too many accidents have occurred due to only a single physicist having performed these very important calculations during commissioning. Establishing local networks with three to four hospitals where the physics groups can support each other's dosimetry processes can be very beneficial. It is also important that the national professional societies or the regulator support and manage clinical review and audit programmes.

What is the balance between QC and production (treating patients)? New tools have been explored within radiation oncology that have been adopted from industry, i.e. failure mode and effect analysis [11, 12], check sheets, control charts (e.g. statistical process control [13–15]).

2.6. Treatment planning system

A new treatment planning system (TPS), which included corrections for inverse square law for isocentric treatments, was introduced at a hospital in the United Kingdom. The problem was, however, that the staff at the treatment units continued to perform manual correction of the monitor units for the shorter distance, resulting in too low doses being given to about 1000 patients. The main reason for this was probably a combination of a lack of communication between different staff members, and a lack of understanding (incomplete commissioning) of the tools in the new TPS and that the new system included correction for the inverse square law when performing isocentric treatments. This resulted in an under dosage of 5–35% over a ten year period until a new TPS was purchased, and it was realized that this correction had been performed twice [16, 17].

Similarities exist between this accident and the single overdosage in Glasgow of a young girl in 2006. Both happened after the introduction of a new computer based system and not all of the consequences were evaluated prior to clinical use. In both cases, for a subgroup of patients, the old methods/procedures were used, not considering the changes that the new system had for consecutive subprocesses.

2.6.1. Tools

Introducing new TPSs or changing the pre-planning process is a very complicated process; most importantly, as has been shown, the problem is to cover all processes in the department. Usually, the major tracks are identified but some very low frequency tracks can be missed, such as in the Glasgow problem. In some cases, even the low frequency of patients of certain categories combined

with specific protocols used prior to the new system may give rise to problems. Thus, the introduction of new systems requires in-depth risk analysis and it may be that radiation oncology professionals need support from other areas.

One must also recognize the need for education and training of all personnel involved, especially medical physicists and dosimetrists, when a new TPS is introduced. Nowadays, these systems are often like big black boxes and there are also systems that include several black boxes within a single system. One cannot emphasize enough the need for training and education of the staff prior to clinical use of these systems.

Benchmarking and audits may also be beneficial to improve the safety of these systems.

3. SUMMARY AND CONCLUSION

This paper has reviewed the major steps in radiation oncology. For each step, known incidents and potential problems that can occur have been presented, together with available tools or barriers that have the potential to identify these problems, and hopefully to be able to prohibit them before they influence the treatment of the patient. The barriers that should exist in a radiotherapy process can always be discussed and it is a balance of risk and resources (human resources and/or economics). A way to evaluate the effectiveness of such barriers, as well as to identify other areas where potential incidents can evolve, is to have an incident reporting system either locally (this is mandatory in many countries) and more globally, e.g. ROSIS (Radiation Oncology Safety Information System)[3] [18] or, more recently, the SAFRON (Safety in Radiation Oncology)[4] system from the IAEA (see also Refs [19, 20] on incident reporting systems in general).

More specific conclusions following this review of the process are:

— Working with awareness and alertness: Unusual and complex treatments should always trigger an extra warning and each staff member should be aware and alert in such situations. One should also think in terms of ‘time-out’ and take a step back to a second review of the situation before continuing with treatment.
— Procedures, comprehensive protocols and procedures covering the various steps in the process should exist covering the major part of the

[3] http://www.rosis.info/index.php
[4] http://rpop.iaea.org/safron

department's activity. For most critical steps, such as commissioning and calibration of equipment, these steps should always be reviewed, either internally or, preferably, via an external audit.

— Training and understanding: Continuous professional training of staff covering the very fast developments in radiation oncology will facilitate a safer environment for patients as well as staff.

— Responsibilities: All functions and responsibilities should be unambiguous and understood by all staff.

Indications of improved outcome in clinical trials have been seen when a well managed quality system is in place and this is the primary goal for the individual patient — being cured safely.

REFERENCES

[1] STEENBAKKERS, R.J., et al. Reduction of observer variation using matched CT-PET for lung cancer delineation: a three-dimensional analysis, Int. J. Radiat. Oncol. Biol. Phys. **64** 2 (2006) 435-448.

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Investigation of an Accidental Exposure of Radiotherapy Patients in Panama, IAEA, Vienna (2001).

[3] KNÖÖS, T., "Uncertainties in the evaluation of treatment plans", Uncertainties in External Beam Radiation Therapy (PALTA, J.R., MACKIE, T.R., Eds), American Association of Physicists in Medicine, Medical Physics Monograph No. 35, 2011, Medical Physics Publishing, Madison, WI (2011).

[4] OTTOSSON, R.O., et al., The feasibility of using Pareto fronts for comparison of treatment planning systems and delivery techniques, Acta Oncol. **48** 2 (2008) 233–237.

[5] LEFRESNE, S., et al., Impact of quality assurance rounds in a Canadian radiation therapy department, Int. J. Radiat. Oncol. Biol. Phys. **85** 3 (2013) 117–121.

[6] BOGDANICH, W., The radiation boom — Radiation offers new cures, and ways to do harm, New York Times (2010), http://www.nytimes.com/2010/01/24/health/24radiation.html?ref=radiation_boom&_r=0

[7] THE SCOTTISH EXECUTIVE, Unintended Overexposure of Patient Lisa Norris during Radiotherapy Treatment at the Beatson Oncology Centre, Glasgow in January 2006, Report of an Investigation by the Inspector Appointed by the Scottish Ministers for the Ionising Radiation (Medical Exposures) Regulations 2000 (2006), http://www.scotland.gov.uk/Publications/2006/10/27084909/0

[8] WILLIAMS, M.V., Radiotherapy near misses, incidents and errors: Radiotherapy incident at Glasgow, Clin. Oncol. (R. Coll. Radiol.) **19** 1 (2007) 1–3.

[9] TOBIAS, J.S., What went wrong at Exeter? BMJ 297 6645 (1988) 372–373.

[10] DUNSCOMBE, P., LAU, H., SILVERTHORNE, S., The Ottawa Orthovoltage Incident, Report of the Panel of Experts convened by Cancer Care Ontario (2008), https://www.cancercare.on.ca/cms/one.aspx?pageId=34940
[11] HUQ, S., "New paradigms for quality management in radiation therapy based on risk analysis", Quality and Safety in Radiotherapy (PAWLICKI, T., DUNSCOMBE, P.B., MUNDT, A.J., SCALLIET, P., Eds), CRC Press, Boca Raton, London and New York (2010).
[12] THOMADSEN, B., "Risk analysis and control for brachytherapy treatments", Quality and Safety in Radiotherapy (PAWLICKI, T., DUNSCOMBE, P.B., MUNDT, A.J., SCALLIET, P., Eds), CRC Press, Boca Raton, London and New York (2010).
[13] PAWLICKI, T., et al., Moving from IMRT QA measurements toward independent computer calculations using control charts, Radiother. Oncol. **89** 3 (2009) 330–337.
[14] NORDSTRÖM, F., et al., Control chart analysis of data from a multicenter monitor unit verification study, Radiother. Oncol. **102** 3 (2012) 364–370.
[15] BREEN, S., GERARD, K., "Process control and quality improvement", Quality and Safety in Radiotherapy (PAWLICKI, T., DUNSCOMBE, P.B., MUNDT, A.J., SCALLIET, P., Eds), CRC Press, Boca Raton, London and New York (2010).
[16] WEST MIDLANDS HEALTH AUTHORITY, Baldwin Report, Report of an Investigation into the Conduct of Isocentric Radiotherapy at the North Staffordshire Royal Infirmary between 1982 and 1991, West Midlands Health Authority, Birmingham, First report, August 1992. Second report, March 1994.
[17] ASH, D., BATES, T., Report on the clinical effects of inadvertent radiation underdosage in 1045 patients, Clin. Oncol. (R. Coll. Radiol.) **6** 4 (1994) 214–226.
[18] CUNNINGHAM, J., COFFEY, M., KNÖÖS, T., HOLMBERG, O., Radiation Oncology Safety Information System (ROSIS) — profiles of participants and the first 1074 incident reports, Radiother. Oncol. **97** 3(2010) 601–607.
[19] HOLMBERG, O., "Error and near missing reporting: View from Europe", Quality and Safety in Radiotherapy (PAWLICKI, T., DUNSCOMBE, P.B., MUNDT, A.J., SCALLIET, P., Eds), CRC Press, Boca Raton, London and New York (2010).
[20] MUTIC, S., BRAME, S., "Error and near missing reporting: View from North America", Quality and Safety in Radiotherapy (PAWLICKI, T., DUNSCOMBE, P.B., MUNDT, A.J., SCALLIET, P., Eds), CRC Press, Boca Raton, London and New York (2010).

MEDICAL ISSUES ASSOCIATED WITH RADIOTHERAPY ACCIDENTS

Some examples and lessons learned

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1. INTRODUCTION

Over the past one hundred years and longer, since the discovery of ionizing radiations, radiotherapy has made great contributions to controlling human cancer. Clinical practice has improved most dramatically over the past decade as a result of better tools/computers for the identification of clinical cancer target volumes and with more precision delivery of the radiation, with the consequent sparing of normal tissues. Unfortunately, however, radiotherapy accidents, resulting in serious physical, functional and even emotional injury to cancer patients, do occur. It is, therefore, appropriate that this symposium review some of these accidents, as an attempt to better understand how to incorporate better preventive measures and to develop better medical management of the outcomes. Prevention of such accidents is, of course, always the most important way to minimize the complex medical and social issues resulting from such accidents, which always affect the patient, their families and friends, as well as the morale of the caregiver staff.

As such accidents are never planned, it is important, when they do occur, to capture and record as much information as possible. The REAC/TS has for the past 40 years maintained a radiation accident registry for this purpose. The REAC/TS registry is far from complete; data from it are used as a basis for this discussion. Our worldwide registry data consist of many types of radiation accident, including industrial, nuclear power plant and medical sources, as is shown in Fig. 1. However, it is noteworthy that the most common cause of death listed in this registry in the United States of America is due to the misuse or misadministration of medical sources, as is noted in the ‘circled’ group in Fig. 2. A brief review and discussion of several of the more severe radiotherapy accidents listed in the REAC/TS registry (involving both sealed and unsealed radiotherapy sources) are presented and discussed.

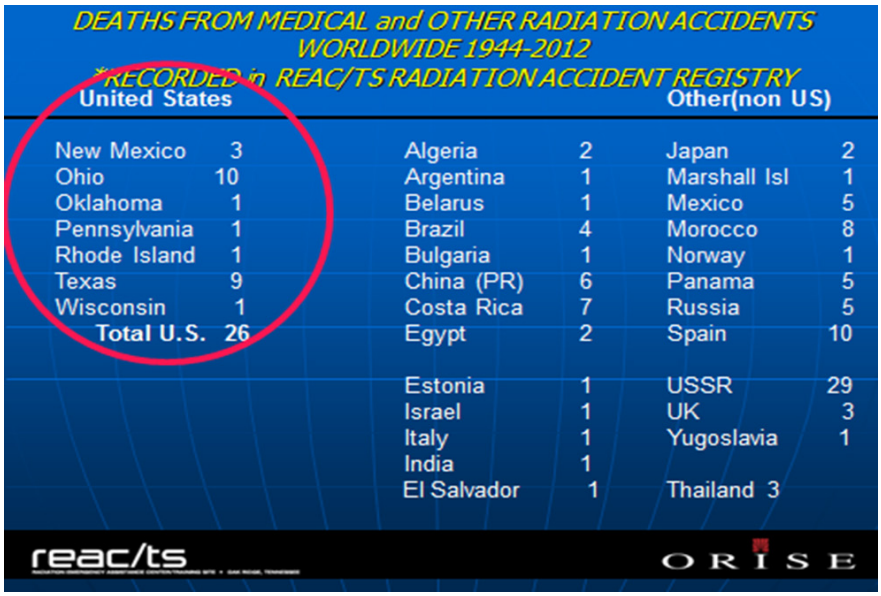

FIG. 1. Deaths from medical and other radiation accidents worldwide (1944–2012).

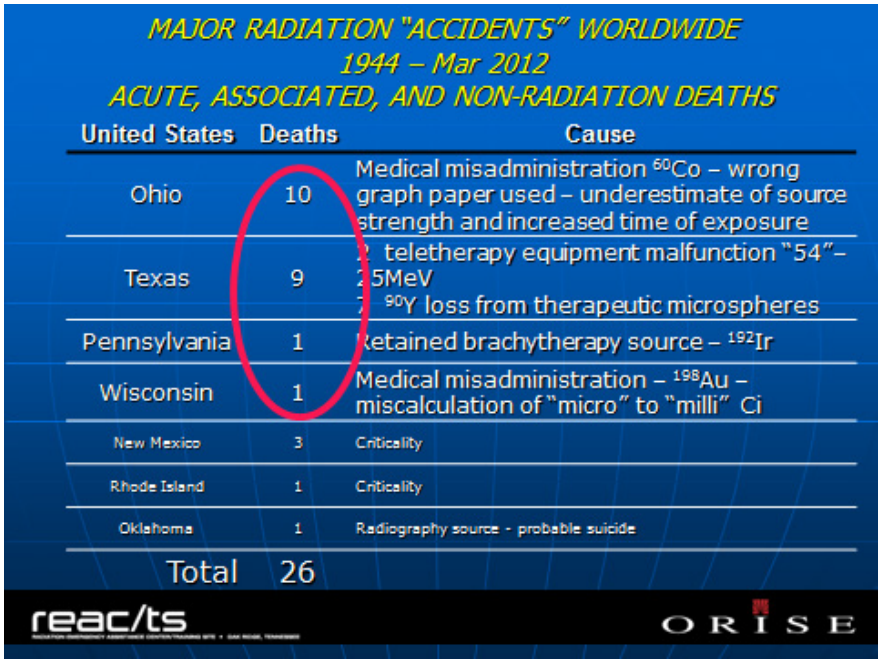

FIG. 2. Major radiation 'accidents' worldwide (1944–March 2012).

2. EXAMPLE OF AN UNSEALED SOURCE TYPE OF RADIOTHERAPY ACCIDENT: ^{90}Y RADIOPHARMACEUTICAL

In the USA in the 1970s and 1980s, oncologists were attempting to develop better ways of treating hepatic metastasis (an unfortunate frequent consequence of colon and breast carcinoma). One type of therapy under development at that time in several US cancer centres was the use of ^{90}Y, which was generally bound to 20–50 μm glass or plastic spheres. These ^{90}Y labelled spherical particles (about 45–85 mCi (1.7–3.1 GBq)) were then injected (intra-arterially) into an artery supplying the hepatic tumour, generally the common hepatic artery, or some other regional artery; and these particles were then trapped in the capillary sized tumour vessels, thereby allowing delivery of the ^{90}Y beta radiation (average energy: 934 keV) primarily to the local tumour tissue (the beta range in soft tissue is about 5 mm). Unfortunately, at one of the clinical investigative sites in the USA, perhaps the most severe radiotherapy accident ever to occur in the USA involved this type of radiotherapy procedure. Specifically, the physicochemical attachment process of the ^{90}Y to the microspheres was apparently faulty; and soon after the intra-arterial injection, the ^{90}Y became disassociated from the 20–50 μm particles and the free ^{90}Y atoms then targeted the bone marrow [1] rather than the tumour tissue.

Eight of the patients in this series died, which perhaps is not unexpected, since they all had metastatic cancer. Seven out of eight patients died shortly after the ^{90}Y misadministrations, with significant depressions of haematopoietic function, which is consistent with the estimated bone marrow radiation doses (CED) from the ^{90}Y beta irradiation (estimated to be from 3.5 to 6.2 Gy). This dose, if delivered in a relatively short time (^{90}Y half-life: 64.1 h), is in the dose range that can cause lethal, hematopoietic acute radiation sickness.

As a result of these types of therapeutic radiopharmaceutical accidents, the US Nuclear Regulatory Commission (NRC) developed new guidelines and regulations on the use of unsealed by-product materials [2]. In addition, in the 1970s and 1980s, we at the University of Wisconsin Clinical Cancer Center were developing and using new intra-arterial chemotherapy protocols for the clinical treatment of hepatic metastasis and unresectable pancreatic cancer [3, 4]. We were also planning to use concurrent ^{90}Y microsphere therapy with the chemotherapy. However, we became concerned at that time (not only about the stability of the ^{90}Y radiopharmaceuticals, as a result of the ^{90}Y accident reports) about another issue regarding the use of such intra-arterial therapies — i.e. in our intra-arterial chemotherapy studies, we had noted the presence of significant arterio-venous (A-V) shunts in hepatic metastasis, and other tumour vessels [5]. Accordingly, we then had become concerned that clinical tumours with large A-V shunting could also lead to a significant pulmonary deposition of ^{90}Y microspheres with

possible consequent early and late pulmonary radiotoxicity. We then developed a clinical nuclear medicine test to allow us to detect and quantitate A-V tumour shunting, prior to giving either intra-arterial chemotherapy or therapeutic doses of radiopharmaceuticals. This test consisted of giving an intra-arterial 'test dose' of ^{99m}Tc-macroaggregated albumin (^{99m}Tc-MAA) (approximately 30 μm in size) into the tumour specific artery and then evaluating for the presence and the amount of A-V tumour artery shunting by monitoring the ^{99m}Tc-MAA on gamma camera lung scans [5, 6].

Thus, with the implementation of new NRC regulations and the policy of developing pre-therapy screening tests (such as the ^{99m}Tc-MAA test) (prior to the delivery of therapeutic doses of radiopharmaceuticals), this form of therapy is now much safer. Even so, we at REAC/TS occasionally get calls regarding a clinically significant systemic release of ^{90}Y during therapy. So, it is also good to keep in mind that significant mitigation of the bone marrow dose from systemic ^{90}Y is possible by clinical treatment with DTPA (diethylenetriaminepentaacetic acid) [1].

3. EXAMPLE OF A SEALED SOURCE RADIOTHERAPY ACCIDENT: ^{192}Ir HIGH DOSE RATE SOURCE

A female nursing home patient was receiving ^{192}Ir high dose rate (HDR) radiotherapy treatments at an outpatient radiotherapy centre to the lower pelvic area for treatment of a recurrent carcinoma. HDR treatments were being given for a few minutes per day for several days a week. The 4.2 Ci (155 GBq) source moved from the HDR container on a cable through catheters which had been surgically implanted into the tumour volume and the source then stayed in that part of the catheter, residing in the tumour for a predetermined time during each treatment. Following the appropriate treatment time in the tumour, the ^{192}Ir source was then routinely mechanically moved back into the HDR source container until the next treatment session. These treatments were given with both the HDR unit and the patient located in a shielded linear accelerator vault. However, during one of the treatment sessions, the cable broke, leaving the source in the patient in the catheter tumour area of the lower pelvis. The patient was then transferred back to the nursing home with the source, since the clinic staff were unaware that the source had broken off the cable and was now in the patient. Over the next five days, the patient became seriously ill with many of the signs and symptoms of acute radiotoxicity. However, the nursing home staff were not trained to recognize such clinical effects and the patient died as a result of severe radiation injury, primarily to pelvic organs. The source had fallen out of the patient with bloody debris on the fourth day; and it was unknowingly discarded

into a biohazard waste can (which was stored near a piano in the nursing home recreation room).

Consequently, in this nursing home, many caretakers, nursing home residents and visitors were unknowingly exposed to this ^{192}Ir radiotherapy source (Fig. 3). The biohazard waste at the nursing home was picked up several days later by a waste disposal truck and driven to a dump site in another state. When the truck containing the source entered the waste disposal site, a radiation area alarm sounded; and the truck driver was forced to drive for several more hours back to where he had picked it up. The source was then quickly located in the waste and traced back to the nursing home. This prompted an NRC investigation and many people, besides the patient, were identified as having had some exposure to the source — these people included nurses and other staff, visitors to the nursing home, the truck driver and other patients who used the recreation room. The body was exhumed for a pathology examination and severe radiation damage was noted in the bowel, pelvic soft tissue, bladder and pelvic bone marrow. Calculated doses to various organs for the 96 h period are shown in Fig. 4.

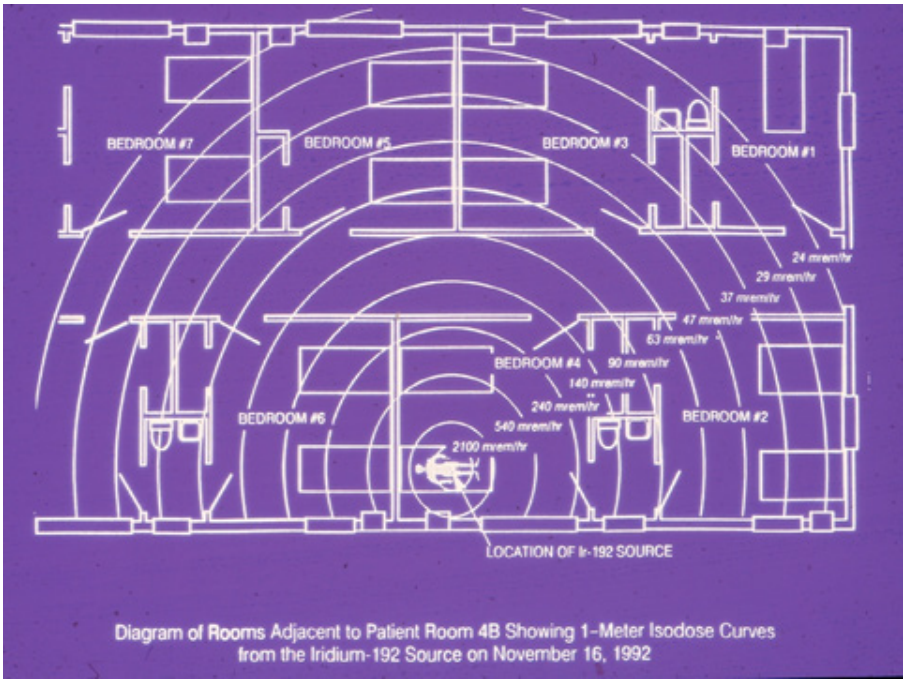

FIG. 3. Diagram of rooms adjacent to patient room 4B showing 1 m isodose curves from the ^{192}Ir source on 16 November 1992.

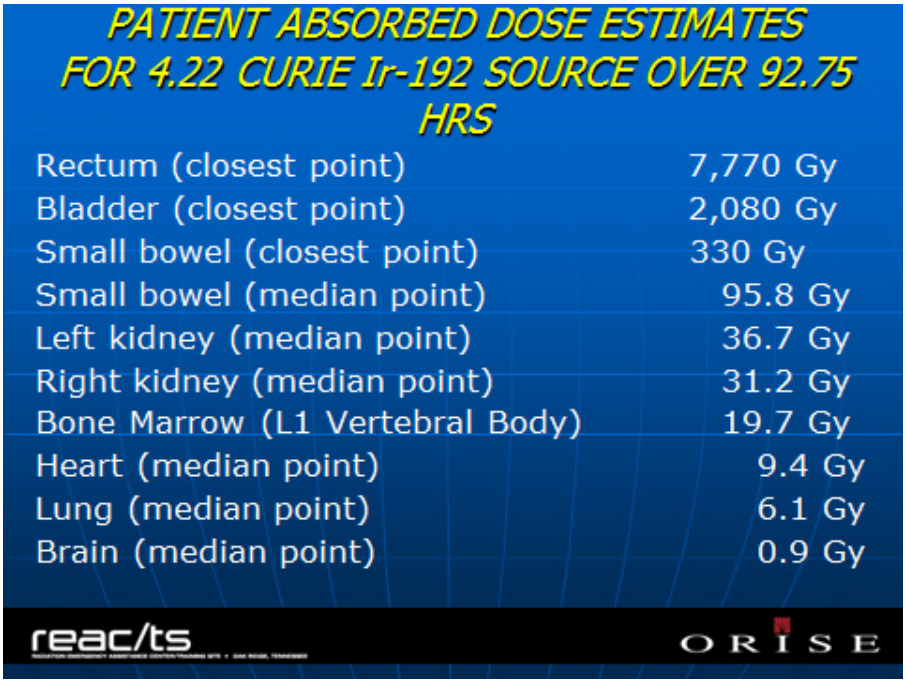

FIG. 4. Patient absorbed dose estimates for a 4.22 Ci ^{192}Ir source over 92.75 h.

This radiotherapy accident was a uniquely complicated and serious radiotherapy accident because it caused the very tragic death of the patient, as well as a significant public health issue due to the radiation exposures to numerous other people. REAC/TS conducted dicentric cytogenetic biodosimetry on 94 of the exposed people and fortunately most of these people could then be reassured with respect to stochastic risks, since for over 90% of the people, their biodosimetry doses were less than 10 cGy.

As a result of this particular accident, the NRC implemented a number of new regulations regarding HDR sources. These measures included requiring that during any HDR treatment a radiation oncologist and a medical physicist must be present; they are also required to conduct an independent radiation survey with a hand-held monitor unit before the patient leaves the treatment area. Mandatory training of all HDR staff on emergency HDR procedures (with an annual HDR staff drill) is also now required. Certain mechanical design changes in the HDR unit for facilitating emergency management of source location and retrieval were also required.

4. EXAMPLES OF ^{60}Co AND LINEAR ACCELERATOR RADIOTHERAPY ACCIDENTS

Over the past 30 years, linear accelerators have become the primary type of radiation producing equipment used in the treatment of cancer. These machines have undergone frequent changes in design and in capability, primarily due to the rapid evolution in computer technology. Some severe accidents have occurred with linear accelerators, primarily due to 'human error', leading to miscalibration of the radiation beam as well as from faulty electronics and/or errors in computer software.

Cobalt-60 units (up to 10 000 Ci) are much simpler in operation. Thus far, ^{60}Co teletherapy has been limited in the technical capability to rival the much more sophisticated, precisely tailored dose distributions that are now possible with linear accelerators. Serious radiation accidents, however, have occurred with both types of equipment.

For example, a rather simple error occurred in the calculation of the dose rate at a ^{60}Co teletherapy unit in the USA (Ohio), where the use of the wrong type of graph paper was used for correcting for the ^{60}Co decay. Unfortunately, this very 'simple human error' tragically contributed significantly to the death of ten cancer patients (Fig. 2).

Our registry also has reference to several other linear accelerator based radiotherapy accidents, as referred to in Fig. 2. Specifically, there was a series of radiotherapy overexposure accidents, causing severe morbidities in patients in several states and Canada, including two deaths. This is known as the 'malfunction 54 accident', which was the result of a software error.

A number of other linear accelerator accidents have occurred in recent years in the USA and other countries, and the IAEA has published monographs with extensive, detailed discussion of these accidents, such as the monographs on radiotherapy accidents in Costa Rica, Panama and Poland [7–9]. These accidents as well as accidents with similar morbidities and deaths have also occurred in the USA and other countries, where the primary causes were faulty procedures, faulty correction factors and measurements in the calibration processes of the radiation energy and/or dose rates.

This symposium has many papers and posters discussing improvements in the physics aspects of improving radiotherapy safety, so this topic is not further discussed here.

5. SPECIAL RADIATION INJURY ISSUES

The best medicine, in general, is always to try to establish effective preventive medicine policies; and this statement is, of course, also true for the medical practice of radiotherapy. However, as in any technical field, accidents do happen; and, when they do, the next best policy is to have plans for attempting to mitigate the medical and psychological injury with appropriate countermeasures. Since management of such radiotherapy accidents, as described in the above examples, is both medically and socially complex — i.e. there may be radiation injury to multiple organ systems, and the psychological well being of both the patients and their family and friends must be considered — plans must be continually addressed. A number of medical countermeasures may also need to be considered, such as hyperbaric oxygen treatments and a variety of drugs, such as pentoxphylamine, ACE inhibitors, antioxidants, steroids, anticoagulants and cytokines, plastic surgery and stem cell transplants.

6. SUMMARY

Three different types of radiotherapy accident are discussed with reference to specific accidents listed in the REAC/TS worldwide radiation accident registry. Some lessons learned and ideas for prevention and mitigation of the injury from such accidents are discussed. In general, human error is the most common cause and the development of preventive medical and physics protocols (IAEA dosimetry lab and the SAFRON (Safety in Radiation Oncology)[1] system) and exercises are encouraged.

REFERENCES

[1] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Management of Persons Contaminated with Radionuclides: Handbook, 2 vols, Report No. 161, NCRP, Bethesda, MD (2010).

[2] NUCLEAR REGULATORY COMMISSION, Medical Use of Byproduct Material, 10 CFR 35, US Govt Printing Office, Washington, DC (2002).

[3] WILEY, A.L., Jr., WIRTANEN, G.W., STEPHENSON, J.A., RAMIREZ, G., Combined hepatic artery 5-flurorouracil and irradiation of liver metastases: A randomized study, Cancer **64** (1989) 1783–1789.

[1] https://rpop.iaea.org/SAFRON

[4] WILEY, A.L., Jr., WIRTANEN, G.W., MENTA, M.P., RAMIREZ, G., SHAHABI, S., The treatment of probable subclinical liver metastases and gross pancreatic carcinoma with hepatic artery 5-flurorouracil infusion and radiation therapy, Acta Oncol. **27** 4 (1988) 377–381.

[5] WILEY, A.L., Jr., WIRTANEN, G.W., HOLDEN, J.E., POLCYN, R.E., "Utilization of a selective tumour artery catheterization technique for the intra-arterial delivery of chemotherapeutic agents and radiopharmaceuticals in a combined chemotherapy-radiotherapy clinical research programme", Radiobiological Research and Radiotherapy (Proc. Symp. Vienna, 1976), Vol. 1, IAEA, Vienna (1977) 389–412.

[6] WILEY, A.L., Jr., WIRTANEN, G.W., CHIEN, I.-C., "Utilization of special computerized tomography and nuclear medicine techniques for quality control and for the optimization of combined precision chemotherapy and precision radiation therapy", Diagnostic Imaging in Medicine (Reba, R.C., Goodenough, D.J., Davidson, H.F., Eds) (presented at the NATO Advanced Study Institute, Castelvecchic Pascoli, Italy, 1981), NATO-ASI Series, Martinus Nijhoff Publishers, The Hague (1982) 574–589.

[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica, IAEA, Vienna (1998).

[8] INTERNATIONAL ATOMIC ENERGY AGENCY, Investigation of an Accidental Exposure of Radiotherapy Patients in Panama, IAEA, Vienna (2001).

[9] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in Bialystok, IAEA, Vienna (2004).

RADIATION PROTECTION OF PATIENTS AND STAFF IN DIAGNOSTIC NUCLEAR MEDICINE AND HYBRID IMAGING

(Session 3)

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Rapporteur

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RADIATION PROTECTION OF PATIENTS AND STAFF IN DIAGNOSTIC NUCLEAR MEDICINE AND HYBRID IMAGING

Introduction of the topic

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Abstract

Radiation protection is an important task in nuclear medicine. It is essential to make sure that the investigation is justified and that the radiation absorbed dose to the patients as well as to staff members and other individuals involved is kept as low as reasonably achievable. Dose limits (for occupational exposures) and other constraints (e.g. for pregnant and breastfeeding women) also have to be applied. The paper is an introduction to and an overview of the topic of radiation protection in diagnostic nuclear medicine.

1. INTRODUCTION

Over the past 25 years, impressive progress has been made within all fields of medical imaging. Nuclear medicine is responsible for a small number of investigations compared, for example, to diagnostic radiology: globally, only 1% of the number of examinations in diagnostic radiology; in Sweden, 2%; in the United States of America, 5%. The contributions to the collective doses are, however, larger: 2, 4 and 26%, respectively [1–3].

Nuclear medicine is expanding. Besides bone, thyroid and renal investigations, current clinical applications include the ability to diagnose various types of tumour, neurological disorders (e.g. Alzheimer's and Parkinson's diseases) and cardiovascular diseases in their initial stages, and to make a non-invasive assessment of therapeutic response. Radioactive tracers are increasingly being used in surgical practices, such as identification of lymph node involvement in breast cancer and colon cancer. Nuclear medicine also has

a unique and important potential in medical, biomedical and pharmacological research. It has been a 'molecular' science since the beginning, with radionuclides able bind to specific biomolecules.

The number of positron emission tomography (PET) substances with higher photon energies (511 keV) than the previously dominating radionuclides (^{99m}Tc: 141 keV and ^{123}I: 159 keV) is increasing. In parallel to this, there is increasing use of so-called hybrid techniques combining PET or single photon emission computed tomography (SPECT) with computed tomography (CT) to get PET/CT and SPECT/CT (now also PET/magnetic resonance imaging). PET units require specific site planning, shielding and radiation protection activities.

The increased use of PET/CT and SPECT/CT has improved the accuracy of detection, localization and characterization of diseases, but has also increased the radiation exposure of patients. CT has, for a number of years, been identified as a high dose investigation and considerable efforts have been made to reduce CT doses [4]. So far, this has widely been conducted through automatic exposure control and now also through the use of iterative CT reconstruction technologies. A further problem is that most PET and some SPECT investigations also give a comparatively high patient dose — of the same magnitude as the CT part of the investigation. Thus, PET/CT and some of the SPECT/CT investigations are high-dose investigations.

The introduction of PET and PET/CT techniques and the increasing use of positron emitters have also increased the radiation dose to staff in nuclear medicine departments [5], as well as at cyclotrons and in hot radiochemistry laboratories used for the production of radiopharmaceuticals.

The introduction of hybrid imaging stresses the importance of properly trained personnel and adequate quality control programmes. It highlights the need for education and training of all categories of staff — from referring physicians to technicians, nuclear medicine specialists, medical physicists, engineers and others involved.

2. NEED FOR ACTION WITH REGARD TO PATIENTS — MORE WORK ON JUSTIFICATION OF INVESTIGATIONS AND OPTIMIZATION THROUGH OBSERVER PERFORMANCE STUDIES

For patients, radiation protection is ensured (i) by performing only those tests that are necessary (justification), and (ii) by optimization, using the best radiopharmaceuticals, using optimally adjusted equipment to provide the best results, and having knowledgeable and trained personnel. A comprehensive quality assurance programme, which includes radiopharmacy and equipment quality control, is important to obtain optimal diagnostic information from the

procedures. The overriding principle is that any investigation should offer the maximum benefit to the patient and limit the radiation exposure.

The concepts of justification and optimization have been part of the International Commission on Radiological Protection (ICRP) system of radiological protection for more than 40 years [6]. These principles have been widely accepted and have been introduced into the legal framework in most countries around the world. In spite of this, there have been many reports of radiological examinations that were not justified [7, 8]. It is evident that the implementation of the justification principle is not satisfactory, neither in nuclear medicine nor in diagnostic radiology, although some very helpful work has been done, for example, by the Royal College of Radiologists in the United Kingdom [9] and by the European Commission [10]. From the radiation protection point of view, it is a real challenge to use such guidelines in daily clinical work.

Once clinically justified, each diagnostic examination should be conducted so that the dose to the patient is the lowest necessary to achieve the clinical aim. The optimization process necessarily requires a balance between administered activity, patient radiation dose [11] and image quality. In nuclear medicine, there is an urgent need to define objective criteria of what should be seen in an acceptable image and for systematic observer performance studies of the same type as has been carried out in diagnostic radiology for a decade [12]. Today, the quality of nuclear medicine images is most often assessed through subjective judgements. Diagnostic reference activities should be implemented as a first step to eliminate inappropriate imaging conditions.

3. SPECIFIC PATIENT GROUPS — CHECK PREGNANCY AND BREASTFEEDING

Nuclear medicine investigations should normally not be done during pregnancy. However, radiopharmaceuticals are occasionally administered to pregnant patients either due to clinical necessity or by mistake. In the first case, the diagnostic test is of high importance for maintaining the health of the mother. In the second case, an embryo or foetus may be irradiated unintentionally because the mother is not aware of her pregnancy, does not wish to admit it, or — against international recommendations [6] — has not been asked whether she is pregnant. Female patients of fertile age should routinely be interviewed and tested for pregnancy before an investigation [13]. As routine pregnancy tests may give misleading results, additional investigations by means of ultrasound could be performed to exclude pregnancy at the time of investigation. It is also necessary to have strict procedures to verify that the patient is not breastfeeding.

The ICRP has issued detailed recommendations concerning radiation protection during pregnancy, and when breastfeeding should be stopped and resumed [14–16]. In Europe, the Medical Exposure Directive 97/43 [17] introduces special attention to the protection of the unborn and breastfed child exposed in medicine.

4. NEED FOR ACTION WITH REGARD TO STAFF — KEEPING FINGER DOSES UNDER CONTROL — EDUCATION AND TRAINING

Staff members are exposed to radiation during production, labelling, transport, injection and being close to patients. External radiation exposure to staff members is a challenge in radiation protection in all nuclear medicine and especially in PET/CT practices. It is necessary to take radiation protection aspects into account already at the design stage of the facility and to install shielding [18].

For the staff, one important source of radiation exposure is handling of radioactive material during its compounding and administration to patients, the need to position the patients for imaging, attending patients who have had radioactive compounds administered to them, and the operation of equipment used. Doses to fingers and hands can be high [19, 20]. In a study of the doses to fingers and hands, it was shown [20] that training and education in good practice are more relevant parameters for dose reduction than the worker's experience level. It is not sufficient to work fast. The use of shields and increasing the distance are more important. By using an automatic injection technique, most of the hand doses can be avoided.

For the lens of the eyes, recent evaluations [21] show threshold doses for induction of cataract, which are ten times lower than deduced from earlier studies. Thus, the yearly equivalent dose limit for the lens of the eye at occupational exposure has been reduced from 150 to 20 mSv (averaged over 5 years and not more than 50 mSv in any one year) [21].

Personnel involved in nuclear medicine must have good knowledge of radiation protection. This is vital for patient safety as well as for the staff's own safety. With good routines, yearly effective doses to staff members in a nuclear medicine department can be limited to a few millisieverts. Ward nursing staff may also be exposed from patients who need extensive nursing care and this category of staff can also reach effective doses of a few millisieverts per year. For this group, it is especially essential to be provided with information and education in radiation protection. For all groups of staff, it is essential to establish routines which guarantee that doses to pregnant women are such that the dose to an embryo/foetus is kept under 1 mSv [11].

REFERENCES

[1] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2008 Report to the General Assembly with Scientific Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).

[2] ALMÉN, A., RICHTER, S., LEITZ, W., Number of Radiological Examinations in Sweden, Rep. 2008:03, Swedish Radiation Protection Authority (2008) (in Swedish).

[3] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Ionizing Radiation Exposure of the Population of the United States, Report 160, NCRP, Bethesda, MD (2009).

[4] MATTSSON, S., SÖDERBERG, M., Radiation dose management in CT, SPECT/CT and PET/CT techniques, Radiat. Prot. Dosimetry **147** 1–2 (2011) 13–21.

[5] LEIDE-SVEGBORN, S., External radiation exposure of personnel in nuclear medicine from ^{18}F, ^{99m}Tc and ^{131}I with special reference to fingers, eyes and thyroid, Radiat. Prot. Dosimetry **149** 2 (2012) 196–206.

[6] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, Publication 103, Pergamon Press, Oxford (2007).

[7] MALONE, J.F., New ethical issues for radiation protection in diagnostic radiology, Radiat. Prot. Dosimetry **129** 1–3 (2008) 6–12.

[8] OIKARINEN, H., et al., Unjustified CT examinations in young patients, Eur. Radiol. **19** 5 (2009) 1161–1165.

[9] ROYAL COLLEGE OF RADIOLOGISTS, iRefer: Making the Best Use of Clinical Radiology, 7th edn, The Royal College of Radiologists, London (2012).

[10] EUROPEAN COMMISSION, Radiation Protection 118, Referral Guidelines for Imaging, Office for Official Publications of the European Communities, L-2985 Luxembourg, http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/118_en.pdf

[11] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Dose to Patients from Radiopharmaceuticals — Addendum 3 to ICRP Publication 53, Publication 106, Pergamon Press, Oxford (2008).

[12] CHAKRABORTY, D.P., New developments in observer performance methodology in medical imaging, Semin. Nucl. Med. **41** 6 (2011) 401–418.

[13] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Pregnancy and Medical Radiation, Publication 84, Pergamon Press, Oxford (2000).

[14] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, "Annex D: Recommendations on breast-feeding interruptions", Radiation Dose to Patients from Radiopharmaceuticals — Addendum 3 to ICRP Publication 53, Publication 106, Pergamon Press, Oxford (2008).

[15] CANTONE, M.C., "Radiation exposure of the embryo/foetus and the newborn child", Radiation Protection in Nuclear Medicine (MATTSSON, S., HOESCHEN, C., Eds) Springer, Berlin-Heidelberg (2013) 49–67.

[16] NOSSKE, D., MATTSSON, S., JOHANSSON, L., "Dosimetry in nuclear medicine diagnosis and therapy", Medical Radiological Physics (KAUL, A., Ed.), Landolt-Börnstein New Series VIII/7a Springer, Berlin-Heidelberg (2012).

[17] EUROPEAN COMMISSION, Council Directive 97/43/EURATOM of 30 June 1997: On Health Protection of Individuals against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/Euratom, Official Journal of the European Communities No. L 180/22-27, 9.7.1997.
[18] LONSDALE, M.N., "Examples of shielding calculations for a PET/CT installation", Radiation Protection in Nuclear Medicine (MATTSSON, S., HOESCHEN, C., Eds), Springer, Berlin-Heidelberg (2013) 109–128.
[19] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, "Annex E: Radiation exposure of hands in radiopharmacies: Monitoring of doses and optimisation of protection", Radiation Dose to Patients from Radiopharmaceuticals — Addendum 3 to ICRP Publication 53, Publication 106, Pergamon Press, Oxford (2008).
[20] CARNICER, A., et al., "Occupational exposure: with special reference to skin doses in hands and fingers", Radiation Protection in Nuclear Medicine (MATTSSON, S., HOESCHEN, C., Eds), Springer, Berlin-Heidelberg (2013) 93–108.
[21] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Statement on Tissue Reactions/Early and Late Effects of Radiation in Normal Tissues and Organs — Threshold Doses for Tissue Reactions in a Radiation Protection Context, Publication 118, Elsevier (2012).

RADIATION PROTECTION CHALLENGES AND TRENDS IN PET/CT

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1. BACKGROUND

Positron emission tomography (PET)/computed tomography (CT) is now an essential imaging modality in various clinical circumstances, especially in the management of oncology patients. Customization of therapy through PET/CT imaging is actually becoming an indispensable process in the strategy of oncological management, that is, initial diagnosis and staging, treatment selection, planning of external beam radiation therapy, and follow-up and detection of recurrence after therapy. Standardization of PET/CT images for therapy response assessment and application of high precision radiation therapy planning will require strict quality control of the imaging. Considering the increasing number of PET/CT procedures and such higher imaging quality, measures of radiation protection for both patients and staff members should evolve to sustain the application of this modality in medical practices.

2. METHODS

Issues related to radiation protection of patients and staff members were reviewed and analysed by considering calculation and evaluation of radiation doses.

2.1. Radiation protection of patients

Radiation exposures derived from PET radiopharmaceuticals (i.e. FDG) and X ray CT were evaluated respectively, and key issues were extracted accordingly.

2.2. Radiation protection of staff

External radiation exposure to staff members is a challenge in radiation protection in PET/CT practices. Designing the layout of a facility and appropriate installation of shields are mandatory. Furthermore, elderly patients often have problems with activities of daily living (ADL), and need extensive nursing care; such care may cause radiation exposure of staff. In such circumstances, a graded analytical approach to caring for patients according to their ADL may help staff members to balance radiation protection and good care. A graded approach for physically challenged patients (with poor ADL) during PET examination was conducted in our facility. Patients were categorized into five groups on the basis of ADL (ADL 1: normal; ADL 5: needs extensive care). The contact time between nurse and patient, and exposed radiation dose of nurses were recorded and assessed.

3. RESULTS AND DISCUSSIONS

In patients undergoing PET/CT, dose reduction for the CT part of PET/CT was a key issue. So far, this has been widely conducted through the automatic exposure control mechanism. On top of this, iterative CT reconstruction technologies should be employed and installed in PET/CT scanners to achieve dose reduction from now on. Development of PET detectors for low dose PET pharmaceutical scanning is also expected.

Good layout of a facility and appropriate installation of shields reduce the radiation dose to staff members. An analytical approach according to patients' ADL demonstrated that the radiation dose of nurses was 0.22, 0.68, 0.93 and 2.40 μSv, while contact time was 1, 4, 4 and 10 min per patient with grades 1, 2, 3 and 5; the fraction of grade 5 patients was only 4.0% among all patients. This means that it is reasonable for nurses to shorten contact time with patients with a good ADL, and to focus on caring for patients with a poor ADL to perform good PET/CT examinations, and not to give a feeling of isolation to such patients.

4. CONCLUSIONS

Analytical approaches to dose evaluation were effective to apply radiation protection in PET/CT practices. New technologies, such as iterative CT reconstruction, should be employed as well as high sensitivity PET detectors to reduce overall radiation doses in PET/CT.

BIBLIOGRAPHY

INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection in Newer Medical Imaging Techniques: PET/CT, Safety Reports Series No. 58, IAEA, Vienna (2008).

SHRIMPTON, P.C., HILLIER, M.C., LEWIS, M.A., DUNN, D., Doses from Computed Tomography (CT) Examinations in the UK — 2003 Review, NRPB-W67, National Radiological Protection Board, Chilton, Didcot (2005).

DOSE REDUCTION IN NUCLEAR CARDIOLOGY

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Abstract

The media has drawn strong attention to the field of imaging and especially to that of nuclear cardiac imaging with respect to radiation doses arising therefrom. The paper provides some background on how to reduce doses in the field while keeping quality high.

As referred to in several peer reviewed papers that were read to get the background on this subject, I found an interesting fact. As stated by Kaufmann and Knuuti: "Interestingly, half of all nuclear medicine procedures worldwide and 25% of all X-ray studies are performed in the USA (constituting 5% of the world's population), doubling and tripling that of other developed countries" [1]. This article also states: "Although in a recent US survey CT and nuclear imaging accounted for just 21% of the total number of procedures, they resulted in >75% of the total cumulative effective radiation dose" [1].

The peer reviewed articles all support the recommendation from the American Society of Nuclear Cardiology (ASNC) that in patients who are symptomatic with suspected coronary artery disease, a radionuclide stress test can only significantly lower radiation doses to the patient when using a ^{99m}Tc based isotope instead of a ^{201}Tl based isotope. This can be done by performing the stress portion first. If the camera has an attenuation correction feature with either a transmission scan or computed tomography (CT) based attenuation, the artefacts that sometimes arise from cardiac perfusion imaging can be decreased. To incorporate this recommendation into practice, several quality control steps have to be added to the programme. The first step would be to have a physician review the images when the stress portion is complete along with the gated images. If the scan is normal, the resting part of the study can then be cancelled. A large single-centred study with 16 854 patients and an experienced reader demonstrated this very point [2]. If the situation arises with the question of a diaphragmatic attenuation in the inferior wall, prone imaging can be performed

to help determine whether this is truly an artefact or indeed disease. By incorporating prone imaging into practice, serial imaging can be eliminated, which is another recommendation from the ASNC.

If the camera has a software feature that allows the transmission scan to be moved around in the cardiac programme, effective radiation dose to the patient can be further reduced by only performing one transmission scan, and processing both the stress and rest portions with this same transmission scan. The mA on the CT scan should be reduced to as low as possible, which will further reduce the effective radiation dose to the patient. The Image Wisely web site documents effective dose as low as 0.04 mSv for the transmission scan with CT and 0.73 mSv for the CT scout [3].

According to DePuey's article on patient centred imaging, "effective radiation dose using a rest-stress protocol with 10.0 and 30.0 mCi is estimated at 11.4 mSv for Tc-99m sestamibi and 9.3 mSv for Tc-99m tetrofosmin" [4]. Again, wherever possible, protocols should be incorporated that allow you to do stress tests only to give the patient the lowest dose achievable. To provide the highest quality study, a two day protocol will need to be incorporated for patients who are over 90 kg. Patients who are above this weight tend to have a scan with an attenuation artefact and this can lead to non-diagnostic studies with low dose imaging. Prone is again an option to use whenever there may be questions about artefacts in the inferior wall. Peer reviewed literature supports the fact that this patient population has a tendency to have diaphragmatic attenuation artefacts. The most important point to take from DePuey's article is that the effective dose using a stress-only protocol with 25 mCi is estimated at 6.8 mSv for ^{99}Tc-sestamibi and 5.8 mSv for ^{99m}Tc-tetrofosmin [4].

If a new camera based solid state detector is available, which generally has higher sensitivity and employs the newer reconstruction algorithms, it may be possible to adjust the dose as low as 50% as compared to gamma cameras that use sodium iodide crystals. These cameras were first introduced in an upright position, which eliminated some of the attenuation artefacts that showed up during supine imaging. Owing to the short imaging time, a half dose full time imaging or a full dose half time imaging can be employed, depending on the age and condition of the patient. This alone can greatly reduce the dose to the patient population, especially in younger patients where the radiation is more pertinent to their lifetime accumulation to cancer risk. Caesium iodide or cadmium zinc telluride have proven to be very expensive but improve sensitivity and energy resolution. This may be an option to consider in a future camera purchase [4].

Whenever possible, positron emission tomography (PET) should be used in place of traditional single photon emission computed tomography (SPECT) imaging, as it has the lowest radiation dose to the patient. Using PET is advantageous in both younger patients, where radiation exposure is a concern,

and also in obese patients, where artefacts may be a concern, although the amount of dose given to the patient depends on the crystal type and the mode of acquisition. Generally, cameras that use 3-D mode need less of a radioisotope than cameras that have to operate in 2-D mode. Operating in 3-D mode makes it possible to decrease the dose to the patient to as much as 1.88 mSv using 20 mCi doses of rubidium. If there is a cyclotron in the hospital, and ammonia can be used, an even lower dose could be given as in 3-D mode only about 10 mCi is needed, which puts the effective dose at roughly 1.99 mSv according to Dorbala's article from the November Dose Wisely section for Nuclear Perfusion Cardiac PET Imaging [5]. PET cameras that use BGO (bismuth germanate) crystals use higher doses than cameras that use the new LSO (lutetium oxyorthosilicate) crystals. Owing to the short half-life of the radioisotopes used, the lowest dose to the patient can be achieved using PET. The largest dose can generally come from the transmission scan when it is done with CT and if mA is not being sufficiently lowered. There are studies that report that, with list-mode and the right use of processing software, one dynamic study can be acquired and the software can be used to create the gated and perfusion images. With this type of hardware and software, the effective radiation dose to the patient can again be reduced just by eliminating extra acquisition scans. Older cameras that do not have this type of hardware and software would require that four doses be injected to achieve both the dynamic study for coronary flow and another for the gated imaging. Relatively low radiation exposures between 1.75 and 7.5 mSv are reported, depending on the type of camera crystal, list-mode capability and type of attenuation [4–6].

The lowest exposure is with the ^{13}N ammonia with approximately 1.5 mSv effective dose for 10 mCi rest and stress dose [4]. The most difficult part of using ammonia is still the difficulty of having a cyclotron near the facility, which is why the ^{82}Rb PET can be a better option. Rubidium can be produced in a generator every four, five or six weeks depending on the number of patients.

Whenever possible, if PET is available, FDG should be used to assess patients for myocardial viability. The normal injected dose for this study is 3.0–4.0 mCi ^{201}Tl. With this type of dose, the effective dose is 15.3 mSv. Even with the 110 min half-life, the radiation exposure for FDG is much lower than with ^{201}Tl, as low as 6.6 mSv effective dose for 10 mCi of FDG.

Technically, the technologist can also influence the exposure to a patient by adjusting several of the components of the cardiac study. First of all, if the energy window is widened, there can be an impact on the counts acquired in a study. This option also lowers the injected dose to the patient. As a technologist, it is necessary to note the downside of widening the window, as it will also increase the scatter, which reduces image contrast. If the camera has iterative scatter correction, there will be less of a problem with this reduction in image contrast.

Continuous acquisition can additionally reduce the dose by about 5%. Generally, step-and-shoot reconstruction algorithms are set up to input data that are collected at distinct angles. With continuous acquisitions, many more counts can be received, which allows the reduction in dose.

Both of these last two recommendations, in theory, will reduce the effective radiation dose a patient receives. There may still need to be further research on the parameters to implement this in practice.

REFERENCES

[1] KAUFMAN, P.A., KNUUTI, J., Ionizing radiation risks of cardiac imaging: estimates of the immeasurable, Eur. Heart J. **32** 3 (2011) 269–271.

[2] FAZEL, R., et al., Exposure to low-dose ionization radiation from medical imaging procedures, N. Engl. J. Med. **361** 9 (2009) 849–857.

[3] CHANG, S.M., et al., Normal stress-only versus standard stress/rest myocardial perfusion imaging: Similar patient mortality with reduced radiation exposure, J. Am. Coll. Cardiol. **55** 3 (2010) 221–230.

[4] DePUEY, E.G., et al., Patient-centered imaging, ASNC Preferred Practice Statement, J. Nucl. Cardiol. **19** 2 (2012) 185–215.

[5] DORBALA, S., Standard Myocardial Perfusion and Cardiac FDG PET Protocols and Associated Patient Radiation Doses, http://www.imagewisely.org/Imaging-Modalities/Nuclear-Medicine/Articles/Standard-Myocardial

[6] CERQUEIRA, M.D., et al., Recommendations for reducing radiation exposure in myocardial perfusion imaging, J. Nucl. Cardiol. **17** 4 (2010) 709–718.

ASSESSING AND REDUCING EXPOSURES TO NUCLEAR MEDICINE STAFF

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Abstract

Nuclear medicine involves the handling of unsealed radiation sources. Occupational monitoring in nuclear medicine, thus, includes assessment of both external irradiation of the body and internal exposure due to inhalation or ingestion of radioactive substances. When appropriate radiation protection measures are applied, the annual effective dose to nuclear medicine staff is low (around 2–3 mSv). However, hand doses can be very high and can even exceed the regulatory limit for skin equivalent dose, without workers being aware of it. The paper presents the main results of the European Atomic Energy Community's Seventh Framework Programme project, Optimization of Radiation Protection of Medical Staff (ORAMED), within the field of extremity dosimetry of nuclear medicine staff, and proposes recommendations to improve radiation protection in occupational exposure in nuclear medicine.

1. INTRODUCTION

Radiation protection of workers is an important issue in nuclear medicine since, first, high radionuclide activities are needed, from a few tens to several thousand megabecquerels. Secondly, the procedures require the handling of radiopharmaceuticals in contact with, or very close to the extremities (hands, fingers). Thirdly, pure beta emitters and mixed photon/beta emitters are often used. Nuclear medicine workers are, thus, potentially exposed to external radiation and to internal contamination in case of accidental intake. If adequate protocols are used, in general, contamination leads to negligible exposure of staff. External whole body exposures of nuclear medicine staff mostly come from patients, in particular in positron emission tomography (PET) procedures, but the annual effective dose is usually low (2–3 mSv for gamma procedures, around 6 mSv for PET). However, the exposure of the extremities during preparation and administration of radiopharmaceuticals can be high. The hands often remain unprotected and, thus, fingertips can receive high doses which are likely to exceed the dose limit for extremities whenever the level of radiation protection is insufficient or the workload is too high. One of the main difficulties is that the dose limit of 500 mSv per year is valid for the 1 cm^2 of skin that is most exposed. This location of maximum dose is not known in advance and can vary for each exposure. Not much data are available yet on eye lens doses in nuclear medicine, but it can be expected that they are of the same order of magnitude as the whole body doses [1].

Monitoring of internal exposure for nuclear medicine workers requires frequent measurements due to the short physical half-lives of most radionuclides used in this field. Baechler et al. [2] describe a protocol used in Switzerland to perform screening measurements of nuclear medicine workers at the workplace to detect whether potential intake has occurred. The intakes from ingestion and inhalation are usually negligible, provided that adequate protection measures are applied. However, when volatile radionuclides such as iodine are used, it is recommended that workplace conditions be monitored, in particular to control contamination levels in the air.

2. THE ORAMED PROJECT

From January 2008 to February 2011, the collaborative project, Optimization of Radiation Protection of Medical Staff (ORAMED)[1], was set

[1] www.oramed-fp7.eu

up and funded within the European Atomic Energy Community's Seventh Framework Programme. One of the working groups in ORAMED, work package 4, aimed at the study of extremity dosimetry within nuclear medicine.

In order to determine the dose distribution across the hands and to supply information on reference dose levels for the most frequent nuclear medicine procedures, an extensive measurement campaign was performed within the ORAMED project. It included 139 workers from 35 nuclear medicine departments in 7 European countries (Belgium, France, Germany, Italy, Slovakia, Spain and Switzerland) [3]. The experimental data were complemented with Monte Carlo simulations to better determine the main parameters that influence extremity exposure, the effectiveness of different radiation protection measures and the degree of variability that could be 'intrinsically related' to each monitored procedure. Details of the Monte Carlo protocol and results are described by Ferrari et al. [4].

For the measurement campaign, a common protocol was established to be able to compare and evaluate the data from the different hospitals. The operational personal dose equivalent $H_p(0.07)$ was measured at 11 positions on each hand. The most frequently employed radionuclides were considered, i.e. ^{99m}Tc and ^{18}F for diagnostic applications, and ^{90}Y for therapy. Measurements were performed separately for each radionuclide and independently for preparation and administration. For each worker, a set of 4–5 measurements were taken, except for therapy, where this was not always achievable.

3. RESULTS

The tips of the fingers of both hands, especially the index and thumb, were identified to be the highest exposed positions. The least exposed positions were found to be the wrists, followed by the bases of the fingers. A clear trend was observed for the non-dominant hand to be more exposed than the dominant hand, in particular for radionuclide preparation. However, this trend was strongly linked to individual working habits. For therapy, spatial dose inhomogeneity is usually much more pronounced, but generally also the same positions as for diagnostics were the most exposed. In most cases, the index tip of the non-dominant hand is the most exposed specific position.

TABLE 1. MEAN, MEDIAN, MAXIMUM AND MINIMUM VALUES OF $<H_p(0.07)_{max}/A>$ OF ALL MONITORED WORKERS PER PROCEDURE *(A: administration, P: preparation)* [5]

	Maximum doses from all workers (mSv/GBq)			
	Mean	Median	Minimum	Maximum
P — ^{99m}Tc	0.4	0.25	0.03	2.1
A — ^{99m}Tc	0.2	0.12	0.01	0.9
P — ^{18}F	1.2	0.83	0.1	4.4
A — ^{18}F	0.9	0.64	0.1	4.1
P — ^{90}Y Zevalin	11	9.5	1.2	44
A — ^{90}Y Zevalin	5	2.9	1.0	12

Table 1 presents the range, median and mean of $<H_p(0.07)_{max}/A>$ over all monitored workers, classified per procedure. It is shown that preparation of radiopharmaceuticals involves higher finger doses per unit activity than administration because the procedures take longer and there are more steps requiring manipulations of the vials and/or syringes with higher activities, some of them without a shield. Therapy procedures involve generally higher mean normalized skin dose to the hands than diagnostics. Within diagnostics, ^{18}F involves higher skin doses per unit activity than ^{99m}Tc because of the different dose rates at contact.

Although experimental doses presented high variability, the ORAMED database was sufficient to analyse the main parameters of influence in the measured doses. The Monte Carlo simulation sensitivity study revealed that short source displacements (of up to a few centimetres), orientation and volume changes (of up to 3 mL) can increase the maximum dose by a factor of three to five depending on the source. Shielding was found to be the most important parameter affecting skin dose levels, both for diagnostics and especially for therapy. Even though the use of shields slows down the whole procedure, increases the difficulty of visualizing the required volume and offers less comfort, especially for heavy and thick shields, it provides a protection which mostly cannot be replaced by increasing working speed.

All practices avoiding direct contact whenever possible, enlarging the distance to the sources and speeding up procedures can be considered good practices. Most bad working habits involved direct source contact. Often, staff are not aware that near the bottom of a shielded syringe the dose rate is very high. Using tweezers is a very effective means of dose reduction when vials or syringes have to be held without a shield and also during connecting and separating the syringe to or from needles or butterflies.

Dose distribution data were used to identify the best monitoring position. The ratios between the highest dose and the dose at the most common monitoring positions were calculated and are summarized in Table 2. It is shown that even with the exclusion of outliers, the distribution of ratios is very wide. For the recommended monitoring position (base of the index finger), a factor of six must be applied to estimate the maximum dose. Finally, it should be noted that there is broad agreement that, in nuclear medicine, the ring dosimeter should be preferred to the wrist dosimeter, which underestimates the maximum dose by a factor of 20.

TABLE 2. RANGE, MEDIAN AND MEAN VALUES OF THE RATIOS BETWEEN THE MAXIMUM DOSE AND THE DOSE AT THE BASE OF THE INDEX, BASE OF THE RING AND TIP OF THE INDEX FINGERS CALCULATED FOR THE NON-DOMINANT HAND [5]

		Maximum dose/Dose at other positions			
		Wrist	Base index	Base ring	Index tip
Diagnostics	Range	3–93	2–38	2–60	1–12
	Median	16	4	7	2
	Mean	20	6	10	2
^{90}Y Zevalin	Range	3–94	2–47	1–87	1–17
	Median	14	7	9	2
	Mean	21	10	15	3

4. RECOMMENDATIONS

From the analysis of ORAMED results [6] and other published work on extremity dosimetry in nuclear medicine, nine recommendations are proposed to improve radiation protection of nuclear medicine staff:

(1) Extremity monitoring is essential in nuclear medicine. The choice of thermoluminescent dosimeter (TLD) and TLD position are important for an accurate dose assessment. Thin layer TLDs (below 10 mg/cm^2) are most appropriate when beta emitters are used.
(2) To determine the position for routine monitoring, the most exposed position on the hand for each worker should be found by individual measurements for a short trial period. If, for practical reasons, these measurements are not possible, the base of the index finger of the non-dominant hand with the sensitive part of the dosimeter placed towards the inside of the hand is the recommended position for routine extremity monitoring in nuclear medicine.
(3) To estimate the maximum dose, the reading of the dosimeter worn at the base of the index finger of the non-dominant hand should be corrected by a factor of six.
(4) Shielding of vials and syringes is essential. This is a precondition, but not a guarantee for low exposure, since not all parts (e.g. bottom of the syringe) are shielded during use.
(5) The minimum acceptable thickness of shielding for a syringe is 2 mm of tungsten for ^{99m}Tc and 5 mm of tungsten for ^{18}F. For ^{90}Y, 10 mm of PMMA completely shields beta radiation, but shielding of 5 mm of tungsten provides better protection, as it cuts down bremsstrahlung radiation.
(6) The minimum acceptable shielding required for a vial is 3 mm of lead for ^{99m}Tc and 3 cm of lead for ^{18}F. For ^{90}Y, acceptable shielding is obtained with 10 mm of PMMA with an external layer of a few millimetres of lead.
(7) Any device or tool increasing the distance (e.g. forceps, automatic injector) between the hands/fingers and the source is very effective for dose reduction.
(8) Training and education in good practices (e.g. procedure planning, repeating procedures using non-radioactive sources, estimation of doses to be received) are more relevant parameters than the worker's experience level.
(9) Working fast is not sufficient; the use of shields or increasing the distance are more effective than working quickly.

REFERENCES

[1] KOPEC, R., et al., On the relationship between whole body, extremity and eye lens doses for medical staff in the preparation and application of radiopharmaceuticals in nuclear medicine, Radiat. Meas. **46** 11 (2011) 1295–1298.

[2] BAECHLER, S., STRITT, N., BOCHUD, F.O., Individual monitoring of internal exposure for nuclear medicine workers in Switzerland, Radiat. Prot. Dosimetry **144** 1–4 (2011) 464–467.

[3] SANS-MERCE, M., et al., Recommendations to reduce hand exposure for standard nuclear medicine procedures. Radiat. Meas. **46** 11 (2011) 1330–1333.

[4] FERRARI, P., et al., Main results of the Monte Carlo studies carried out for nuclear medicine practices within the ORAMED project, Radiat. Meas. **46** 11 (2011) 1287–1290.

[5] CARNICER, A., et al., "Occupational exposure: with special reference to skin doses in hands and fingers", Radiation Protection in Nuclear Medicine (MATTSSON, S., HOESCHEN, C., Eds), Springer-Verlag, Berlin-Heidelberg (2013).

[6] EUROPEAN RADIATION DOSIMETRY GROUP, ORAMED: Optimization of Radiation Protection of Medical Staff, EURADOS Report 2012-02, EURADOS, Braunschweig (2012).

RADIATION PROTECTION OF PATIENTS, STAFF AND THE PUBLIC DURING THERAPEUTIC USE OF SEALED AND UNSEALED RADIOACTIVE SOURCES

(Session 4)

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RADIATION PROTECTION OF PATIENTS, STAFF AND THE PUBLIC DURING THERAPEUTIC USE OF SEALED AND UNSEALED RADIOACTIVE SOURCES

Introductory remarks

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1. CHALLENGES

For decades, radioactive substances have been used for beneficial medical treatments. Nowadays, radiotherapy is a dynamic medical area. In recent years, there has been rapid technological development of hardware and software, new procedures, new treatment protocols and novel application of radionuclides. This requires a qualified control of medical radiation exposure. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) estimated that in 2007 the global use of radiotherapy increased to 5.1 million treatment courses per year [1], with a rising tendency. The major challenges of radiation protection for new techniques and new procedures in radiotherapy are their complexity and the high radioactivity of the applied sealed or unsealed sources.

Radioactive sources — unsealed or sealed — are characterized by their type of radiation, the particle energy, the chemical composition, and their format and size. In addition, such sources cannot be switched off easily as can be done with X ray machines and accelerators. Thus, there is a high potential for the occurrence of accidents with serious consequences with such applications. In recent years, there have been reports of accidents in which there were unnecessary exposures to a large number of patients.

Improving patient dosimetry and avoiding unnecessary exposures, particularly in unusual and novel applications, are important goals in medical radiation protection, in particular as international recommendations and basic safety standards in radiation protection do not suggest and implement any exposure limits for medical exposure. Appropriate control of the correct functioning of devices (hardware and software) as well as of the dose delivered to the patient is necessary.

Beyond that, radionuclide therapy demands radiation protection measures for medical staff, comforters, caregivers and members of the public. Staff members can be exposed during preparation and application of high activity unsealed sources, e.g. in radiosynoviorthesis (treatment of inflammation

in joints). Partial high skin doses exceeding the limits for occupational exposure are measured in connection with these procedures. To reduce the doses, it is essential to increase staff awareness as part of an appropriate radiation protection culture. Improved occupational radiation protection of medical staff has to be a fundamental element in the establishment of new techniques and new procedures, connected with appropriate training in both the technical skills and radiation protection.

Radionuclide therapy also holds challenges for protection of the public. The most common application is the administration of ^{131}I. Issues, such as patient release, that are connected with exposure of family members, caregivers, hotel workers and those travelling with public transport, have to be taken into account, considering the legal limits for public exposure. In addition, the impact on the environment/cost to the population has to be assessed in this context.

2. BRACHYTHERAPY

Brachytherapy is a very old method that can be traced back to 1901 when Pierre Curie proposed to H.-A. Danlos to insert a source into a tumour to shrink it [2].

Better known is the interstitial radium therapy that was used from around 1930. Gold seeds filled with radium were implanted. Owing to the high activity of these sources, there was an increased risk for operators and patients to be exposed unnecessarily. Since the late 1960s, the risk of unnecessary radiation exposure could be evidently reduced by using newly developed remote afterloading systems and also other radioactive sources. Nowadays, brachytherapy is considered a safe and effective treatment for many types of cancer supplemented by 3-D imaging modalities and computerized treatment planning systems. Nevertheless, the management of highly radioactive sources and the associated equipment still requires attention. The team play between operator and manufacturer is essential, considering the accidents that have happened with brachytherapy equipment recently. For instance, 28 incidents occurred in Germany in the past ten years, with causes such as construction errors, insufficient training, malfunctions (sources stuck outside of the shielding) and systematic error in calculation of the dose (overdose). It is obvious that manufacturers also have a non-negligible responsibility for radiation safety in the medical application. The importance of reducing medical staff doses and the likelihood for incidents with unnecessary exposure was recognized by the International Commission on Radiological Protection (ICRP). The ICRP established a task group to evaluate the radiation safety of medical staff involved with brachytherapy applications [3].

Despite the availability of newer technologies, there is still the question of whether the old radium brachytherapy should be phased out globally or whether its use is still justified in low and medium income countries.

2.1. Intraoperative radiotherapy

Intraoperative radiotherapy (IORT) is a technique that is more than 20 years old which is used instead of (or in combination with) conventional teletherapy or brachytherapy with radioactive sources. This treatment method is an excellent example of an expanding technology and the development of new types of machine. For instance, compact mobile X ray sources are used inside the 'open' body of a patient: that means that the source of radiation is located close to the tumour. It is a challenge for radiation protection because it is difficult to verify exactly the dose given to the patient. Do health care workers have to trust the manufacturer of the equipment? The ICRP investigated and reported on an incident in which such a radiotherapy device was delivered from the manufacturer to the hospital without any information on measurements of absorbed dose or measurement geometry and only with pre-installed calibration files (important for the calculation of treatment time). The local medical physicist discovered, with phantom measurements, a discrepancy between the calibration files of the two applicators which could cause a treatment dose 20% different from that intended. This fact was denied by the engineer of the company. The ICRP draws the following lessons learned from this incident [4]:

— The hospital has the ultimate responsibility (before applying ionizing radiation to the patient) to investigate observed discrepancies thoroughly.
— There is always a responsibility of the manufacturer and supplier to deliver correct operating equipment with sufficient documentation (and in appropriate language). To ensure error-free function, effective internal quality control procedures are necessary.
— The manufacturer and supplier shall be committed to providing correct and sufficient information in the case of comments and questions from the hospital.
— The supplier must ensure that their service personnel have the appropriate training to perform tests and to advise hospital staff.

3. RADIATION SAFETY ISSUES

Patient dosimetry is essential for the determination of doses to treatment areas or organs at risk to avoid unnecessary exposure. Patient safety can only

be ensured by qualified treatment planning and dose calculations. How can it be controlled? What are effective measures? Highly sophisticated software, which is increasingly inseparably connected with newer technologies and techniques, has to undergo a stringent validation procedure.

Radionuclide therapies with unsealed sources hold the risk for incorporation by medical staff during the preparation and application of the radiopharmaceuticals, as well as for external exposure by contamination. Furthermore, external and internal contaminations of members of the public after the release of therapy patients or the discharge of radionuclides into the environment have to be taken into account in safety assessments. Cremation, in particular after the sudden death of patients with implants, is becoming of greater importance regarding safety considerations.

Brachytherapy using sealed sources or seeds has the potential for high external exposure in cases of incidents and accidents caused by technical errors, malfunctions or improper/inappropriate actions of staff as mentioned in the previous paragraphs.

4. RADIATION SAFETY MEASURES

The general target of radiation protection of patients, staff and the public during therapeutic use of sealed and unsealed sources is to minimize the risk of accidents and to ensure high and consistent standards of practice worldwide.

A broad range of necessary measures to improve safety in medical applications of ionizing radiation could be listed. Many of them are addressed by the three As campaign of the IAEA — awareness, appropriateness and audit — such as the communication issue. It is important to increase and qualify the communication between the referring medical practitioner and the radiological medical practitioner, but also the communication with the patient.

The revised Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (BSS) [5], as well as UNSCEAR, indicate that quality assurance for medical exposure is an essential criterion for improving radiation safety in the medical application of ionizing radiation. The BSS require that registrants and licensees establish a comprehensive programme of quality assurance which includes, inter alia:

— Evaluation of patients during and after treatment;
— Education and training of radiological medical practitioners, technologists, medical physicists, radiochemists, radiopharmacists and also non-radiology professionals;

— Commissioning, calibration and maintenance of equipment;
— Independent audits for dosimetry and treatment planning;
— Maintaining records of relevant procedures and results;
— Protocols for treatment procedures;
— Supervision of delivery.

The application of sealed or unsealed sources for the treatment of patients requires the optimized and safe management of radioactive waste, including the discharge of activity into the environment to provide for the radiation protection of medical staff and, in particular, of the public. The BSS require that: "Registrants and licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy" [5]. Within the radiation protection community, an interesting question is being discussed: Are holding tanks for radioactive waste after radionuclide therapy with iodine necessary from the radiation protection perspective or would it be more effective to dilute the waste in a continuous modern sewage system? The IAEA recommends in its statement "that in most situations it is better to dilute and disperse the waste activity in a continuous sewage system, rather than to concentrate and store activity for decay" [6]. This procedure was also favoured by the majority of the Group of Experts according to Article 31 of EURATOM during the revision of the European Basic Safety Standards for Radiation Protection.

REFERENCES

[1] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2008 Report to the General Assembly with Scientific Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).
[2] GUPTA, V.K., Brachytherapy — past, present and future, J. Med. Phys. **20** 2 (1995) 31–38.
[3] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Task Group 89: Occupational Radiological Protection in Brachytherapy, http://www.icrp.org/icrp_group.asp?id=69
[4] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, Publication 112, Elsevier (2009).
[5] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation

Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Position Statement on Release of Patients after Radionuclide Therapy, rpop.iaea.org/RPOP/RPoP/Content/Documents/Whitepapers/position-statement.pdf

RADIATION PROTECTION IN BRACHYTHERAPY IN THE NEXT DECADE

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Abstract

Brachytherapy procedures are increasing in number, and account for an important share of radiation exposure in medicine at a time when there is a dramatic rise in cancer across the developing world. Important areas in relation to radiation safety in brachytherapy include that all efforts be made to ensure that protection in the treatment is optimized and all measures are taken to prevent accidental exposures from occurring. Historical and ongoing accidents that have resulted in patient and public doses or inappropriate medical outcomes represent opportunities for continuous improvement in radiation protection. Additionally, staff in brachytherapy treatment facilities may receive high radiation doses if radiological protection tools are not used properly. Brachytherapy uniquely presents the possibility for doses that require active management. In modern brachytherapy centres, radiation doses are incurred by staff (e.g. loading of seeds, plaques, caesium implants, associated fluoroscopy). There is also a large variation in the practice of brachytherapy on a global scale and several facilities still practise older techniques with significantly higher staff dose potential. In addition, technological developments and newer techniques present new radiation protection concerns and an increasing blurring of historical responsibilities that need to be addressed with specific recommendations for the practising medical community. Along with an increase in equipment and to safeguard resources, additional qualified and trained brachytherapy staff are required worldwide.

1. INTRODUCTION

Brachytherapy is a method of radiation therapy in which a source (typically encapsulated or electronic) is utilized to deliver gamma or beta radiation at a distance of up to a few centimetres either by surface, intracavitary or interstitial applications. In the past 10–15 years, brachytherapy has undergone major changes due to continued technological improvements and demographics of patient care [1–4]. As of 2007, the worldwide average number of persons treated with

brachytherapy per year was estimated at more than 0.4 million, with most of these for gynaecological and genitourinary tumours followed by prostate, breast, head and neck, and others [5]. The International Commission on Radiological Protection (ICRP) has estimated that high dose rate (HDR) brachytherapy cases alone represent perhaps more than 0.5 million treatments per year [6]. Several countries report the use of brachytherapy almost exclusively in females [5]. In some regions, the mean number of brachytherapy treatment patients per centre has increased by almost 50% [3]. As of 2007, the average annual frequency of brachytherapy treatments in level I countries (0.12 treatment per 1000 population) was about 1/18 of that for teletherapy. In level II countries, practice in brachytherapy is lower by a factor of about two compared with level I. The global average annual frequency assessed for brachytherapy treatments (0.07 per 1000 population) is about 1/10 of that for teletherapy treatments [5]. Permanent seed implants continue to rise, for example in the United States of America, where approximately 220 000 new cases of prostate cancer are diagnosed each year, and more than 40 000 implantations for localized prostate neoplasms are performed annually [7]. In Europe, as in other locations, several thousand cases are already treated annually and this number continues to increase.

In brachytherapy, patients are exposed to ionizing radiation from various and differing modalities: brachytherapy, radiography, fluoroscopy, computed tomography (CT) and/or nuclear medicine. These modalities differ considerably in the frequency with which they are performed, in patient radiation doses, in the way radiation is administered to the patient, and in radiation dose potentials to operators and staff. In addition to the principles of justification and optimization, the need for ongoing attention to overall radiation protection is essential for brachytherapy [6, 8–10]. Patients undergoing radiation therapy should have available to them the necessary facilities and staff to provide safe and effective treatment. There is a critical need for improved training in both the technical practice and radiation protection associated with brachytherapy. For example, many radiation therapy centres in level II, III and IV countries do not have sufficient numbers of remote afterloading brachytherapy units [11]. Clearly, national and regional studies on the patterns of use and radiation protection aspects of brachytherapy are an aspect of continuous improvement that could provide information where there has been a significant lack of specific data previously. Such studies serve to suggest areas for additional regional, national and international research and prioritization.

2. NEED FOR ACTION WITH REGARD TO PATIENTS

The aims of brachytherapy are to ensure an accurate and safe dose delivery to a target volume, while avoiding unnecessary dose to surrounding healthy tissue. Often, brachytherapy is used for the application of a boost dose, in combination with or as an alternative to (or part of) external beam radiation therapy (EBRT). Recent advances in technology and technique make brachytherapy an increasingly competitive alternative to EBRT and surgery. Primary target doses of ~60 Gy and organ doses outside of the treatment volume of ~1 Gy [12] demonstrate the ballistics advantage of brachytherapy and suggest a possible reduction in the risk of secondary cancers when compared to EBRT [12, 13]. In addition, brachytherapy is minimally invasive and may not require overnight hospitalization. The treatment often has little or no effect on the patient's lifestyle, thereby allowing for a speedy return to normal activities [4].

The standard brachytherapy techniques include low (LDR), mid (MDR) and high (HDR) dose rate or pulsed dose procedures, permanent source implants, opthalmic plaques, and endovascular dose delivery. Newer brachytherapy mechanisms now include intraoperative techniques and devices, electronic dose delivery, new plaques/films, microspheres, and seeds for imaging and localization. HDR and other afterloading procedure brachytherapy offer advantages over the manual LDR technique, for example, in terms of improved geometrical stability for patients during the shorter treatment times (and an associated reduced staff exposure potential). However, because HDR brachytherapy techniques use IAEA category 2 sources to deliver a very high dose, of the order of 1.6–5.0 Gy/min, mistakes can lead to under- or overdosage with the potential for clinical adverse effects. Remote afterloading equipment is typically the most complex equipment in brachytherapy [14]. More than 500 HDR accidents (including one death) have been reported along the entire chain of procedures from source packing to delivery of dose. Human error has been the prime cause of radiation events [6].

Brachytherapy treatment planning and dosimetry can still be performed based on plain film and ultrasound techniques; however, advanced dosimetric techniques such as CT, positron emission tomography/CT, magnetic resonance imaging and in vivo or intraoperative planning continue to gain adherents. In addition, in advanced brachytherapy centres, there is a shift towards image guided brachytherapy (IGBT) relying on a mix of real time ultrasound, fluoroscopy, cone-beam CT and standard CT techniques. Image guidance will continue to increase in use over the next 10 years. While such applications serve to increase the usefulness and safety of brachytherapy treatments, it also suggests that ongoing expansion of both the equipment and training of staff [15] associated with such advanced treatments [16] will be necessary to ensure optimized treatments and safe applications.

3. NEED FOR ACTION WITH REGARD TO STAFF

Staff in brachytherapy treatment facilities may receive high radiation doses if radiological protection tools are not used properly. While EBRT results in minimal (or no) occupational doses with an appropriately shielded facility, brachytherapy uniquely presents the possibility for doses that require active management. Brachytherapy may be performed manually using gamma-emitting sealed sources, typically ^{103}Pd or ^{125}I for prostate, ^{192}Ir for interstitial and intravascular, ^{137}Cs for intracavitary treatment, and occassionally ^{131}Cs, ^{125}I and ^{198}Au for other procedures. This may result in individuals receiving some whole body radiation exposure. In modern brachytherapy centres, radiation doses are incurred by staff (e.g. loading of seeds, plaques, caesium implants, associated fluoroscopy) [17]. While HDR afterloader techniques typically reduce staff doses (with good facility design and equipment), it is essential that well planned and exercised emergency response plans exist. The IAEA and the ICRP have several excellent guides with regard to safe applications of brachytherapy [6, 8, 9, 18–20] and the ICRP has recently initiated a task group specifically to evaluate brachytherapy staff safety [21].

There is clearly a demonstrated and ongoing need for well designed programmes of quality assurance (QA) in brachytherapy departments. The goal should be the consistency of the administration of each individual treatment, the realization of the clinical intent of the radiation oncologist and the safe execution of the treatment [22–28]. The ICRP evaluated historical HDR brachytherapy accidents and noted that many accidents could have been prevented if staff had had functional monitoring equipment and paid attention to the results [6]. They further point out that accidents and incidents should be reported and the lessons learned should be shared with other users to prevent similar mistakes. In a separate report [29], the IAEA evaluated accidental exposures in radiotherapy which included 32 accidents related to the use of sealed sources. Accidents were caused by incorrect source strength, dose calculation errors, equipment failure, errors in quantities and units, badly implanted sources, removal of sources by patients or otherwise dislodged sources. Several high profile [30] permanent implant errors, and a recognition that these can and do occur with some frequency, have resulted in a re-emphasis on programme QA, training and discussions on how to most appropriately define dosimetry [31, 32].

As newer brachytherapy techniques are developed (e.g. intraoperative radiation therapies, new plaque designs, new source uses), there is a need for both newer and older (tried and true) radiation safety fundamentals. In addition, the onset of IGBT techniques suggests that the boundaries between historically more isolated medical practices (e.g. radiation oncology, brachytherapy, radiology

and nuclear medicine) are being blurred. There is a critical need to ensure that responsibilities are clearly delineated.

As in all areas of radiation protection in medicine, brachytherapy requires a well staffed set of uniquely qualified individuals. It is essential that a team of trained personnel follow QA procedures and programmes, that include peer review of cases, to prevent accidents. However, there is a worldwide lack of qualified and trained [33] individuals for brachytherapy procedures and quality management programmes [15]. This is especially acute with regard to both the older brachytherapy techniques (still affordably practised in several countries) and newer highly technical methods requiring signficant equipment and human resources. There must be sufficient trained and knowledgeable staff with clinical and medical physics expertise to deliver a safe and effective radiation dose. Appropriate facilities and radiation protection infrastructure for monitoring and regulatory control with regard to brachytherapy are needed.

4. NEED FOR ACTION WITH REGARD TO FAMILY MEMBERS, COMFORTERS AND THE GENERAL PUBLIC

While there are important considerations for family members and comforters during LDR treatments, doses are typically manageable through time, distance and shielding applications. The ongoing growth in the application of LDR permanent seed brachytherapy in the world emphasizes the need for consistent sound radiological protection practices and precautions for patients leaving the hospital setting with radioactive material ‘on board’. ICRP Publication 98 [8], specifically addressing radiation safety aspects associated with brachytherapy for prostate cancer using permanently implanted sources, concludes that no adverse effects to medical staff and/or the patients’ families have been reported to date; the annual dose from implanted patients to family or household members remains well below 1 mSv in almost all cases; expulsion of sources through urine, semen or the gastrointestinal tract is a rare event mitigated with simple recommendations. The patient must be provided with specific recommendations concerning the previous points, subsequent pelvic or abdominal surgery, fathering of children and possible triggering of some security monitors. It is further suggested that all patients receive a wallet card with all relevant information about the implant. Various recent studies continue to support these overall findings [34–36].

Cremation is becoming a more important consideration worldwide. There are specific concerns after unexpected early death (e.g. <12 months) after the implantation, especially with regard to cremation of bodies. In an interesting twist on population management and overall globalization trends, the cremation of bodies, already common in some countries (e.g. Japan), is now also increasing

in others. In fact, it has been estimated that by the year 2020, cremation will be the chosen method in more than 50% of deaths in the USA. This confluence of factors suggests that increased attention and care are needed to ensure that potential exposures of the public (and workers) are mitigated. The ICRP concluded that cremation can be allowed if 12 months have elapsed since the implantation. If cremation is to be considered before that time, specific measures must be taken. A recent study in Japan [7, 36] shows that only 0.28% of implanted patients died within the first 12 months and that the largest proportion of early deaths was because of cerebrovascular or cardiovascular disease, followed by malignant tumour and respiratory disease or infection. In addition, they found that in the overwhelming majority of early death cases, the brachytherapy source was retrieved together with the prostate gland at autopsy (as suggested by international recommendations).

Security provisions are required for brachytherapy sources to deter unauthorized access, and to detect unauthorized access and acquisition of the source in a timely manner. This may require locked and fixed devices, rooms, access control, continuous surveillance or other security provisions [19].

5. CONCLUSIONS

Brachytherapy continues to serve an important role in radiotherapy and has generally been successfully and safely practised. An emphasis on radiation safety principles is needed in the next decade as current methods mature and newer techniques are developed. Significant opportunities for improvement exist in the areas of quality management (and accident prevention) along with infrastructure needs, including equipment availability, sufficiently trained human resources and security safeguards.

REFERENCES

[1] GUEDEA, F., et al., Patterns of care for brachytherapy in Europe: updated results for Spain, Clin. Transl. Oncol. **14** 1 (2012) 36–42.

[2] GUEDEA, F., et al., Patterns of care for brachytherapy in Europe: updated results, Radiother. Oncol. **97** 3 (2010) 514–520.

[3] GUEDEA, F., et al., Overview of brachytherapy resources in Latin America: a patterns-of-care survey, Brachytherapy **10** 5 (2011) 363–368.

[4] GUEDEA, F., et al., Patterns of care for brachytherapy in Europe: facilities and resources in brachytherapy in the European area, Brachytherapy **7** 3 (2008) 223–230.

[5] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2008 Report to the General Assembly with Scientific Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).
[6] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of High-dose-rate Brachytherapy Accidents, Publication 97, Pergamon Press, Oxford (2005).
[7] DAUER, L.T., Globalization, implantation, cremation...Oh, my! Brachytherapy **11** 3 (2012) 197–198.
[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Safety Aspects of Brachytherapy for Prostate Cancer Using Permanently Implanted Sources, Publication 98, Pergamon Press, Oxford (2005).
[9] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Medicine, Publication No. 105, Pergamon Press, Oxford (2007).
[10] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
[11] BARTON, M.B., FROMMER, M., SHAFIQ, J., Role of radiotherapy in cancer control in low-income and middle-income countries, Lancet Oncol. **7** 7 (2006) 584–595.
[12] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Second Primary Cancers and Cardiovascular Disease after Radiation Therapy, Rep. 170, NCRP, Bethesda, MD (2011).
[13] ZELEFSKY, M.J., et al., Incidence of secondary cancer development after high-dose intensity-modulated radiotherapy and image-guided brachytherapy for the treatment of localized prostate cancer, Int. J. Radiat. Oncol. Biol. Phys. **83** 3 (2012) 953–959.
[14] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Particular Requirements for the Basic Safety and Essential Performance of Automatically-controlled Brachytherapy Afterloading Equipment, IEC 60601-2-17 Ed 2.0: Medical Electrical Equipment — Part 2-17, IEC, Geneva (2004).
[15] INTERNATIONAL ATOMIC ENERGY AGENCY, A Silent Crisis: Cancer Treatment in Developing Countries, IAEA, Vienna (2003).
[16] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Syllabus for the Education and Training of Radiation Oncologists, Endorsed by the American Society for Radiation Oncology (ASTRO) and the European Society for Therapeutic Radiology and Oncology (ESTRO), Training Course Series No. 36, IAEA, Vienna (2009).
[17] SCHWARTZ, D.J., et al., Radiation exposure to operating room personnel during transperineal interstitial permanent prostate brachytherapy, Brachytherapy **2** 2 (2003) 98–102.
[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Applying Radiation Safety Standards in Radiotherapy, Safety Reports Series No. 38, IAEA, Vienna (2006).

[19] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection in the Design of Radiotherapy Facilities, Safety Reports Series No. 47, IAEA, Vienna (2006).
[20] INTERNATIONAL ATOMIC ENERGY AGENCY, Implementation of Microsource High Dose Rate (mHDR) Brachytherapy in Developing Countries, IAEA-TECDOC-1257, IAEA, Vienna (2001).
[21] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Task Group 89: Occupational Radiological Protection in Brachytherapy, http://www.icrp.org/icrp_group.asp?id=69
[22] EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY, GEBAULET, A., et al. (Eds), The GEC ESTRO Handbook of Brachytherapy, ESTRO, Leuven, Belgium (2002).
[23] KUBO, H.D., et al., High dose-rate brachytherapy treatment delivery: Report of the AAPM Radiation Therapy Committee Task Group No. 59, Med. Phys. **25** 4 (1988) 375–403.
[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Oncology Physics: A Handbook for Teachers and Students (PODGORSAK, E.B., Ed.), IAEA, Vienna (2005).
[25] INTERNATIONAL ATOMIC ENERGY AGENCY, Calibration of Photon and Beta Ray Sources Used in Brachytherapy, IAEA-TECDOC-1274, IAEA, Vienna (2002).
[26] INTERNATIONAL ATOMIC ENERGY AGENCY, Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement, Quality Assurance Team for Radiation Oncology (QUATRO), IAEA, Vienna (2007).
[27] INTERNATIONAL ATOMIC ENERGY AGENCY, Setting up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects, IAEA, Vienna (2008).
[28] EUROPEAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY, A Practical Guide to Quality Control of Brachytherapy Equipment, European Guidelines for Quality Assurance in Radiotherapy (VENSELAAR, J., PEREZ-CALATAYUD, J., Eds), Booklet No. 8, ESTRO, Brussels (2004).
[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Lessons Learned from Accidental Exposures in Radiotherapy, Safety Report Series No. 17, IAEA, Vienna (2000).
[30] NUCLEAR REGULATORY COMMISSION, NRC's Response to Medical Events at the Veterans Affairs Medical Center in Philadelphia, Pa., USNRC, Washington, DC (2010).
[31] NUCLEAR REGULATORY COMMISSION, Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs, USNRC, Washington, DC (2012).
[32] ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES (ACMUI), Permanent Implant Brachytherapy Revised Final Report, USNRC ACMUI, Washington, DC (2012).
[33] EUROPEAN COMMISSION, Guidelines on Education and Training in Radiation Protection for Medical Exposures, Radiation Protection 116, Office for Official Publications of the European Communities, Luxembourg (2000).

[34] DAUER, L.T., et al., Less-restrictive, patient-specific radiation safety precautions can be safely prescribed after permanent seed implantation, Brachytherapy **9** 2 (2010) 101–111.
[35] COSSET, J.M., Prostate brachytherapy patients are (almost) normal people! Brachytherapy **9** 2 (2010) 112–113.
[36] SATOH, T., et al., Deaths within 12 months after (125)I implantation for brachytherapy of prostate cancer: An investigation of radiation safety issues in Japan (2003–2010), Brachytherapy **11** 3 (2012) 192–196.

RADIATION PROTECTION IN RADIONUCLIDE THERAPY IN THE NEXT DECADE

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Abstract

Radiation protection in radionuclide therapy concerns patients, staff members, comforters and caregivers, other family members and the general public. Still, most patient treatments are planned up to the tolerance level for normal organs and tissues such as kidneys and bone marrow. For an optimal treatment, an individual dose calculation — based on an individual biokinetics study for the substance to be used — needs to be performed in advance. It is necessary to have strict procedures to verify that the patient is not pregnant or breastfeeding. For the personnel, local skin doses to the fingers and hands from the β emitters used can reach high values if the staff members are not aware of the problem and do not take steps to reduce the dose. Individuals belonging to the ward nursing staff can easily reach effective doses of a few millisieverts per year. It is essential that information and education in radiation protection and the establishment of routines guarantee that doses to pregnant staff members are such that the dose to an embryo/foetus is kept under 1 mSv.

1. INTRODUCTION

The number of radionuclide or radiopharmaceutical therapies is a small fraction (2–4%) of the total number of nuclear medicine (diagnostic and therapeutic) procedures [1]. Most therapeutic procedures are still for the treatment of hyperthyroidism using ^{131}I-iodide. The introduction of new radiopharmaceuticals for systemic cancer treatment in situations where surgery and external radiation therapy have failed is, however, progressing. Radiation protection in radionuclide therapy concerns patients, staff members, comforters and caregivers, other family members and the general public [2]. These aspects are discussed in the paper.

2. RADIONUCLIDE THERAPY TODAY

Ever since the 1940s, the most common application of radionuclide therapy is in the treatment of hyperthyroidism by oral administration of ^{131}I-iodide. Cancer treatment with radioactive substances started at the same time with treatment of thyroid cancer, also with ^{131}I-iodide. For a long time, ^{32}P orthophosphate has been used for treatment of polycythaemia. A number of radionuclides in different chemical forms are currently used for palliative treatment of skeletal metastases; the most common are ^{153}Sm-EDTMP (ethylenediaminetetramethylene phosphonic acid) and ^{89}Sr chloride. Neuroendocrine tumours are treated with ^{131}I-MIBG (metaiodobenzylguanidine) or somatostatin analogues labelled with ^{90}Y or ^{177}Lu. There are a few antibodies available on the market, labelled with ^{131}I or ^{90}Y, mainly for non-Hodgkin's lymphoma (^{90}Y-ibritumomab tiuxetan and ^{131}I-tositumomab) [3, 4].

3. ANTICIPATED DEVELOPMENT DURING THE NEXT DECADE

There are now several proofs of the principle that adding a radionuclide to a targeting molecule enhances the clinical efficacy when compared with treating the patient with the non-radioactive targeting molecule alone [4]. In parallel to monoclonal antibodies and antibody fragments, very small molecular carriers such as peptides, have been found to offer advantages for certain targeting applications. Ongoing clinical and preclinical work involves their labelling with a number of β emitters other than ^{131}I, ^{90}Y and ^{177}Lu: ^{166}Ho, ^{186}Rh, ^{188}Re, ^{87}Cu, ^{149}Pr, ^{199}Au and ^{105}Rh [5, 6]. It is very likely that this trend will continue and be intensified. Phase I clinical trials have been performed with α emitting ^{213}Bi monoclonal antibodies on patients with leukaemia and ^{211}At monoclonal antibodies on patients with brain tumours [5] and ovarian cancer [7]. Another α emitter, ^{223}Ra, is being evaluated in breast and prostate cancer patients with bone metastases. Auger electron emitters, such as ^{77}Br, ^{111}In, ^{123}I and ^{125}I, are also being investigated.

There are currently hundreds of new pathway-targeted anticancer agents undergoing phase II and phase III clinical trials. It is likely that some of these agents could be good carriers for radionuclides.

Radiation synovectomy has, for a long time, been used as an alternative to surgery for the treatment of rheumatoid arthritis. As it is relatively simple, costs less than surgery and can be performed on an outpatient basis, its use is expected to increase [5].

4. NEED FOR ACTION WITH REGARD TO PATIENTS

In order to obtain tumour control in external radiation therapy, the absorbed dose delivered to the tumour should be determined with a high degree of accuracy, if possible within 1–2%. This high accuracy is, however, with presently used methods, not at all achievable in radionuclide therapy. The medical community currently does not even always have easy access to methods and protocols for the collection of useful biokinetics or dosimetrics data. As quantitative imaging and dosimetry are seldom performed, many treatments are effectively given blind. This severely constrains development.

4.1. Need for individual patient dosimetry

For an optimal treatment with radionuclides, an individual dose calculation needs to be performed in advance. For this purpose, an individual biokinetics study for the substance used is needed, primarily for critical or at risk organs. The result of such a study should then be used as the source for a calculation of the absorbed dose. For this, a voxel phantom constructed from a whole body computed tomography (CT) study of the individual patient can be used. A factor to bear in mind is that the calculated doses are average doses to organs and tissues. The dose is, however, not completely homogeneously distributed, depending on the non-uniform distribution of the radiation source [8].

At present, the established method for dosimetry for therapeutic as well as diagnostic purposes is based on a measurement of the biokinetics by serial gamma camera images. However, the quantification of the activity in different organs from planar data is hampered by inaccurate attenuation and scatter correction as well as influences of background and organ overlay. Dosimetry based on quantitative 3D data can be more accurate provided that effects that degrade the quantitative content of the images have been corrected for. Matched anatomical imaging, such as combined single photon emission computed tomography (SPECT)/CT and positron emission tomography (PET)/CT, has also made it possible to obtain tissue density information in conjunction with the radionuclide distribution. Coupled with iterative reconstruction algorithms, these advances have made it possible to perform patient specific dosimetry (see, for example, Ref. [9]). Advances in imaging will also increase the possibilities to evaluate the spatial distribution of radionuclides within tumours and normal organs at various times after administration. It is also essential to collect information about the correlation between estimated doses and biological effects in the form of normal tissue tolerance and antitumour efficacy in the same way as is done for external beam radiation therapy. Today, there is also research going on to use radiobiological modelling to convert the spatial

and temporal distribution of absorbed dose to a biologically effective dose [10] for tumour tissue and for normal tissues.

4.2. Multimodality treatment

For the control of metastatic cancer, multimodality treatment is almost always required. The synergistic combination of chemotherapy and radionuclides has the potential to enhance efficacy and minimize toxicity. Chemotherapeutic agents often radiosensitize tumours to targeted radionuclide treatment, and cytotoxic effects are additive. Biological molecular targeted agents may also be pro-apoptotic or increase radionuclide induced tumour cell death [4].

4.3. Short range particle emitters

In recent years, there has been an increasing interest in combining biologically specific targeting agents (i.e. antibodies, antibody fragments, peptides, etc.) with short range particulate radiation emitters (α and β particles, Auger electron emitters) [5]. This therapeutic combination offers the potential of delivering lethal doses of radiation to individual tumour cells, including metastases, while minimizing the volume or normal tissue irradiated. In these therapeutic applications, the absorbed dose needs to be determined on a scale that is comparable with the range of the emitted particles. This scale is on the order of millimetres for β particles, micrometres for α particles and nanometres for Auger electrons. Both so-called small scale dosimetry and microdosimetry have up until now had limited applications in clinical practice. Accurate and complete small scale dosimetry and microdosimetry require knowledge of the source distribution as a function of time on the cellular/subcellular scale. In microdosimetry and small scale dosimetry, assessment of the geometric target is even more difficult as the target can range from single cells in suspension (i.e. ascites, blood borne diseases) to small metastatic clusters to potentially macroscopic tumour masses. The targets are much smaller than structures available from current anatomical imaging methods (CT or magnetic resonance imaging). It is a challenge to develop small scale dosimetry and microdosimetry for particle emitters for use in conjunction with cellular studies in vitro as well as in vivo studies in animals and later in man.

4.4. Pregnancy and breastfeeding

Pregnant patients should not be treated with radiopharmaceuticals, unless it is needed to save the mother's life. Female patients of fertile age should routinely be interviewed and tested for pregnancy before treatment. As routine pregnancy

tests may give misleading results, investigations by means of ultrasound could be done to exclude pregnancy at the time of treatment [11]. It is also necessary to have strict procedures to verify that the patient is not breastfeeding.

5. NEED FOR ACTION WITH REGARD TO STAFF

The radiation detriment from exposure of both the staff and other individuals is part of the justification of medical exposures and of the optimization process. In therapy, higher activities per patient are handled than for diagnostic purposes and the radionuclides are often different from those used in diagnostic nuclear medicine. They are usually β emitters, sometimes low energy electron and α emitters with longer physical and biological half-times and, therefore, constitute a greater radiation protection problem. Therapy radionuclides may require different facilities to radionuclides used for diagnostic procedures, to ensure the safe preparation and administration of the radiopharmaceutical. Local skin doses to the hands of the personnel due to β emitters can reach high values. There are situations where the equivalent dose at the fingertips could considerably exceed the recommended annual limit, which is 500 mSv [12, 13]. Optimized working conditions can, however, keep the doses to staff well below the limits for occupational exposure both for the dose to the extremities (500 mSv/year) and to the eyes (20 mSv/year[1]) [13]. In both diagnostic and therapeutic nuclear medicine, the patient becomes a source of radiation not only for him/herself but also for staff, caregivers, family members and the general public, and remains so until the radioactive material has decayed or is excreted from the body [14]. On the other hand, the number of therapy patients is much lower than the number of patients undergoing diagnostic investigations [1] and the yearly contribution to the effective dose to most staff members is usually small. However, members of ward nursing staff can easily reach effective doses of a few millisieverts per year. For this group, it is essential that information and education in radiation protection and establishment of routines guarantee that doses to pregnant staff members are such that the dose to the embryo/foetus is kept under 1 mSv [11].

[1] Averaged over 5 years and not more than 50 mSv in any one year.

6. NEED FOR ACTION WITH REGARD TO FAMILY MEMBERS, COMFORTERS AND THE GENERAL PUBLIC

After the patient is released from the hospital, the most important critical groups are caregivers and family members. The exposure of caregivers is considered a medical exposure and, therefore, international organizations recommend dose constraints instead of dose limits (International Commission on Radiological Protection, IAEA: 5 mSv per episode; European Commission: 1 mSv for children, 3 mSv for adults under 60 years and 15 mSv for adults over 60 years) [14]. Here also routines are needed to guarantee that the dose to the embryo/foetus is kept below 1 mSv [11].

REFERENCES

[1] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2008 Report to the General Assembly with Scientific Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).

[2] MATTSSON, S., "The importance of radiation protection in nuclear medicine", Radiation Protection in Nuclear Medicine (MATTSSON, S., HOESCHEN, C., Eds), Springer, Berlin-Heidelberg (2013) 1–3.

[3] NOSSKE, D., MATTSSON, S., JOHANSSON, L., "Dosimetry in nuclear medicine diagnosis and therapy", Medical Radiological Physics (KAUL, A., Ed.), Landolt-Börnstein New Series VIII/7a, Springer, Berlin-Heidelberg (2012).

[4] TURNER, J.H., Perspective: Multimodality radionuclide therapy of progressive disseminated lymphoma and neuroendocrine tumors as a paradigm for cancer control, Cancer Biother. Radiopharm. **27** 9 (2012) 525–529.

[5] NATIONAL RESEARCH COUNCIL, Advancing Nuclear Medicine Through Innovation, National Academies Press, Washington, D.C. (2007), http://www.nap.edu/catalog/11985.html

[6] McPARLAND, B.J., Nuclear Medicine Radiation Dosimetry, Advanced Theoretical Principles, Springer, London (2010).

[7] ANDERSSON, H., et al., Intraperitoneal alpha-particle radioimmunotherapy of ovarian cancer patients: Pharmacokinetics and dosimetry of ^{211}At-MX35 F(ab′)$_2$ — A phase I study, J. Nucl. Med. **50** 7 (2009) 1153–1160.

[8] THIERENS, H.M., et al., Dosimetry from organ to cellular dimensions, Comput. Med. Imaging Graph. **25** 2 (2001) 187–193.

[9] LJUNGBERG, M., et al., A 3-dimensional absorbed dose calculation method based on quantitative SPECT for radionuclide therapy: Evaluation for ^{131}I using Monte Carlo simulation, J. Nucl. Med. **43** 8 (2002) 1101–1109.

[10] PRIDEAUX, A.R., et al., Three-dimensional radiobiologic dosimetry: Application of radiobiologic modeling to patient-specific 3-dimensional imaging-based internal dosimetry, J. Nucl. Med. **48** 6 (2007) 1008–1016.

[11] CANTONE, M.C., "Radiation exposure of the embryo/foetus and the newborn child", Radiation Protection in Nuclear Medicine (MATTSSON, S., HOESCHEN, C., Eds), Springer, Berlin-Heidelberg (2013) 49–67.
[12] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, "Annex E: Radiation Exposure of Hands in Radiopharmacies: Monitoring of Doses and Optimisation of Protection", Radiation Dose to Patients from Radiopharmaceuticals — Addendum 3 to ICRP Publication 53, Publication 106, Pergamon Press, Oxford (2008).
[13] CARNICER, A., et al., "Occupational exposure: With special reference to skin doses in hands and fingers", Radiation Protection in Nuclear Medicine (MATTSSON, S., HOESCHEN, C., Eds), Springer, Berlin-Heidelberg (2013) 93–108.
[14] ZONTAR, D., "Radiation doses from patients to staff members, comforters and caregivers and to the general population", Radiation Protection in Nuclear Medicine (MATTSSON, S., HOESCHEN, C., Eds), Springer, Berlin-Heidelberg (2013) 109–128.

DEVELOPMENTS IN PATIENT DOSIMETRY FOR UNSEALED SOURCES

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Abstract

In molecular radiotherapy, treatment planning essentially is the determination of the activity to administer to optimize safety and efficacy of a treatment. Individualization is possible, for example, by using quantitative imaging modalities, external counting and blood sampling for pre-therapeutic biokinetics measurements. Patient specific dosimetry can be performed as in radiation therapy. Over- or undertreatment of patients can be avoided. Here, the standard methods and the expected advances in performing individualized dosimetry are discussed.

1. INTRODUCTION

In molecular radiotherapy (MRT), a radionuclide or a radioactively labelled pharmaceutical is administered to the patient. The administered activity should accumulate selectively in tumour cells and, thus, kill or sterilize the target cells, while avoiding adverse effects to other organs as far as possible. The administered activity for treatment must be properly determined for optimal safety and efficacy of the treatment. Two principal ways of determining the activity exist.

First, the determination of the treatment activity may be determined analogously to chemotherapy, i.e. the amount of drug (activity) is determined on a cohort based method in a dose escalation trial. This approach is simple, but leads to over- and undertreatment of some patients as individual biokinetics are not considered. Second, patient specific dosimetry may be performed as in radiation therapy. This much more complex approach should, if properly performed, avoid over- and undertreatment of patients and should, consequently, be preferred.

In the following section, the steps of nuclear medicine dosimetry are presented [1], and advances and challenges are briefly discussed [2]. A more detailed guide through the corresponding steps is given in the EANM Dosimetry Committee Guidance Document: Good Practice of Clinical Dosimetry Reporting [3].

2. PATIENT SPECIFIC NUCLEAR MEDICINE DOSIMETRY

2.1. Quantification of patient specific pharmacokinetics

Nowadays, planar gamma camera imaging is performed most frequently, followed by manual region drawing. Although this is a large improvement compared to non-patient specific approaches, the well known limitations of planar imaging cannot easily be overcome [4]. In contrast, tomographic imaging using combined modalities — single photon emission computed tomography (SPECT)/computed tomography (CT), positron emission tomography (PET)/CT or PET/magnetic resonance imaging (MRI) — will not only allow an improved quantitation in the future, but also a more reproducible region drawing in the 3D datasets [5].

Furthermore, whole body counting and blood or urine sampling can provide additional information on the biokinetics of a given substance.

2.2. Kinetic model

Usually, the measured time points of the patient's biokinetics were simply fitted by sums of exponentials [6, 7]. Thus, the result depends on the chosen fit function. To eliminate this dependence on the observer, fit function selection should be performed using an adequate model selection criterion, e.g. the Akaike information criterion [8, 9]. An important quality control is the presentation of the standard errors of the residence times [3, 7].

Provided that the input data are accurate, the use of physiologically based pharmacokinetic (PBPK) models will allow both a more accurate and precise determination of the corresponding residence times, as a lower number

of parameters need to be estimated. In addition, PBPK models enable in silico optimization of the biodistribution [10–12].

The sampling schedule is mostly defined using rules of thumb [4, 13], e.g. three measurements per exponential. This can be improved using standard methods based on population kinetics to calculate the optimal sampling schedule [14–16]. This, in turn, will lead to an increased precision of the calculated residence times for a given number of measurements.

2.3. Prediction of pharmacokinetics during therapy

The possibility that the biokinetics change between pre-therapeutic measurements and therapy is often neglected. The validity of this assumption must be verified, as it was already shown that the amount of (unlabelled) substance influences the biodistribution [17–19].

In the future, the active modulation of the biodistribution using PBPK modelling will also allow for improved therapeutic indices [18, 20].

2.4. Absorbed dose calculation

Standard absorbed dose calculations rely on whole body or organ level of anthropomorphic phantoms as provided, for example, by OLINDA/EXM [21]. Using individual S factors or voxel and cellular level S factors will further improve individualized treatment [22].

2.5. Therapy planning

Standard dose prescription often relies only on the absorbed dose. However, by including radiobiology, the concept of biologically effective dose has already shown promising results in peptide receptor radionuclide therapy [23, 24]. In some cases, surrogate parameters, such as the absorbed dose to the blood as a surrogate for the dose to the bone marrow, ensure the safety of a treatment [25, 26].

2.6. Treatment and quality control measurements

Therapeutic dose verification is performed only occasionally. Therefore, routine quality control methods must still be developed, for example quantification of bremsstrahlung imaging for ^{90}Y or the measurement of serum kinetics during therapy [19, 27].

3. CONCLUSION

Individualized treatment planning in MRT is very sophisticated and not every centre may be able to develop new effective and safe MRT, as elaborate data need to be collected and properly analysed. However, after adequate development, the implementation in centres with the necessary equipment should be achievable.

ACKNOWLEDGEMENTS

This work was partially supported by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation, GL236/7-2) and by the German Ministry of Education and Research (BMBF-01EZ1130).

REFERENCES

[1] KONIJNENBERG, M., From imaging to dosimetry and biological effects, Q. J. Nucl. Med. Mol. Imaging **55** 1 (2011) 44–56.

[2] GLATTING, G., LASSMANN, M., Nuclear medicine dosimetry: Quantitative imaging and dose calculations, Z. Med. Phys. **21** 4 (2011) 246–247.

[3] LASSMANN, M., et al., EANM Dosimetry Committee guidance document: Good practice of clinical dosimetry reporting, Eur. J. Nucl. Med. Mol. Imaging **38** 1 (2011) 192–200.

[4] SIEGEL, J.A., et al., MIRD pamphlet No. 16: Techniques for quantitative radiopharmaceutical biodistribution data acquisition and analysis for use in human radiation dose estimates, J. Nucl. Med. **40** 2 (1999) 37S–61S.

[5] FLUX, G., et al., The impact of PET and SPECT on dosimetry for targeted radionuclide therapy, Z. Med. Phys. **16** 1 (2006) 47–59.

[6] STRAND, S.E., ZANZONICO, P., JOHNSON, T.K., Pharmacokinetic modeling, Med. Phys. **20** 2 (1993) 515–527.

[7] GLATTING, G., et al., Internal radionuclide therapy: The ULMDOS software for treatment planning, Med. Phys. **32** 7 (2005) 2399–2405.

[8] KLETTING, P., GLATTING, G., Model selection for time-activity curves: The corrected Akaike information criterion and the F-test, Z. Med. Phys. **19** 3 (2009) 200–206.

[9] GLATTING, G., et al., Choosing the optimal fit function: Comparison of the Akaike information criterion and the F-test, Med. Phys. **34** (2007) 4285–4292.

[10] KLETTING, P., RESKE, S.N., GLATTING, G., Dependence of the anti-CD66 antibody biodistribution on the dissociation constant: A simulation study, Z. Med. Phys. **21** 4 (2011) 301–304.

[11] BOIS, F.Y., Physiologically based modelling and prediction of drug interactions, Basic Clin. Pharmacol. Toxicol. **106** 3 (2010) 154–161.
[12] KLETTING, P., MEYER, C., RESKE, S.N., GLATTING, G., Potential of optimal preloading in anti-CD20 antibody radioimmunotherapy: An investigation based on pharmacokinetic modeling, Cancer Biother. Radiopharm. **25** 3 (2010) 279–287.
[13] INTERNATIONAL COMMISSION ON RADIATION UNITS AND MEASUREMENTS, Absorbed-dose Specification in Nuclear Medicine, Rep. 67, Nuclear Technology Publishing, Ashford, United Kingdom (2002).
[14] OGUNGBENRO, K., AARONS, L., An effective approach for obtaining optimal sampling windows for population pharmacokinetic experiments, J. Biopharm. Stat. **19** 1 (2009) 174–189.
[15] KALICKA, R., BOCHEN, D., Properties of D-optimal sampling schedule for compartmental models, Biocybern. Biomed. Eng. **25** 1 (2005) 23–36.
[16] D'ARGENIO, D.Z., Optimal sampling times for pharmacokinetic experiments, J. Pharmacokinet. Biopharm. **9** 6 (1981) 739–756.
[17] VELIKYAN, I., et al., In vivo binding of [^{68}Ga]-DOTATOC to somatostatin receptors in neuroendocrine tumours — Impact of peptide mass, Nucl. Med. Biol. **37** 3 (2010) 265–275.
[18] KLETTING, P., et al., Differences in predicted and actually absorbed doses in peptide receptor radionuclide therapy, Med. Phys. **39** 9 (2012) 5708–5717.
[19] KLETTING, P., et al., Radioimmunotherapy with anti-CD66 antibody: Improving the biodistribution using a physiologically based pharmacokinetic model, J. Nucl. Med. **51** 3 (2010) 484–491.
[20] KLETTING, P., et al., Optimal preloading in radioimmunotherapy with anti-CD45 antibody, Med. Phys. **38** 5 (2011) 2572–2578.
[21] STABIN, M.G., SPARKS, R.B., CROWE, E., OLINDA/EXM: The second-generation personal computer software for internal dose assessment in nuclear medicine, J. Nucl. Med. **46** 6 (2005) 1023–1027.
[22] STABIN, M., Review: Nuclear medicine dosimetry, Phys. Med. Biol. **51** (2006) R187–R202.
[23] BARONE, R., et al., Patient-specific dosimetry in predicting renal toxicity with ^{90}Y-DOTATOC: Relevance of kidney volume and dose rate in finding a dose–effect relationship, J. Nucl. Med. **46** Suppl. 1 (2005) 99S–106S.
[24] CREMONESI, M., et al., Dosimetry for treatment with radiolabelled somatostatin analogues. A review, Q. J. Nucl. Med. Mol. Imaging **54** 1 (2010) 37–51.
[25] LASSMANN, M., et al., EANM Dosimetry Committee series on standard operational procedures for pre-therapeutic dosimetry I: Blood and bone marrow dosimetry in differentiated thyroid cancer therapy, Eur. J. Nucl. Med. Mol. Imaging **35** 7 (2008) 1405–1412.
[26] HAHNER, S., et al., [^{131}I]iodometomidate for targeted radionuclide therapy of advanced adrenocortical carcinoma, J. Clin. Endocrinol. Metab. **73** 3 (2012) 914–922.
[27] MINARIK, D., et al., ^{90}Y Bremsstrahlung imaging for absorbed-dose assessment in high-dose radioimmunotherapy, J. Nucl. Med. **51** 12 (2010) 1974–1978.

RADIATION PROTECTION OF PATIENTS AND STAFF IN INTERVENTIONAL PROCEDURES

(Session 5)

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RADIATION PROTECTION OF PATIENTS AND STAFF IN INTERVENTIONAL PROCEDURES

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Abstract

While radiation risks in most diagnostic radiological procedures (primarily risk of cancer) are uncertain and speculative, the radiation effects in interventional procedures have been documented both in patients and in staff. Every action to protect patients will result in a proportionate effect on staff protection, but the reverse is not true. When protection methods and tools are employed, the safety of patients and staff can be achieved.

1. INTRODUCTION

A number of procedures use fluoroscopy to guide interventions such as opening a blocked artery and inserting stents to keep an artery open, cutting off the blood supply to a tumour (embolization), taking a piece of tissue for testing (biopsy) and removing fluid from a diseased area. Most of these interventions replace open surgical procedures that are cumbersome and involve higher risks. Some interventional procedures involve managing complicated situations within the body and, thus, require a longer fluoroscopy time and consequently a higher radiation dose and radiation risk to the patient. While radiation risks in most diagnostic radiological procedures (primarily risk of cancer) are uncertain and speculative, the radiation risk with interventional procedures, such as skin injury that has been documented in a few hundred patients over the past two decades and continue to be reported every year, is visible [1, 2]. Cataracts in eyes of operators and support staff in interventional suites has also been documented [3–6] as has loss of hair on legs of staff [2].

2. WHO IS INVOLVED IN INTERVENTIONAL PROCEDURES?

An increasing number of clinical professionals are involved in performing interventional procedures. Initially, the procedures used to be performed in radiology departments with the support of radiologists, but currently are performed by cardiologists, electro-physiologists, vascular surgeons, orthopaedic surgeons, urologists, gastroenterologists, anaesthetists and others, either by themselves or with the support of radiologists. Among radiologists, a branch of interventional radiologists working in various specialties has emerged. Besides those directly performing interventional procedures, there are assistants, nurses, anaesthetists and, sometimes, technologists who tend to be in the interventional suite for a reasonable time with potential for higher exposures.

3. LACK OF TRAINING AND POTENTIAL FOR RADIATION RISKS

Unlike radiologists, clinical professionals in most countries lack training in radiation protection and it is only in recent years that some countries have initiated training for non-radiologists in radiation protection. Lack of training with high usage of radiation creates the potential for radiation risk to patients and staff. The International Commission on Radiological Protection recommends that the amount of training depend on the level of radiation employed at work, and the probability of overexposure of the patient or staff [7, 8].

The IAEA has been active in training interventionists, in particular interventional cardiologists [9] and doctors using fluoroscopy in operating theatres, such as urologists, orthopaedic surgeons, vascular surgeons and gastroenterologists. Moreover, the IAEA has made training material available, which can be freely downloaded for these specialists (see Section 6).

4. PATIENT PROTECTION

The protection of patients requires monitoring of patient dose, keeping irradiation time as short as possible, using a lower frame rate and a smaller number of frames, maintaining the highest possible distance from the X ray tube to the patient, keeping the image receptor as close to the patient as possible, and using filters and collimation, and lower magnification, among other things. Using the appropriate technique, it is possible to achieve patient protection in terms of avoidance of effects such as tissue reactions (primarily skin injuries), whereas stochastic effects such as cancer cannot be ruled out, but the probability can be minimized.

4.1. Skin injuries

It has been estimated that about 1680–3600 cases of skin injuries may occur globally every year from interventional procedures [2]. Since only a few cases are reported, most possibly remain undiagnosed and unreported. This poses a great challenge of awareness, detection, reporting and management. Although most reports of skin injuries have emanated from the United States of America, there have been reports in other countries too [2, 10, 11]. The usage of interventional procedures in many developing countries is as high as in developed countries, also in children [12]. There are reports of patients with a skin injury going from one hospital to another, but the diagnosis being missed and the patient finding a correlation of skin injury with the interventional procedure from the Internet. Although the number and frequency of skin injuries may be small, the agony associated with injury is substantial, at least for severe ones. Topical treatment is often ineffective. The patients may exhaust their insurance limits, may not be able to lie down on their back, cannot be at work for months, have pain and, in some cases, may require skin grafting.

4.2. Justification and appropriateness

There is a common belief that all interventional procedures are justified and that they are appropriate, unlike diagnostic examinations, where the magnitude of inappropriate examinations is reported to be high [13]. This is not really true in light of recent papers [14, 15]. In a large multicentre, prospective study of patients within the National Cardiovascular Data Registry of the USA undergoing percutaneous coronary intervention (PCI), between 1 July 2009 and 30 September 2010, at 1091 US hospitals, for non-acute indications, 12% were classified as inappropriate, with a substantial variation across hospitals [14]. In a complete cohort of PCIs performed in Washington state, 1% of PCIs for acute indications and 17% of PCIs for non-acute indications were classified as inappropriate [15].

5. STAFF PROTECTION

The common dictum is that every action to protect patients will result in a proportionate effect on staff protection, but the reverse is not true. For example, lead aprons worn by staff, as other protective devices, will protect staff significantly without any effect on patient protection. The major issue concerning staff protection is currently protection of the lens of the eye. Recent studies conducted in an IAEA project have documented a substantial risk of lens

opacities among staff in interventional suites [3–6]. There is a strong need for protection of the lens of the eye using a variety of protective devices which are very effective: ceiling suspended screen (when used properly), lead glass eye wear, zero gravity shields and other mobile screens. There is a need to use hanging curtains to protect the lower part of legs that remains unprotected by the lead apron.

6. IAEA RESOURCES FOR RADIATION PROTECTION IN INTERVENTIONAL PROCEDURES

— 10 Pearls: Radiation Protection of Patients in Fluoroscopy (poster), https://rpop.iaea.org/RPOP/RPoP/Content/Documents/Whitepapers/poster-patient-radiation-protection.pdf
— 10 Pearls: Radiation Protection of Staff in Fluoroscopy (poster), https://rpop.iaea.org/RPOP/RPoP/Content/Documents/Whitepapers/poster-staff-radiation-protection.pdf
— Interventional Fluoroscopy, https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/4_InterventionalRadiology/index.htm
— INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing Guidance Levels in X ray Guided Medical Interventional Procedures: A Pilot Study, Safety Reports Series No. 59, IAEA, Vienna (2009).
— INTERNATIONAL ATOMIC ENERGY AGENCY, Patient Dose Optimization in Fluoroscopically Guided Interventional Procedures, IAEA-TECDOC-1641, IAEA, Vienna (2010).
— IAEA Training Material for Free Download, https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/index.htm

REFERENCES

[1] REHANI, M.M., ORTIZ-LOPEZ, P., Radiation effects in fluoroscopically guided cardiac interventions — Keeping them under control, Int. J. Cardiol. **109** (2006) 147–151.
[2] REHANI, M.M., SRIMAHACHOTA, S., Skin injuries in interventional procedures, Radiat. Prot. Dosimetry **147** 1–2 (2011) 8–12.
[3] REHANI, M.M., VAÑO, E., CIRAJ-BJELAC, O., KLEIMAN, N.J., Radiation and cataract, Radiat. Prot. Dosimetry **147** 1–2 (2011) 300–304.

[4] CIRAJ-BJELAC, O., et al., Risk for radiation induced cataract for staff in interventional cardiology: Is there reason for concern? Catheter. Cardiovasc. Interv. **76** (2010) 826–834.
[5] CIRAJ-BJELAC, O., et al., Radiation induced eye lens changes and risk for cataract in interventional cardiology, Cardiology **123** 3 (2012) 168–171.
[6] VAÑO, E., KLEIMAN, N.J., DURAN, A., ROMANO-MILLER, M., REHANI, M.M., Radiation-associated lens opacities in catheterization personnel: Results of a survey and direct assessments, J. Vasc. Interv. Radiol. **24** 2 (2013) 197–204.
[7] INTERNATIONAL COMMSSION ON RADIOLOGICAL PROTECTION, Education and Training in Radiological Protection for Diagnostic and Interventional Procedures, Publication 113, Elsevier (2009).
[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Fluoroscopically Guided Procedures Performed outside the Imaging Department, Publication 117, Elsevier (2010) 1–102.
[9] REHANI, M.M., Training of interventional cardiologists in radiation protection — The IAEA's initiatives, Int. J. Cardiol. **114** (2007) 256–260.
[10] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Avoidance of Radiation Injuries from Medical Interventional Procedures, Publication 85, Pergamon Press, Oxford and New York (2000).
[11] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Cardiology, Publication 120, Elsevier (2013) 1–125.
[12] TSAPAKI, V., et al., Radiation exposure to patients during interventional procedures in 20 countries: Initial IAEA project results, AJR Am. J. Roentgenol. **193** 2 (2009) 559–569.
[13] REHANI, M., FRUSH, D., Tracking radiation exposure of patients, Lancet **376** 9743 (2010) 754–755.
[14] CHAN, P.S., et al., Appropriateness of percutaneous coronary intervention, JAMA **306** 1 (2011) 53–61.
[15] BRADLEY, S.M., MAYNARD, C., BRYSON, C.L., Appropriateness of percutaneous coronary interventions in Washington State, Circ. Cardiovasc. Qual. Outcomes **5** 4 (2012) 445–453.

IMPROVING PROTOCOLS AND PROCEDURES FOR STRENGTHENED RADIATION PROTECTION IN INTERVENTIONAL PROCEDURES

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Abstract

Fluoroscopic interventions in radiology and cardiology are the two most frequent procedures involving a significant radiation exposure of patients as well as an occupational exposure of staff. For example, the increase of coronary interventions in different European countries is in the range of 4–12% per year. Hence, there is increasing concern about radiation protection of patients and health care personnel. The majority of measures in radiation protection help to reduce the patient dose as well as occupational exposure. Furthermore, protective devices reduce personnel dose and some measures reduce dose and deterministic risks of patients. The paper gives an overview of the minimal requirements, current state of the art and future developments in radiation protection for patients and personnel.

1. TECHNICAL MINIMUM REQUIREMENTS FOR ALL INTERVENTIONAL FLUOROSCOPY SYSTEMS

— C-arm system with under table X ray tube (for monoplane system or first biplane tube);
— Pulsed fluoroscopy;
— Last image hold/run system;
— Automatic exposure control;
— Selectable dose and/or image quality for fluoroscopy and angiography mode;
— Removable grid;
— Additional filtration (copper filter, especially for children);
— Dose area product meter;
— Basic protective shielding;
— Contrast agent injector.

2. STATE OF THE ART TECHNIQUE FOR NEW INTERVENTIONAL FLUOROSCOPY SYSTEMS

— Flat panel detector;
— Simulation of table movement, collimation and wedges without radiation;
— Roadmapping, DSA overlay, store of fluoroloops;
— Second monitor for reference images;
— Third monitor for images of other modalities (computed tomography (CT), magnetic resonance imaging, ultrasound, cone beam CT, patient monitoring);
— Display of all exposure parameters, including thresholds for skin entrance dose;
— Automatic contrast agent injector with programmable flow protocols;
— DICOM (Digital Imaging and Communications in Medicine) store of exposure parameters (dose of fluoroscopy and every single series);
— Seamless protective under table shielding (Fig. 1(a));
— Additional over table shielding to reduce stray radiation from the patient (Fig. 1(b));
— Rotational angiography and/or cone beam CT for better 3-D visualization.

3. FUTURE TECHNICAL DEVELOPMENTS

— New flat panel detectors with higher quantum efficiency;
— Automatic monitoring of skin dose and exposed areas to control erythema threshold;
— Advanced post-processing for diagnostic image quality with reduced dose;
— Planning, navigation and control of procedures by cone beam CT [1].

4. RADIATION PROTECTION OF THE STAFF

Minimum protective devices for exposed staff should include a lead apron, a lead thyroid collar and lead goggles. Modern aprons are split into a skirt and a vest (Fig. 2). This reduces the weight on the shoulders by approximately 50% and, due to closing the overlapping skirt and vest in front of the body, causes a fourfold protection compared to the single lead thickness of a standard apron.

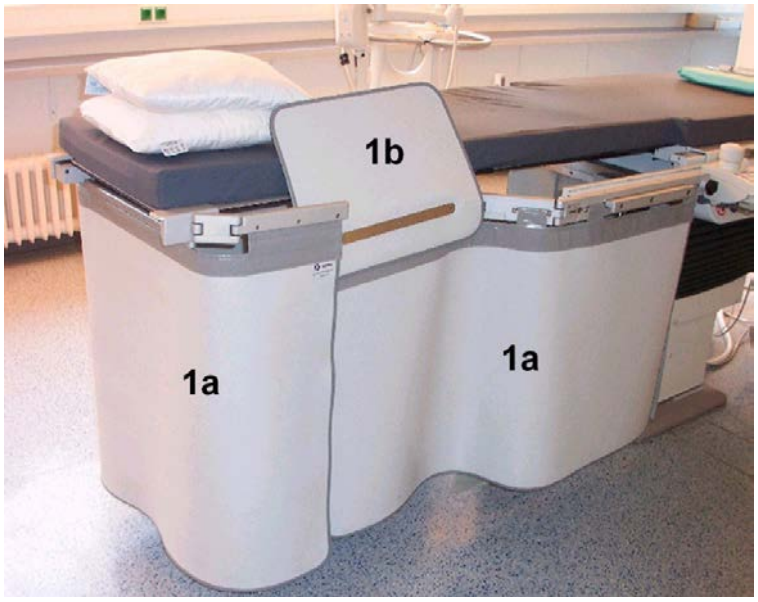

FIG. 1. (a) Optimized shielding of the X ray tube; (b) stray radiation from patient.

FIG. 2. Modern lead apron with overlapping frontal closure.

Published data on the effects of exposure on the lens of the eye increase concern about late effects, such as lens opacities or cataracts, for medical staff [2]. Hence, the use of lead goggles must be emphasized, since the International Commission on Radiological Protection recommended reducing the dose limit for occupational exposure of the lens of the eye from 150 to 20 mSv/a.

Furthermore, in addition to standard dosimetry under the apron, additional dosimetry above the apron and finger ring dosimeters are recommended in some countries. When performing many procedures where the hand or fingers are close to the radiation field, such as biliary interventions, the annual dose limit for extremities and skin of 500 mSv/a may be exceeded. Another procedure where high finger doses have been reported is the selective intra-arterial radiotherapy of liver metastases with β emitters (^{90}Y).

A useful tool increasingly being used to assess occupational exposure immediately is electronic dosimeters. Some of them can be used legally to replace film badges, others with small probes can be placed near the eyes, neck or fingers. It is recommended to use electronic dosimeters whenever new interventional procedures are introduced or the protocols of existing procedures are modified.

5. RADIATION PROTECTION OF STAFF AND PATIENTS

One of the most important measures to reduce patient and staff exposure is to lower the image frequency of pulsed fluoroscopy and the frame rate in angiography to an acceptable minimum without compromising image quality and the safety of the procedure. A typical reduction in cardiology is from 15 to 12.5 f/s [3]. Furthermore, avoiding extreme oblique angulations in cardiology helps to reduce patient and staff dose. In interventional radiology, acceptable low frame rates in fluoro mode are between 3 and 10 f/s. In DSA mode, frame rates of 1 to 7 f/s are sufficient for most examinations. Despite all optimizations of technical equipment and protocols, the training and experience of the interventional physician is one of the most important factors in radiation protection. Dose area product and fluoroscopy time may vary by a factor of five or more between different interventional radiologists or cardiologists.

REFERENCES

[1] ADAMUS, R., PFISTER, M., LOOSE, R.W., Enhancing transjugular intrahepatic portosystemic shunt puncture by using three-dimensional planning based on the back-projection of two two-dimensional portographs, Radiology **251** 2 (2009) 543–547.

[2] CHODICK, G., et al., Risk of cataract after exposure to low doses of ionizing radiation: A 20-year prospective cohort study among US radiologic technologists, Am. J. Epidemiol. **168** 6 (2008) 620–631.

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Training Material on Diagnostic and Interventional Radiology, Radiation Protection of Patients Web Site (RPOP), https://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/Radiology.htm

DIAGNOSTIC REFERENCE LEVELS IN INTERVENTIONAL PROCEDURES

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Abstract

International Commission on Radiological Protection recommendations and limitations on the use of diagnostic reference levels (DRLs) in interventional radiology are presented. The convenience of expanding their use as well as that of individual patient dose distributions to improve optimization are discussed. Some aspects subject to clarification are suggested, such as the disadvantage of using phantoms instead of patient dose values, the introduction of new imaging acquisition modalities, the standardization of the levels of complexity for some common procedures, the need to refine the methodology for establishing DRLs using different sample sizes, the balancing of two or more dose related quantities used to set DRLs, and the possibility of deriving trigger (alarm) levels. Studies have demonstrated that DRLs are useful for process optimization (in the setting of X ray systems, in protocols and in operational procedures). More advice is still needed to improve their utilization in optimization strategies related to stochastic effects but also to avoid tissue reactions (deterministic effects) when the full patient dose distribution is available in the data samples used.

1. INTRODUCTION

International Commission on Radiological Protection (ICRP) Publication 60 [1] proposed some recommendations on diagnostic reference levels (DRLs) that were later expanded in ICRP Publication 73 [2]. The DRL is a form of investigation level to identify unusually high levels, which calls for local review if consistently exceeded. In principle, there could also be a lower level (i.e. below which there is insufficient radiation dose to achieve a suitable medical image).

In 1996, the ICRP published the following advice on the use of DRLs for medical exposures:

> "In the protection of the patient, the detriments and the benefits are received by the same individual, the patient, and the dose to the patient is determined principally by the medical needs. Dose constraints for patients are therefore inappropriate, in contrast to their importance in occupational and public exposure. Nevertheless, some limitation of diagnostic medical exposures is needed and the use of a diagnostic reference level is recommended." [2]

In the wording of the ICRP:

> "The DRL will be intended for use as a simple test for identifying situations where the levels of patient dose are unusually high. If it is found that procedures are consistently causing the relevant DRL to be exceeded, there should be a local review of the procedures and the equipment in order to determine whether the protection has been adequately optimized. If not, measures aimed at reduction of the doses should be taken. Ideally, DRLs should be the result of a generic optimization of protection. In practice, this is unrealistically difficult and it is simpler to choose the initial values as a percentile point on the observed distribution of doses to patients" [2].

The ICRP also stated: "These levels, which are a form of investigation level, apply to an easily measured quantity, usually the absorbed dose in air, or in a tissue-equivalent material at the surface of a simple standard phantom or representative patient" [2].

However, in practice, if a standard phantom is used instead of clinical images to obtain DRLs, difficulties may arise when identifying the problems related to the optimization of imaging procedures. On the one hand, with phantoms, it is possible to identify whether X ray systems are set at a very high dose level (or set to obtain exceedingly high image quality). On the other hand, it is not possible to detect the lack of optimization in the use of image acquisition protocols (e.g. the use of medium or high dose fluoroscopy modes instead of low fluoroscopy mode) or other non-optimized operational details (e.g. lack of collimation or image detector positioned too far from the patient).

This is one of the topics that will be addressed by a working party on DRLs — created by Committee 3 of the ICRP in 2012 — together with the use of DRLs for interventional radiology. Many papers dealing with DRLs in fluoroscopy guided procedures have already been published [3–20].

2. ICRP RECOMMENDATIONS ON DIAGNOSTIC REFERENCE LEVELS FOR INTERVENTIONAL RADIOLOGY

In 2001, the ICRP provided additional advice on the application of DRLs in diagnostic and interventional radiology [21]. Achieving acceptable image quality or adequate diagnostic information, consistent with the medical imaging task was highlighted as the overriding clinical objective. DRLs should be used to help manage the radiation dose to patients, so that the dose is commensurate with the clinical purpose.

Typically, reference levels are used as investigation levels (i.e. as a quality assurance tool) and they are advisory. However, there are exceptions where the approach uses 'achievable levels' indicative of more optimum conditions. When reference levels apply to a selected medical imaging task, the clinical and technical conditions are often not fully defined, as the degree of definition depends on the aim. A number of different quantities have been used for reference levels. The quantity selected is dependent on the type of clinical procedure. A numerical value selected for one situation may not be applicable to different clinical and technical requirements, even if the same area of the body is being imaged [21].

To establish DRLs, a reference group of patients is usually defined within a certain range of physical parameters (e.g. height, weight). If an unselected sample of patients were used as a reference group, it would be difficult to interpret whether the observed value for the sample is higher or lower than the DRL. A DRL is not applied to individual patients.

A DRL can be used to improve a regional, national or local distribution of results observed for a general medical imaging task, by reducing the frequency of unjustified high or low values, to promote attainment of a narrower range of values that represent good practice for a more specific medical imaging task or to promote attainment of an optimum range of values for a specified medical imaging protocol.

For fluoroscopically guided interventional procedures, DRLs, in principle, could be used to promote the management of patient doses with regard to avoiding unnecessary stochastic radiation risks. However, the observed distribution of patient doses is very wide, even for a specified protocol, because the duration and complexity of the fluoroscopic exposure for each conduct of a procedure is strongly dependent on the individual clinical circumstances [21].

A potential approach is to take into consideration not only the usual clinical and technical factors, but also the relative 'complexity' of the procedure. More than one quantity (i.e. multiple DRLs) may be needed to evaluate patient dose and stochastic risk adequately [21].

DRLs are not applicable to the management of deterministic radiation risks (i.e. radiation induced skin injuries) from fluoroscopically guided interventional procedures. In this case, the objective is to avoid deterministic effects in individual patients undergoing justified, but long and complex procedures [2].

Cumulative air kerma values and some additional parameters related to the skin dose distribution, such as the peak skin dose, could prove useful to optimize the dose management for interventional procedures. The working party on DRLs created by Committee 3 of the ICRP will also discuss this topic.

The ICRP summarized the use of DRLs in diagnostic and interventional radiology in Publications 103 and 105 [22, 23].

3. POTENTIAL TO EXPAND THE USE OF DIAGNOSTIC REFERENCE LEVELS FOR INTERVENTIONAL RADIOLOGY

The concept of DRLs is unfortunately still not fully understood by many practitioners and referrers, and some key points should be included in the basic education programmes on radiological protection [24, 25].

Optimization is a challenge in many of the new imaging modalities and new image acquisition protocols. Manufacturers have made an impressive effort in the last few years in hardware and in post-processing tools to reduce patient doses while maintaining or improving image quality.

In the past, mean or median values of different dosimetric quantities were calculated using a small sample of procedures. With the introduction of digital systems, it is now possible to easily collect and archive dosimetric and demographic data of all the imaging procedures as part of the digital imaging and communications in medicine (DICOM) headers or using other DICOM services such as modality performed procedure step (MPPS) or radiation dose structured reports (RDSRs) [26, 27].

The analysis of the results needs to be subjected to quality control and should include: (a) periodic calibration factors for patient dose quantities reported by the X ray systems; (b) automatic detection and alerts of high patient dose values; (c) statistical analysis providing the possibility to update local DRLs and draw comparisons with the national or regional existing DRLs; and (d) suggestion of prompt corrective actions to fulfill quality assurance programmes and clinical audit requirements.

The advantages stemming from digital imaging technology are the following: (a) possibility of processing data from all the procedures (instead of a reduced sample); (b) possibility of doing it automatically; and (c) possibility of processing other procedure data (e.g. geometry details such as C-arm angulation and distances, collimation, use of wedge filters) in addition to dosimetric

parameters. The distribution of patient dose values in a hospital may be analysed in full and not just by using some statistical descriptors (such as median or mean values). Optimization actions can be launched when median or mean values are consistently much higher or much lower than the DRLs as in the past, but also when other parameters are out of the normal range (e.g. the imaging detector is positioned far from the patient or collimation is not used) or when individual patients receive doses higher than several times the value of DRLs. This automatic massive collection and processing of data in real time will be used, when appropriate, to calculate organ patient doses or skin dose maps in order to decide whether some patients should be included in a follow-up protocol for tissue reactions (deterministic effects).

Some experiences for developing automatic management systems have already been made in interventional radiology: one of them, called DOLIR (dose on line for interventional radiology) archives and analyses the major study parameters and patient doses for fluoroscopy guided procedures performed in cardiology and interventional radiology [28].

The European regulations and guidelines suggest that patient doses from interventional procedures should be measured and recorded [29]. In some European countries, this measurement and registration is mandatory, and in the coming new European Directive on Basic Safety Standards [30], this requirement will probably be included as one of the articles in the Directive.

The Society of Interventional Radiology Standards of Practice Committee in North America has recently published an article on quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures [31]. The article states that, ideally, all available patient radiation dose data should be recorded, and recognizes that in the future, this may become an automatic process, as the US Food and Drug Administration has expressed an intention to establish requirements for computed tomography and fluoroscopic devices to provide radiation dose information for use in patient medical records or a radiation dose registry. The guideline suggests adequate recording of different dose metrics for all interventional procedures requiring fluoroscopy, including skin dose mapping. It also suggests establishing thresholds to prompt reviews.

The National Council on Radiation Protection and Measurements (NCRP) in the United States of America has recently published a report on DRLs [32]. Achievable doses represent the median (50th percentile) of the dose distribution, which means that 50% of facilities are operating below this level. The Health Protection Agency (formerly the National Radiological Protection Board) in the United Kingdom has used DRLs (usually considered as the 75th percentile) and achievable doses. DRLs and achievable doses are dynamic values that change over time and with changes in technology [6, 32, 33].

The term ‘substantial radiation dose levels’ (SRDLs) defined as “values below which tissue reactions (deterministic effects) are highly unlikely and above which radiation injuries are possible” is also used in the NCRP publications [32, 34].

The term ‘diagnostic reference levels’ may be confusing for interventional therapeutic procedures and the ICRP might consider the use of a new term in the future. One option could be ‘interventional reference level’.

4. TOPICS LIKELY TO NEED ADDITIONAL ADVICE FOR BETTER OPTIMIZATION

The working party launched by Committee 3 of ICRP in 2012 is expected to discuss the possibility of giving more specific advice on the use of DRLs in new medical imaging techniques and interventional procedures to help with optimization.

Some of the aspects subject to further clarification in interventional radiology could be:

— The use of phantoms versus patient dose values: Phantom based approaches only deal (in general) with equipment issues, while patient dose metric approaches deal with procedure and operator variation.
— DRLs linked to image quality or diagnostic information for different clinical tasks: New imaging acquisition modalities (rotational, cone beam CT, etc.) versus conventional cine or digital subtraction angiography series should be considered.
— Standardization and consensus on the levels of complexity for some common procedures and the impact on DRLs [3, 4, 18].
— Deriving DRLs from different sample sizes (number of procedures per centre) and from centres with very different workloads.
— Balancing the relevance of two or more dose related quantities used to set DRLs (e.g. KAP, cumulative air kerma, number of images, fluoroscopy time) [35–37].
— Recommended periodicity to update DRLs, and factors to be considered to establish such periodicity.
— Possibility of deriving trigger (alarm) levels from DRLs (values two or three times higher than DRLs) to investigate individual cases of high dose values; also considering the number of procedures over the SRDL defined as “values below which tissue reactions (deterministic effects) are highly unlikely and above which radiation injuries are possible” [32, 34] as part of the optimization.

— Exploitation of the full individual patient dose distributions in addition to DRLs to help with optimization [38].
— Use of DRLs as part of the clinical audit: Advantages and limitations.
— Corrections (tolerances) for heavy patients (or for some special groups of patients or pathologies).

5. CONCLUSIONS

DRLs are already being used for fluoroscopy guided interventional procedures and they have proved to be a very useful tool to help with optimization (in the setting of X ray systems, in the protocols used and in the operational procedures). More advice from the ICRP is still needed to clarify some aspects of optimization strategies that would take into account not only stochastic effects but also tissue reactions (deterministic effects). When the full patient dose distribution is available in the data samples used, other optimization options could be considered and implemented (such as decreasing high dose tails in the distributions and discriminating individual high dose values for clinical follow-up).

REFERENCES

[1] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the ICRP, Publication 60, Pergamon Press, Oxford and New York (1991).
[2] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection and Safety in Medicine, Publication 73, Pergamon Press, Oxford and New York (1996).
[3] BALTER, S., et al., A pilot study exploring the possibility of establishing guidance levels in X-ray directed interventional procedures, Med. Phys. **35** 2 (2008) 673–680.
[4] BERNARDI, G., et al., Clinical and technical determinants of the complexity of percutaneous transluminal coronary angioplasty procedures: Analysis in relation to radiation exposure parameters, Catheter. Cardiovasc. Interv. **51** 1 (2000) 1–9.
[5] GRAY, J.E., et al., Reference values for diagnostic radiology: Application and impact, Radiology **235** 2 (2005) 354–358.
[6] HART, D., HILLIER, M.C., SHRIMPTON, P.C., Doses to Patients from Radiographic and Fluoroscopic X-ray Imaging Procedures in the UK — 2010 Review, Rep. HPA-CRCE-034, Health Protection Agency, Chilton, Didcot (2012).
[7] INTERNATIONAL ATOMIC ENERGY AGENCY, Establishing Guidance Levels in X ray Guided Medical Interventional Procedures: A Pilot Study, Safety Reports Series No. 59, IAEA, Vienna (2009).

[8] MARSHALL, N.W., CHAPPLE, C.L., KOTRE, C.J. Diagnostic reference levels in interventional radiology, Phys. Med. Biol. **45** 12 (2000) 3833–3846.
[9] MILLER, D.L., et al., Clinical radiation management for fluoroscopically guided interventional procedures, Radiology **257** 2 (2010) 321–332.
[10] MILLER, D.L., et al., Radiation doses in interventional radiology procedures: The RAD-IR study Part I. Overall measures of dose, J. Vasc. Interv. Radiol. **14** 6 (2003) 711–727.
[11] MILLER, D.L., KWON, D., BONAVIA, G.H., Reference levels for patient radiation doses in interventional radiology: Proposed initial values for U.S. practice, Radiology **253** 3 (2009) 753–764.
[12] NEOFOTISTOU, V., et al., Preliminary reference levels in interventional cardiology, Eur. Radiol. **13** 10 (2003) 2259–2263.
[13] PETERZOL, A., et al., Reference levels in PTCA as a function of procedure complexity, Radiat. Prot. Dosimetry **117** 1–3 (2005) 54–58.
[14] SÁNCHEZ, R., et al., A national programme for patient and staff dose monitoring in interventional cardiology, Radiat. Prot. Dosimetry **147** 1–2 (2011) 57–61.
[15] STECKER, M.S., et al., Guidelines for patient radiation dose management, J. Vasc. Interv. Radiol. **20** 7 Suppl. (2009) S263–273.
[16] VAÑO, E., et al., Importance of dose settings in the X-ray systems used for interventional radiology: A national survey, Cardiovasc. Intervent. Radiol. **32** 1 (2009) 121–126.
[17] VAÑO, E., et al., Patient dose reference levels for interventional radiology: A national approach, Cardiovasc. Intervent. Radiol. **32** 1 (2009) 19–24.
[18] VEHMAS, T., Radiation exposure during standard and complex interventional procedures, Br. J. Radiol. **70** (1997) 296–298.
[19] WALL, B.F., Diagnostic reference levels — The way forward, Br. J. Radiol. **74** 885 (2001) 785–788.
[20] WALL, B.F., SHRIMPTON, P.C., The historical development of reference doses in diagnostic radiology, Radiat. Prot. Dosimetry **80** 1–3 (1998) 15–19.
[21] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Diagnostic reference levels in medical imaging: Review and additional advice, ICRP Supporting Guidance 2, Ann. ICRP **31** 4 (2001) 33–52.
[22] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, Publication 103, Pergamon Press, Oxford and New York (2007).
[23] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Medicine, Publication No. 105, Pergamon Press, Oxford and New York (2007).
[24] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Education and Training in Radiological Protection for Diagnostic and Interventional Procedures, Publication 113, Pergamon Press, Oxford and New York (2009).
[25] VAÑO, E., GONZALEZ, L., Approaches to establishing reference levels in interventional radiology, Radiat. Prot. Dosimetry **94** 1–2 (2001) 109–112.
[26] VAÑO, E., et al., Patient dosimetry and image quality in digital radiology from online audit of the X-ray system, Radiat. Prot. Dosimetry **117** 1–3 (2005) 199–203.

[27] VAÑO, E., et al., Transition from screen-film to digital radiography: Evolution of patient radiation doses at projection radiography, Radiology **243** 2 (2007) 461–466.
[28] TEN, J.I., FERNANDEZ, J.M., VAÑO, E., Automatic management system for dose parameters in interventional radiology and cardiology, Radiat. Prot. Dosimetry **147** 1–2 (2011) 325–328.
[29] EUROPEAN COMMISSION, Council Directive 97/43/EURATOM of 30 June 1997 on Health Protection of Individuals against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/EURATOM, Official Journal of the European Communities No. L 180/22-27, 9.7.1997.
[30] EUROPEAN COMMISSION, Proposal for a Council Directive Laying Down Basic Safety Standards for Protection against the Dangers Arising from Exposure to Ionising Radiation, Brussels, 30.05.2012, COM(2012) 242 final, http://ec.europa.eu/energy/nuclear/radiation_protection/doc/2012_com_242.pdf
[31] MILLER, D.L., et al., Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures, J. Vasc. Interv. Radiol. **23** 1 (2012) 11–18.
[32] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States, NCRP Report 172, NCRP, Bethesda, MD (2012).
[33] INSTITUTE OF PHYSICS AND ENGINEERING IN MEDICINE, Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-ray Examinations, IPEM Report 88, IPEM, York (2004).
[34] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Radiation Dose Management for Fluoroscopically-guided Interventional Medical Procedures, NCRP Report 168, NCRP, Bethesda, MD (2010).
[35] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Part 2-43: Particular Requirements for the Safety of X-ray Equipment for Interventional Procedures, 2nd edn, IEC Report 60601, IEC, Geneva (2010).
[36] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Cardiology, Publication 120, Elsevier (2013).
[37] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Fluoroscopically Guided Procedures Outside the Imaging Department, Publication 117, Elsevier (2010).
[38] INTERNATIONAL ATOMIC ENERGY AGENCY, Joint Position Statement on the IAEA Patient Radiation Exposure Tracking, https://rpop.iaea.org/RPOP/RPoP/Content/News/position-statement-IAEA-exposure-tracking.htm

ASSESSING AND REDUCING EXPOSURES TO CARDIOLOGY STAFF

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Abstract

Interventional radiology and interventional cardiology practices represent the highest radiological workload in hospitals and have the potential for high exposures to staff operating near patients. The IAEA has promoted the Information System on Occupational Exposure in Medicine, Industry and Research (ISEMIR) project where the working group on interventional cardiology assessed levels of exposure and methods applied for individual monitoring, and designed an international database of occupational exposures. Worldwide surveys of interventional cardiologists from 32 countries and 81 regulatory bodies from 55 countries provided information on dosimetry practice: only 57% of regulatory bodies define the number and/or position of dosimeters for staff monitoring and less than 40% could provide doses. The survey results proved poor compliance with staff monitoring recommendations in a large fraction of hospitals and the need for staff monitoring harmonization and monitoring technology advancements. Given the new occupational dose limit for the lens of the eye, the existence of high eye doses in interventional cardiology practice and the general lack of knowledge of actual eye doses in interventional cardiology (and other similar interventional practices), ISEMIR recommends improving training in occupational radiation protection and monitoring methods for assessing eye lens doses, and urging hospital management to utilize the international database under development for benchmarking occupational doses in interventional cardiology and, hence, improve optimization of protection.

1. INTRODUCTION

Interventional radiology and interventional cardiology (IC) practices represent the highest radiological workload in hospitals and have the potential for high exposures to staff operating near patients. In fact, the interventionalist doctor operates in a radiation area where a cumulative annual equivalent ambient dose up to 2 Sv at about 0.8 m from the scattering body area of the patient can be reached.

Over the past few decades, methodologies for personnel monitoring have been developed, including the development of specific dose quantities and monitoring protocols to estimate exposures of personnel working near sources of scattered radiation and wearing protective tools [1–3].

In 2009, the IAEA initiated the Information System on Occupational Exposure in Medicine, Industry and Research (ISEMIR) project to help improve occupational radiation protection practice in targeted areas of medicine, research and industry, where non-trivial occupational exposures occur. A final goal is to establish an international database for the regular collection of occupational dose data in targeted areas of radiation use in medicine, industry and research. Within ISEMIR, a working group on interventional cardiology was set up to assess radiation protection practice and occupational exposure to workers involved in IC. Its main objectives are to gain a worldwide overview of the current situation in this field, identify good practices and deficiencies, and define actions to be implemented to improve occupational radiation protection practice in IC. This paper reports the results of international surveys on requirements for staff dosimetry and on dose data availability at the country and hospital level, recommendations for the improvement of staff monitoring, including the development of monitoring technologies, standards and information systems, and the need for the training certification of operators in IC.

2. STAFF MONITORING PRACTICE AND EXPOSURE LEVELS

ISEMIR sent questionnaires to 191 radiation regulatory bodies in 136 countries and to a sample of IC services. Eighty one regulatory bodies answered and only 50% provided some occupational dose data. Of these, there was a wide variety of responses, ranging from detailed, accurate dose values to data that were inconsistent and/or ambiguous. The others stated that they were not able to provide occupational dose data for IC. The reported annual median effective dose values were lower than expected considering validated data from facility specific studies, indicating that compliance with continuous individual monitoring is often not achieved in IC [4–8]. For the survey of cardiologists, the convenience sample included nearly 200 cardiologists from 32 countries, and 45 IC facilities from 24 countries from all regions of the world. Concerning the dosimetry aspects of IC: 72% of cardiologists claim to always use their personal dosimeter, with 36% always using two, and only 26% of cardiologists knew their personal doses. This probably over-optimistic picture is indicative of the fact that dosimeters are not always used and different monitoring protocols are applied. In fact, concerning requirements for wearing dosimeters, only 57% of regulatory

bodies (45 out of 79) define the number and/or position of dosimeters for staff monitoring in IC (Table 1).

TABLE 1. NUMBER OF PERSONAL DOSIMETERS MANDATED BY REGULATORY BODIES FOR INTERVENTIONAL CARDIOLOGY

Region	Number of regulatory bodies mandating the number and/or position of dosimeters	Number of dosimeters required			
		1	2	3	Not specified
Africa	3	1	1	0	1
Asia Pacific	8	0	2	0	6
Europe	19	10	2	1	6
Latin America	2	0	1	0	1
North America	13	7	3	0	3
Global	45	18 (40)	9 (20)	1 (2)	17 (38)

In another survey, 20 hospitals in 15 countries provided staff dose data and individual workload. The mean (maximum) over apron personal dose equivalent $H_p(10)$ was: 7.6 (42.3), 6.1 (26.3) and 3.4 (14.6) mSv/a, respectively for haemodynamists and electrophysiologists (interventional cardiologists), and nurses.

The left panel of Fig. 1 reports the over apron $H_p(10)$ annual doses for interventional cardiologists versus the number of IC procedures performed. The great number of unrealistic zero values were analysed, taking into account factors such as dose reporting consistency and dose value consistency. The development of a quality factor made it possible to filter dose data (right panel in Fig. 1), obtaining a better relationship of dose values with workload.

These results prove the existence of large exposures in IC facilities. As over apron dose is an indicator of eye lens dose, it can be assumed that a large fraction of interventional cardiologists are receiving annual eye lens dose in excess of the new dose limit recommended by the International Commission on Radiological Protection (ICRP).

A confirmation of the existing high level of exposure of the eyes is derived from a survey performed recently in Italy, showing that, in a large number of hospitals, mean and maximum eye lens doses received by haemodynamists and

electrophysiologists exceed the new ICRP eye dose limit (Fig. 2). Much lower mean doses are reported for nurses and technologists working in the IC room but at a larger distance from the patient; these only rarely exceed the 20 mSv eye dose limit.

In summary, for staff monitoring and staff dose levels in IC:

— There is a lack of knowledge of actual doses;
— There is a large variability of doses;
— There is a great number of unrealistic zero dose values;
— Individual high dose values indicate the existence of high exposures in IC practice;
— Probably a large fraction of interventionalists receive annual eye lens doses well over 20 mSv/a.

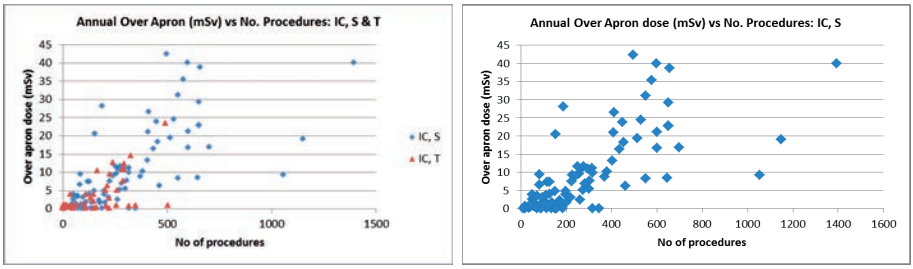

FIG. 1. Over apron annual dose versus number of interventional cardiology procedures performed in a year for interventional cardiologists (IC), staff in training (T) and staff (S). In the right panel, only the more reliable data are plotted [9].

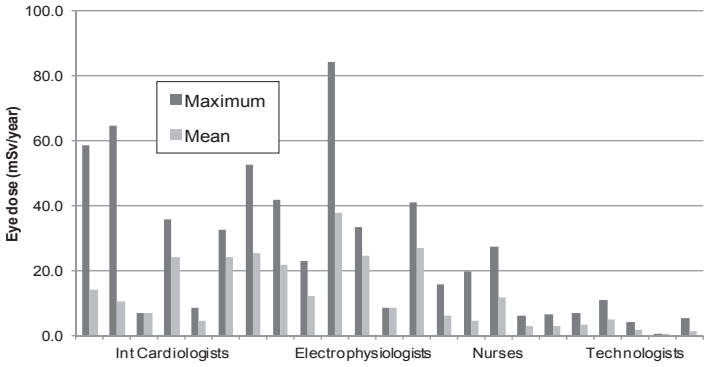

FIG. 2. Over apron mean and maximum annual dose of haemodynamists, electrophysiologists, nurses and technologists in a sample of ten Italian hospitals [10].

3. DOSE ASSESSMENT

ICRP Publication 85 [11] requires the use of robust and adequate monitoring for staff, specifying that a single dosimeter worn under the lead apron yields a reasonable estimate of effective dose and wearing an additional dosimeter at collar level above the lead apron provides an indication of head and eye dose. Several authors have assessed different algorithms to estimate the effective dose from the reading of the over and under apron dosimeters. However, because several factors influence dosimeter readings (e.g. operator position, tube voltage and X ray projection, position of the dosimeter on the operator's body, apron thickness), a large range of effective dose overestimation exists as reported in Table 2 [1].

TABLE 2. OVERESTIMATION OF DOUBLE DOSIMETER ALGORITHMS TO ASSESS EFFECTIVE DOSE FROM UNDER (A) AND OVER APRON (B) DOSIMETER $H_p(10)$ READINGS [1]

Double dosimeter algorithm from Ref. No.	Maximum overestimation of E by a factor of			Maximum underestimation of E by a factor of	
	Others	Schulz	Siiskonen et al.	Others	Schulz
[12]	Up to 1.89	2.25	6.7	Up to 3.3	1.2
[13]	Up to 2.03		16.7		
[14]	<2	2	5.6		1.3
[15]	Up to 1.5	3	9.1		
[16]		4.5	13.4		

Eye exposure measure is influenced by the use of suspended screen, lead glasses, operator position and X ray projection. Eye monitoring can be performed with specifically designed eye dosimeters, measuring and calibrated for $H_p(3)$, difficult for continuous use in practice. More frequently, eye dose is estimated from the reading of a dosimeter at the neck over the apron, applying correction factors in the range of 0.4–0.9, or a mean value of 0.75 as suggested in Ref. [2]. Another source of uncertainty derives from the different level of protection of eyeglasses that, because radiation usually comes from below, causes protection

differences between eyewear models due to the gap created between the eyewear and the cheek and the nose [3]. For all these reasons, the accuracy of eye lens dose estimation is very low and, probably, not acceptable for dose levels of the same order of the dose limit.

The monitoring of hand dose is required mainly in electrophysiology. For the high gradient of dose when the hand is near the X ray field edge, the measurement should be performed with a ring dosimeter facing the X ray tube on the little or ring finger of the most exposed hand. In this case, the accuracy estimated is 10–30% compared to an underestimation up to a factor of three for a bracelet dosimeter [2].

In summary, improvements in dose monitoring are necessary to:

— Develop a more robust monitoring system increasing the accuracy of effective dose and, mainly, eye lens dose assessment;
— Develop active dosimeters designed for interventional practice to provide doses in real time.

4. DOSE REDUCTION METHODS AND RECOMMENDATIONS

As staff exposure in IC is correlated to patient exposure, well known methods to reduce patient exposure: optimization of procedure protocol and proper settings of radiological equipment will help to reduce staff exposure.

Education and training in radiation protection is the primary action to implement. Several guidelines and training tools have been developed over the past decade, and training and training certification should be mandatory by law.

Optimization tools should be developed to assist staff exposure optimization: achievable and investigation levels expressed in dose per patient dose unit and procedure type should be assessed and adopted, together with the achievable and reference levels for patient exposure optimization.

Implementation of internal and/or external audits, as requested by the European Union's Medical Exposure Directive [17] and recommended by the IAEA, is another powerful tool aiming to identify poor practices, and countries should be advised to develop methods and set up audit teams.

These methods can have better efficacy if information systems collecting patient and staff exposures become available. International and standardization bodies should develop standards and manufacturers should develop instruments able to provide integrated information to practitioners and audit teams. The advent of Digital Imaging and Communications in Medicine (DICOM) radiation dose structured reports (RDSRs) and the Radiation Exposure Monitoring profile

(REM, IHE) are good examples of recent standards aiming to support hospital information systems.

Finally, given the new occupational dose limit for the lens of the eye, the potential for high doses in IC practice and the general lack of knowledge of actual eye doses in IC (and other similar interventional practices), ISEMIR recommends improving training in occupational radiation protection and monitoring methods for assessing lens doses, and urging hospital management to utilize the international database under development for benchmarking occupational doses in IC and, hence, improve optimization of protection.

REFERENCES

[1] SCHULTZ, F.W., ZOETELIEF, J., Estimating effective dose for a cardiac catheterisation procedure with single or double personal dosemeters, Radiat. Prot. Dosimetry **118** 2 (2006) 196–204.

[2] MARTIN, C.J., Personal dosimetry for interventional operators: When and how should monitoring be done? Br. J. Radiol. **84** 1003 (2011) 639–648.

[3] GEBER, T., GUNNARSSON, M., MATTSSON, S., Eye lens dosimetry for interventional procedures — Relation between the absorbed dose to the lens and dose at measurement positions, Radiat. Meas. **46** 11 (2011) 1248–1251.

[4] TRIANNI, A., et al., Dose to cardiologists in haemodynamic and electrophysiology cardiac interventional procedures, Radiat. Prot. Dosimetry **117** 1–3 (2005) 111–115.

[5] DELICHAS, M., et al., Radiation exposure to cardiologists performing interventional cardiology procedures, Eur. J. Radiol. **48** 3 (2003) 268–273.

[6] VAÑO, E., et al., Radiation exposure to medical staff in interventional and cardiac radiology, Br. J. Radiol. **71** 849 (1998) 954–960.

[7] KARPPINEN, J., PARVIAINEN, T., SERVOMAA, A., KOMPPA, T., Radiation risk and exposure of radiologists and patients during coronary angiography and percutaneous transluminal coronary angioplasty (PTCA), Radiat. Prot. Dosimetry **57** 1–4 (1995) 481–485.

[8] BOR, D., et al., Assessment of radiation dose to cardiologists during interventional examinations, Med. Phys. **36** 8 (2009) 3730–3736.

[9] PADOVANI, R., et al., International project on individual monitoring and radiation exposure levels in interventional cardiology, Radiat. Prot. Dosimetry **144** 1–4 (2011) 437–441.

[10] ISS/AOUD Project, personal communication (2012).

[11] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Avoidance of Radiation Injuries from Medical Interventional Procedures, Publication 85, Pergamon Press, Oxford and New York (2000).

[12] ROSENSTEIN, M., WEBSTER, E.W., Effective dose to personnel wearing protective aprons during fluoroscopy and interventional radiology, Health Phys. **67** 1 (1994) 88–89.

[13] NATIONAL COUNCIL ON RADIATION PROTECTION & MEASUREMENTS, Use of Personal Monitors to Estimate Effective Dose Equivalent and Effective Dose to Workers for External Exposure to Low-LET Radiation, Report No. 122, NCRP, Bethesda, MD (1994).

[14] NIKLASON, L., MARX, M., CHAN H., The estimation of occupational effective dose in diagnostic radiology with two dosimeters. Health Phys. **67** 6 (1994) 611-615.

[15] FRANKEN, Y., HUYSKENS, C.J., "Guidance on the use of protective lead aprons in medical radiology: protection efficiency and correction factors for personal dosimetry", paper 17, presented at 6th European ALARA Network Workshop, Madrid, 2002.
http://www.eu-alara.net/images/stories/pdf/program6/Session%20E/Y_Franken.pdf

[16] SWISS FEDERAL COUNCIL, Radiological Protection Ordinance, SR 814.501, Federal Authorities of the Swiss Confederation, Bern (1999).

[17] EUROPEAN COMMISSION, Council Directive 97/43/EURATOM of 30 June 1997 on Health Protection of Individuals against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/EURATOM, Official Journal of the European Communities No. L 180/22-27, 9.7.1997.

RADIATION PROTECTION OF PATIENTS IN COMPUTED TOMOGRAPHY

(Session 6)

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RADIATION PROTECTION OF PATIENTS IN COMPUTED TOMOGRAPHY

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The use of radiation for medical diagnostic examinations contributes over 95% of human-made radiation exposure and is only exceeded by natural background as a source of exposure to the world's population. In fact, for several developed countries, the increased use of high dose X ray technology, in particular, computed tomography (CT), has resulted in a situation in which the annual collective and per capita doses of ionizing radiation due to diagnostic radiology have exceeded those from natural background radiation [1]. In light of this marked increase in worldwide collective effective dose from medical diagnostic procedures, and with CT scans accounting for half of this, there is great emphasis on the subject of radiation protection of patients in CT.

On the issue of justification, clinical audits have found a disturbing incidence of inappropriate use of CT, to the degree of at least 25% of scans [2, 3]. Although many resources have been allocated to the setting up of referral guidelines/appropriateness criteria by various national radiological societies, institutions and commissions [4–6], more efforts to address this gap are required, through understanding the issues behind the failure of proper justification and increased awareness through education. The possible causes of poor justification include the practice of self-referral, financially motivated referrals, reimbursement patterns, the practice of defensive medicine and low levels of knowledge of the radiation doses involved in radiological procedures [7].

With regard to dose and optimization, exciting developments in dose reduction are being achieved through improved technology of CT scanners. We are now at the brink of an era of submillisievert CT scans [8]. Overall, there have been great strides made in improving dose optimization, including for paediatric CT with regard to child sizing dose parameters and the development and updating of country-wide DRLs for paediatric CT protocols [9, 10].

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However, it was found in a survey of developing countries that some still use adult CT protocols, and marked variations in dose exposure ($CTDI_{vol}$/DLP) was found across institutions [11, 12].

Further dose reduction may be gained from protocols being optimized for various specific clinical indications instead of having broad generic protocols.

New and evolving applications of CT in hybrid modalities, e.g. positron emission tomography (PET)/CT and single photon emission computed tomography (SPECT)/CT, should be closely monitored and evaluated in terms of appropriateness and dose exposure. In a recent statement by the Society of Nuclear Medicine and Molecular Imaging, it was recommended that PET/CT should not be used for cancer screening in healthy individuals.

Finally, institutions are encouraged to implement audit programmes to monitor appropriateness and dose optimization of CT as part of ongoing continuous quality improvement activities, and to have a rigorous system of reporting errors and events.

REFERENCES

[1] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2008 Report to the General Assembly with Scientific Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).

[2] OIKARINEN, H., et al., Unjustified CT examinations in young patients, Eur. Radiol. **19** 5 (2009) 1161–1165.

[3] BRENNER, D.J., HALL, E.J., Current concepts: Computed tomography — An increasing source of radiation exposure, N. Engl. J. Med. **357** (2007) 2277–2284.

[4] AMERICAN COLLEGE OF RADIOLOGY, ACR Appropriateness Criteria (2013), http://www.acr.org/Quality-Safety/Appropriateness-Criteria

[5] ROYAL COLLEGE OF RADIOLOGISTS, iRefer: Making the Best Use of Clinical Radiology, 7th edn, The Royal College of Radiologists, London (2012).

[6] EUROPEAN COMMISSION, Referral Guidelines for Imaging, Radiation Protection 118, Office for Official Publications of the European Communities, Luxembourg (2001).

[7] MALONE, J., et al., Justification of diagnostic medical exposures: Some practical issues. Report of an International Atomic Energy Agency Consultation, Br. J. Radiol. **85** 1013 (2012) 523–538.

[8] McCOLLOUGH, C.H., et al., Achieving routine submillisievert CT scanning: Report from the summit on management of radiation dose in CT, Radiology **264** 2 (2012) 567–580.

[9] THOMAS, K.E., CT utilization — Trends and developments beyond the United States' borders, Pediatr. Radiol. **41** Suppl. 2 (2011) 562–566.

[10] BERNIER, M.O., et al., Radiation exposure from CT in early childhood: A French large-scale multicentre study, Br. J. Radiol. **85** 1009 (2012) 53–60.
[11] VASSILEVA, J., et al., IAEA survey of paediatric computed tomography practice in 40 countries in Asia, Europe, Latin America and Africa: Procedures and protocols, Eur. Radiol. **23** 3 (2013) 623–631.
[12] MUHOGORA, W.E., et al., Paediatric CT examinations in 19 developing countries: Frequency and radiation dose, Radiat. Prot. Dosimetry **140** 1 (2010) 49–58.

NEW DEVELOPMENTS IN COMPUTED TOMOGRAPHY TECHNOLOGY AND THEIR IMPACT ON PATIENT PROTECTION

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X ray computed tomography (CT) has seen remarkable developments over the last three decades. Both methodological advances, such as the introduction of spiral CT scanning, and technological advances, such as the introduction of multi-row detectors, have led to impressive increases in performance. Whole body scans in just a few seconds with submillimetre spatial resolution are possible today. In addition, cardiac imaging at very high temporal resolution is routinely performed, offering motion-free diagnosis of the coronary artery tree. As a consequence, the number of CT applications has increased tremendously and the benefit for the patient has also increased. As a direct consequence, the cumulative exposure to the population increased. The latter figure is not necessarily relevant, as only patients are exposed when a relevant indication is given but not the general public. We must, therefore, look at the dose to the patient per examination. Fortunately, the technological developments of the past have not only provided improved diagnostic capabilities but also ways of limiting or reducing patient dose significantly.

There are comprehensive data on the exposure to the patient per examination category in the European Union. The European Commission Radiation Protection Report [1], for example, states that the effective dose per examination was, on average, below 10 mSv in the early 2000s. The optimization and the ALARA (as low as reasonably achievable) principle demand that dose is reduced as far as reasonably achievable. Developments in CT since the early 2000s also aimed at reducing patient dose. Quite a number of technological advances were introduced over the past decade; a list of five important steps to be considered is given in Table 1.

TABLE 1. NEW DEVELOPMENTS IN COMPUTED TOMOGRAPHY TECHNOLOGY AIMING AT THE REDUCTION OF PATIENT DOSE

1. Optimized choice of X ray spectra
2. Improved X ray beam collimation
3. Automated exposure control
4. Noise reducing image reconstruction
5. Dose efficient X ray detectors

Considerations regarding the optimal choice of X ray spectra have been neglected for many decades. From the early 1970s, 120 kV was the commonly used voltage value since the respective technology was available. It also seemed to be a good compromise between high enough intensity and penetration power. It has been shown [2] that a significant potential for dose reduction without impairing image quality is possible. Whenever high contrast materials, such as bone or contrast media are to be imaged, a reduction of voltage is indicated. For example, contrast enhanced CT coronary angiography can be carried out at dose levels reduced by 40–50% in small and medium sized patients when switching to 80 kV. This, of course, demands support by the manufacturer, but it has been shown in many studies that adaptations are feasible and very beneficial for patients, especially in paediatric CT. Low kV protocols are becoming more popular.

Dose efficiency can also be improved with respect to X ray collimation. This refers to subtle effects, mostly in spiral scanning, referred to as overbeaming and overscanning [3]. These effects can be taken care of with appropriate technical measures. For example, so-called dynamic collimation reduces unnecessary exposure at the beginning and at the end of a spiral scan by employing collimators which automatically adapt. It has been shown that this can avoid unnecessary exposure and is particularly important if short scans are involved [4]. Taking all possible effects into account, a dose reduction of typically 10–20% is feasible.

Similar to the lack of adaptation of voltage in CT to patient size and diagnostic goal, there was also a lack of adapting the tube current to the attenuation as a function of projection angle and anatomic level. Efforts at modulating the tube current dynamically during the scan, which is possible effectively during a spiral scan, started in the late 1990s [3]. An example is shown in Fig. 1, indicating that image quality is not impaired but rather slightly improved. Tube current per projection is reduced in the anteroposterior and posteroanterior direction where attenuation is lower. In the example shown, mAs was reduced by 49%, which means a reduction of the demand on tube power and an even higher reduction of X ray dose to the patient, because intensity is reduced for the anteroposterior and posteroanterior projections which contribute the strongest to dose.

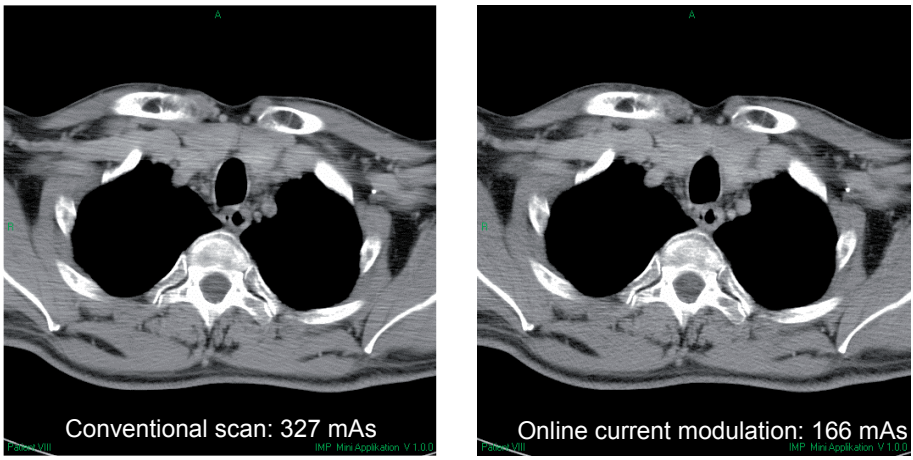

FIG. 1. The mAs product can be reduced by tube current modulation. An average mAs reduction of 53% was found for the shoulder region; in the case shown, it was 49% [3].

Modern systems for automatic exposure control go beyond tube current modulation as a function of projection direction. They also adapt the current in the z direction depending on changes in the cross-section and offer proposals for the choice of voltage depending on patient size. Respective tools are available on most modern scanners, but they are not yet used widely. Substantial reduction of average dose appears possible if this technology were used more frequently. Further training and education are a necessity.

Dose efficient image reconstruction algorithms have been offered by all manufacturers for a few years. They primarily aim at reducing noise without impairing spatial resolution or other image quality features and are mostly marketed as iterative reconstruction methods. A recent review of such techniques was given by Beister et al. [5]. Dose reduction potential of up to 80% has been claimed; a potential reduction of 40% on average appears realistic [3].

A further increase in the dose efficiency of X ray detectors for CT is also possible. Although the absorption efficiency is already close to the limit, increases in detector electronics for the analogue stage have recently received further attention. One important future step would be to also look at geometric efficiency, which today is only around 80–90%. It will decrease further when aiming for higher resolution with smaller detector pixels. A possible solution, and actually the goal of many developments within industry, is the use of so-called directly converting detector materials such as cadmium telluride (CdTe). Since these materials convert X rays to charge immediately, there is no scintillation light and no need for septa between the detector elements. A development in the direction of first clinical application has been proposed for CT of the breast [6]

and shall soon enter clinical studies. It is still an open question when clinical CT, in general, will be able to accommodate direct converters, but it will certainly offer another significant potential for dose reduction.

In summary, an adequate combination of all measures outlined above will enable further significant reduction of patient dose per examination. A total reduction of up to 80% has been indicated and that submillisievert CT may be a realistic option [3]. There are already examples of very successful submillisievert scanning as shown in Fig. 2.

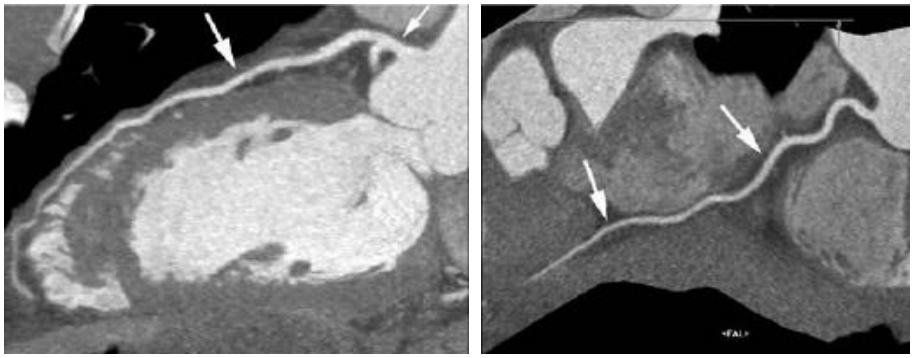

FIG. 2. Cardiac scanning at high pitch and 100 kV with dual source CT is possible at submillisievert levels with high image quality, in this case with 0.8 mSv effective dose (courtesy of S. Achenbach, Erlangen) [7].

Cardiac CT in its early days worked with unnecessarily high dose since scanning aimed at imaging the heart in all phases (4D CT). This can be very useful, but in the majority of cases nowadays, the aim is to image only one phase, e.g. diastole, and to use prospective triggering and very short exposure times. Effective dose values below 1 mSv are the goal today and can be reduced further when using 80 kV and iterative image reconstruction. This reflects the general trend and indicates that we may expect lower doses in CT in the future.

REFERENCES

[1] EUROPEAN COMMISSION, European Guidance on Estimating Population Doses from Medical X-ray Procedures, Radiation Protection Publication No. 154, European Commission, DG-TREN, Luxembourg (2008).

[2] KALENDER, W.A., et al., Application- and patient size-dependent optimization of X ray spectra for CT, Med. Phys. **36** 3 (2009) 993–1007.
[3] KALENDER, W.A., Computed Tomography: Fundamentals, System Technology, Image Quality, Applications, 3rd edn, Publicis, Erlangen (2011).
[4] DEAK, P., LANGNER, O., LELL, M., KALENDER, W.A., Effects of adaptive section collimation on patient radiation dose in multisection spiral CT, Radiology **252** 1 (2009) 140–147.
[5] BEISTER, M., KOLDITZ, D., KALENDER, W.A., Iterative reconstruction methods in X ray CT, Phys. Med. **28** 2 (2012) 94–108.
[6] KALENDER, W.A., et al., High-resolution spiral CT of the breast at very low dose: Concept and feasibility considerations, Eur. Radiol. **22** 1 (2012) 1–8.
[7] ACHENBACH, S., et al., Coronary computed tomography angiography with a consistent dose below 1 mSv using prospectively electrocardiogram-triggered high-pitch spiral acquisition, Eur. Heart J. **31** 3 (2010) 340–346.

RADIATION PROTECTION IN PAEDIATRIC COMPUTED TOMOGRAPHY

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1. BACKGROUND

The number of examinations with radiation exposure has been increasing mainly due to advances in computed tomography (CT) technology, with a rapid expansion of CT utilization. Annually, 3.6 billion diagnostic and medical and dental examinations involving radiation are performed worldwide. The contribution of CT to collective dose due to medical X rays is up to 47–59%. A 2009 report of the National Council on Radiation Protection and Measurements (NCRP) estimates that 8–10% of CT examinations in the United States of America are performed on children; the growth in CT utilization is higher in the paediatric than adult population in the USA; and there is a particularly pronounced rise in adolescents undergoing chest CT in the emergency department setting for suspected pulmonary embolism or trauma [1]. The reasons for the growing incidence of CT are new indications for CT with the advent of multidetector CT, overcautious ordering related to medico-legal problems and probably financial incentive systems.

2. SPECIAL CONSIDERATIONS IN CHILDREN

Children are more sensitive, by a factor of 3–5, relative to adults. Children have more years ahead of them in which cancerous changes might occur. Girls are more at risk than boys. Radiologists tend to demand less noisy images in small patients. Small children have less adipose tissue. About 33–50% of paediatric CT examinations have questionable indications. That means that justification is much more needed in paediatric than adult patients. There is a lack of size based adjustments in technique. As a result, radiation exposure from fixed CT parameters results in a relatively higher dose for a child's smaller

cross-sectional area compared with an adult. Many examinations are still conducted using inappropriate technical factors.

2.1. Justification

Justification is a simple question of whether the study is appropriate. Justification for children means: (i) not performing the study if not indicated; (ii) considering another modality, e.g. ultrasound or magnetic resonance imaging; (iii) communicating with a department of clinical radiology. There are several good guidelines for justification of examinations such as the Appropriateness Criteria of the American College of Radiology, the European Commission guidelines and the United Kingdom's Royal College of Radiologists Referral Guidelines for Imaging [2–4].

2.2. Optimization

Optimization should follow justification. Optimization should include proper patient positioning, limit coverage, adjusting CT parameters such as mAs and kVp, and use of automatic exposure control. The child sizing of a CT scan technique should not be limited to small children, but should also include adolescents. Better reconstruction algorithms should be used. Radiation dose should be calculated and reported.

2.3. Diagnostic reference levels

The International Commission on Radiological Protection recommends the use of diagnostic reference levels (DRLs) for patients [5]. DRLs are used in medical imaging to indicate whether the patient dose from a specific procedure is unusually high or low for that procedure. Reference levels are typically set at the 75th percentile of the dose distribution from a survey conducted. The use of DRLs has been shown to reduce the overall dose and the range of doses observed in clinical practice.

The DRLs of paediatric CT showed a decreasing trend over time. The DRL for head CT for a 5 year old child was 60 mGy in $CTDI_w$ in the European Union in 1996, 45 mGy in $CTDI_w$ in a 2006 United Kingdom national survey, 40 mGy in $CTDI_w$ in an NCRP recommendation in 2012 and 28 mGy in the 2012 KFDA Korean DRL for children.

2.4. Variation in paediatric CT dose

The maximum to minimum radiation dose for paediatric head CT showed more than tenfold variations in estimated median effective dose, within and between trauma centres of Washington state. In a survey in the Republic of Korea, the variation was up to 27-fold between 98 hospitals. The variation in developing countries showed similar ranges. The research showed that the radiation dose of paediatric CT is not so high in developing countries.

3. SUMMARY

— The radiologist is the gatekeeper in the process of justification;
— Be aware of unique considerations for children;
— Perform only necessary CT: communication with a radiologist;
— Adjust exposure parameters for CT;
— Increased awareness through education: radiologist, clinician, technologists, patient;
— Future development of evidence based practice strategies for paediatric emergency room patients;
— DRLs should be updated frequently, especially for paediatric patients.

REFERENCES

[1] NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS, Ionizing Radiation Exposure of the Population in the United States, NCRP Report No. 160, NCRP, Bethesda, MD (2009).
[2] AMERICAN COLLEGE OF RADIOLOGY, ACR Appropriateness Criteria (2013), http://www.acr.org/Quality-Safety/Appropriateness-Criteria
[3] EUROPEAN COMMISSION, Referral Guidelines for Imaging, Radiation Protection 118, Office for Official Publications of the European Communities, Luxembourg (2000).
[4] ROYAL COLLEGE OF RADIOLOGISTS, iRefer: Making the Best Use of Clinical Radiology, 7th edn, The Royal College of Radiologists, London (2012).
[5] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, Publication 103, Pergamon Press, Oxford and New York (2007).

REPORTING OF DOSE IN COMPUTED TOMOGRAPHY

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Abstract

Meaningful measurement and reporting of dose is an ongoing quest in computed tomography (CT). Expressions such as $CTDI_{vol}$ and dose length product are frequently used, but they describe machine output rather than dose to the patient. Further, they can be misleading when certain dose sparing technologies are employed. Size specific dose estimate has been proposed by the American Association of Physicists in Medicine as a more meaningful measure, but it approximates the mean dose to the patient centre rather than the dose to any specific organ. For estimates of patient risk, doses to specific organs are needed, but these are difficult to obtain. Medical physicists continue to try to resolve these issues, so that more meaningful estimates of dose from CT can be acquired. In the meantime, authors of scientific articles should be dissuaded from using meaningless expressions such as 'low dose' and 'ultra-low dose' in their descriptions of CT procedures.

1. INTRODUCTION

The measurement and reporting of dose in computed tomography (CT) procedures are incompletely resolved issues among medical physicists. Complicating these issues is the use of expressions such as 'low dose procedures' and 'ultra-low dose procedures' in the scientific literature. These terms are confusing because what is considered 'low dose' is different today from its definition a few years ago. Further, the interpretation of 'low dose' in some parts of the world may differ from that in other regions. For example, what is considered low dose in North America might be considered unacceptably high in Europe. Finally, CT dose varies substantially among patients, depending on body mass and density, so that low dose is essentially patient specific. For these reasons, the journal Radiology has announced that it will not accept the qualifier 'low dose' or any of its surrogates [1]. Instead, it suggests that the reporting of CT dose should include the dose expressions computed tomography dose index ($CTDI_{vol}$), dose length product (DLP), effective diameter (D_{eff}) and the size specific dose estimate (SSDE). The journal Medical Physics is likely to follow suit in some fashion.

2. DISCUSSION

$CTDI_{vol}$ is the most common expression of CT dose, and has units of milligrays. Several positive features are attributable to this dose expression, because it is: (i) a way to document the amount of radiation delivered in a scan; (ii) displayed in the dose protocol of most CT units; (iii) defined by standards and accepted by regulatory agencies and professional organizations; (iv) used in the CT accreditation programme of the American College of Radiology; (v) measurable with readily available equipment; (vi) useful for comparing protocols and scanners for quality assurance; and (vii) appropriate for accumulating data in CT registries such as the American College of Radiology Dose Registry.

$CTDI_{vol}$ also has several limitations, including: (i) it must be measured with a cylindrical, homogeneous phantom, making $CTDI_{vol}$ a measure of radiation output from the scanner rather than of dose delivered to the patient; (ii) the specific sizes of the phantom (16 or 32 cm diameter) mean that $CTDI_{vol}$ does not reflect patient geometry; (iii) the finite length of the phantom may not provide full scatter geometry, and the integration length of the measurement may be insufficient for large beam widths; (iv) it overestimates the dose to stationary patients, such as those undergoing brain perfusion studies; (v) it may provide incorrect estimates for dose preservation techniques; and (vi) for the same $CTDI_{vol}$, small patients may receive higher doses compared with larger patients. In summary, $CTDI_{vol}$ is a useful machine parameter that expresses radiation output, but it does not describe absorbed doses to organs or specific regions of the patient.

The relationship between CT scanner settings and $CTDI_{vol}$ is shown in Table 1 [2].

One limitation of $CTDI_{vol}$ is that it is not influenced by scan length. To accommodate scan length, the DLP was developed. The DLP is $CTDI_{vol} \times$ scan length and has units of mGy·cm. Similarly to $CTDI_{vol}$, the DLP is a depiction of scanner radiation output, not patient dose, and is independent of patient size.

SSDE was developed to accommodate patient size in the specification of CT dose. To use SSDE, one first obtains the effective diameter D_{eff} of the patient, computed as:

$$D_{eff} = (\text{AP diameter} \times \text{lateral diameter})^{1/2}$$

From D_{eff}, one can obtain a value of f_{size} from tables 1 and 2 of Ref. [3]. SSDE is then:

$$SSDE = CTDI_{vol} \times f_{size}$$

TABLE 1. INFLUENCE OF VARIOUS COMPUTED TOMOGRAPHY SCANNER SETTINGS ON $CTDI_{VOL}$ *(reproduced with permission)* [2]

Parameter	Relationship to $CTDI_{vol}$
Scan Mode	Changes in the Scan Mode may affect $CTDI_{vol}$
Table Feed/Increment	Table Feed affects $CTDI_{vol}$ through its inclusion in Pitch
Detector Configuration	Decreasing the Beam Collimation typically, but not always, increases the $CTDI_{vol}$
Pitch	$CTDI_{vol} \propto 1/Pitch$
Exposure Time per Rotation	$CTDI_{vol} \propto$ Exposure Time per Rotation
Tube Current	$CTDI_{vol} \propto$ Tube Current
Tube Potential	$CTDI_{vol} \propto (kVp_1/kVp_2)^n$ $n \sim 2$ to 3
Tube Current Time Product	$CTDI_{vol} \propto$ Tube Current Time Product
Effective Tube Current Time Product	$CTDI_{vol} \propto$ Effective Tube Current Time Product
Field of Measurement	Changes in the Field of Measurement may affect $CTDI_{vol}$
Beam Shaping Filter	Changes in the Beam Shaping Filter may affect $CTDI_{vol}$

This value approximates the mean dose to the patient centre and, in that sense, is an estimated patient dose, although it is not the dose to any specific organ.

Some methods have been developed to estimate organ dose from CT scans. These methods are described by terms such as ImpactDose [4] and CT-Expo [5]. They furnish approximations to organ dose and their accuracy may be impacted by variables such as patient size differences, scanner variations and the use of various dose preservation technologies. Better methods are needed for estimating organ doses from CT, and various groups, including members of the American Association of Physicists in Medicine, are working on their development.

Many CT scanners adjust the scanner settings (scan acquisition parameters) to achieve a desired level of image quality and/or to reduce the dose to an acceptable level. These techniques vary with the scanner manufacturer, model and version of the software employed in the scanner.

The image quality scan setting allows the user to define the desired quality of the resulting CT scan. Increasing the quality setting yields images with reduced quantum noise, at the expense of increased $CTDI_{vol}$ and patient dose. The opposite is also true; decreasing the image quality setting yields a noisier image but results in less patient dose.

Modern CT scanners permit modulation of the tube current (mA) in the angular (x–y axis) and longitudinal (z axis) directions to adjust for differences in attenuation as the X ray beam moves around and along the patient. Tube current modulation is intended to yield satisfactory images at reduced patient dose, although, in certain circumstances, it can increase the dose when obese patients and highly attenuating areas are scanned.

Cardiac CT scans can be gated to acquire data only during selected phases of the cardiac cycle. Prospective gating is accomplished in real time by adjusting the tube current so that data are collected only at desired times in the cycle. Retrospective gating means that data are acquired over the entire cycle, but post-scan software is used to examine only the data relevant to a particular portion of the cycle. Obviously, the dose to the patient is much less with prospective gating compared with retrospective gating.

Organ based tube current modulation is used to decrease the tube current when the X ray beam directly irradiates sensitive tissues such as the breasts or eye lenses that are near the surface of the body. To maintain image quality, the tube current may have to be increased in other orientations of the X ray beam. This feature may reduce the dose to superficial organs but increase the dose to other organs.

With most CT units, the $CTDI_{vol}$ for a particular protocol is displayed on the console of the unit when the protocol is selected for an examination. In addition, the $CTDI_{vol}$ delivered during the examination is reported in a data page or DICOM (Digital Imaging and Communications in Medicine) structured dose report once the examination has been completed. The DLP is also usually displayed. In California, these two dose metrics must be included in the radiology report for all patients undergoing diagnostic CT scans. These reporting requirements do not apply to CT scans used for purposes other than diagnosis, such as radiation therapy treatment planning, attenuation correction in positron emission tomography, and CT imaging used for guidance of biopsy needles.

The American College of Radiology manages a National Radiology Data Registry that includes a Dose Index Registry to which a member institution may voluntarily submit CT doses (values of $CTDI_{vol}$) for specific CT examinations

conducted in the institution [6]. Each institution is provided periodic reports comparing its doses by body part and examination type to aggregate results from all institutions. The data for each institution are kept confidential, and an institution only sees its data and the composite results for all institutions. Data collected from the registry will ultimately be used to establish national benchmarks for CT dose indices.

Several technological advances may have a current or future impact on the dose from CT scanners. One advance is the use of iterative reconstruction of images in place of filtered back projection deployed in earlier scanners [7]. Iterative reconstruction does not automatically reduce patient dose, but it does yield improved image quality which could permit reduction in patient dose for studies where an improvement in image quality is not essential.

3. CONCLUSION

Three caveats should be considered in each and every protocol selected for CT scanning of a patient. They are:

(a) A CT study should use as little radiation as possible, while still furnishing the image quality needed for accurate interpretation.
(b) A CT study that uses too little radiation yields a noisy image that may be non-interpretable, requiring a repeat study with additional radiation.
(c) In every appropriate CT study, the benefits to the patient outweigh the risks.

REFERENCES

[1] BANKIER, A.A., KRESSEL, H.Y., Through the Looking Glass revisited: The need for more meaning and less drama in the reporting of dose and dose reduction in CT, Radiology **265** 1 (2012) 4–8.
[2] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Computed Tomography Radiation Dose Education Slides (2012), www.aapm.org/pubs/CTProtocols/
[3] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, Size-specific Dose Estimates (SSDE) in Pediatric and Adult Body CT Examinations, Report of Task Group 204, AAPM Report No. 204, AAPM, College Park, MD (2011).
[4] LEWIS, M.A., et al., Estimating patient dose on current CT scanners: Results of the ImPACT* CT dose survey, 'Rad' magazine (2000), http://www.impactscan.org/dosesurveysummary.htm

[5] STAMM, G., NAGEL, H., CT-expo — A novel program for dose evaluation in CT, Rofo **174** 12 (2002) 1570.
[6] AMERICAN COLLEGE OF RADIOLOGY, About Dose Index Registry (DIR), http://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Dose-Index-Registry
[7] FESSLER, J., Iterative Image Reconstruction for CT, AAPM Image Educational Course (2011), http://www.aapm.org/meetings/amos2/pdf/59-17244-92247-397.pdf

RADIATION PROTECTION OF PATIENTS IN FILM BASED AND DIGITAL RADIOGRAPHY, DIAGNOSTIC FLUOROSCOPY AND MAMMOGRAPHY

(Session 7)

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RADIATION PROTECTION OF PATIENTS IN FILM BASED AND DIGITAL RADIOGRAPHY, DIAGNOSTIC FLUOROSCOPY AND MAMMOGRAPHY

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Abstract

The paper outlines the emerging challenges and possible solutions for radiation protection in medicine. These challenges include increased use, inappropriate use, practitioner knowledge and competency, issues with recommendations and guidance tools, workforce shortage, health care resources and access, infrastructure and policies, action fragmentation and discontinuity, change management, volunteering and funding. The solutions are based on teamwork and an integrated framework, which are applicable to both health care systems and end users. Using this approach, a range of radiation protection actions are being developed and implemented. Ultimately, these actions will improve patient care by ensuring that the right procedure is done (justified) and that the procedure is done right (optimized and without error).

1. INTRODUCTION

Over the years, many actions have been taken to improve the radiation protection of patients, addressing the needs of the health care systems and end users. Health care systems provide a framework of recommendations and tools, and the end users apply these and teamwork to improve radiation protection. The key stakeholders in everyday practice are the patients, referrers, providers and payers. Despite their differing perspectives and needs, the stakeholders share a common goal: patient focused care; and correct, safe and appropriate use of procedures.

2. EMERGING CHALLENGES

Increased use, whether appropriate or inappropriate, increases radiation exposure and cost [1]. Increased caseload increases the probability of human error in the performance of procedures and interpretation, thus lowering diagnostic accuracy. The follow-up of incidental findings further compounds these concerns. Technological advances and an ageing population increase the demand for diagnostic imaging services. Inappropriate use, self-referral and defensive medicine contribute to unnecessary exposure and waste. Reports showing an increased cancer risk from medical radiation highlight the need for action to ensure a more appropriate use of procedures [2].

Inappropriate use could be due to ineffective justification, poor optimization or human error. Poor awareness of stakeholders' roles, responsibilities and the reasons for inappropriate use contribute to this challenge. Some fluoroscopic equipment users have not received proper training in radiation safety and protection. Inadequate user training prior to the implementation of new equipment, for example, digital radiography or digital mammography, hinders the optimization of dose, image quality and radiation protection.

In many undergraduate courses, medical imaging, radiation protection and safety are poorly covered. Practitioners are too busy with clinical and administrative work; ongoing professional development and teaching methodology may not be optimal for adult education. Some referrers do not appreciate the difference in the use of medical imaging between community and tertiary settings. Inexperience and insufficient training contribute to interpretation errors, e.g. mammography.

The challenges for guidance tools to facilitate the lowering of exposure in radiography, fluoroscopy and mammography are access to them, and the ways they are presented.

The workforce shortage is global and is compounded by inequitable distribution, migration and changing practice models, e.g. international teleradiology. Policy change by one system or stakeholder can have an impact on another. With the shortage of radiologists, there are opportunities for role extension, e.g. radiographer performed fluoroscopy and interpretation; and extended responsibility in justification and optimization in teleradiology. These issues are complex and are beyond the scope of the paper.

Resources vary between countries, and between urban and rural settings. In many settings, radiography is used even when ultrasound is more appropriate. In others, while magnetic resonance imaging is available and more appropriate, its use is limited by criteria to contain cost. Access to screening mammography is age dependent. The resources available to accurately monitor and record patient dose in radiography, fluoroscopy and mammography vary greatly.

Poor system infrastructure and weak policies limit the implementation of recommendations. It is becoming challenging for some authorities to implement timely policy updates. However, regulations should be in place to ensure safe and sound practice, e.g. in the case of outsourcing and teleradiology. For the end users, teleradiology threatens communication and disrupts team efforts in justification, optimization, error reduction, quality assurance, the control of repeats, the audits of doses and image quality, and the use of diagnostic reference levels, etc.

For actions involving many stakeholders, there is a risk of poor coordination or fragmentation. Without good communication and collaboration, duplication and unintended complication are possibilities. Personnel and leadership changes could lead to discontinuity of long term actions. For any action, the aim is to improve practice. However, inertia to change and transient improvement is the reality. There is a need to encourage and maintain change.

Experts prepare recommendations and tools. Ineffective advocacy, poor awareness and inadequate peer support are threats to volunteering. Radiation protection actions compete with other projects for funding, thus joint resource mobilization is more effective. Many system based actions have a long lead-time and it is important to persevere, stay focused and maintain motivation with these long term plans.

3. POSSIBLE SOLUTIONS

To tackle the challenges, two key solutions are proposed. The first is a *framework* of measures, strategies and process improvements for health care systems and end users [3]. The three measures are justification, optimization and error minimization, which are used along the patient journey. For the realization of any action, it is important to narrow the gaps between knowledge and practice.

The second solution is good *teamwork*. Each step of an action requires the contribution from different stakeholders who play unique roles. Development requires expertise and resources. Effective advocacy improves the probability of policy adoption and use by practitioners. Together, these efforts narrow the gaps between knowledge and practice.

Under this radiation protection framework, a range of implementation strategies is used. Research includes conducting population exposure surveys and procedure exposure in facilities. The strengthening of advocacy, awareness, training, workforce capacity, physical infrastructure, policies, evaluation and ongoing improvement apply to health care systems and end users. There is synergy between these strategies and collectively they add value to each other.

The common vehicles supporting these actions are evidence based recommendations and tools. However, providing resources alone does not

guarantee their use in practice. Keeping these tools current; matching the contents to the setting; improving their user friendliness, format, media and search function; and securing end user support will lead to better acceptance and use. The key is to identify and strengthen the weakest link in this process. All actions are interrelated and synergy should be sought to maximize the outcome. Based on the findings of population and procedure exposure surveys, improvement actions should follow. The surveys provide the diagnosis but treatment requires medication. Similarly laboratory developed quality control measures should be integrated into daily practice when appropriate.

One of the issues limiting the development and implementation of these actions is the availability of human and financial resources. To maximize resources and synergy, and to minimize duplication, collaboration under an integrated framework is useful. A global platform such as this forum, the International Action Plan for the Radiological Protection of Patients [4], the International Basic Safety Standards [5], the World Health Organization's Global Initiative on Radiation Safety in Healthcare Settings [6] and the global referral guidelines project [7] facilitate leader and stakeholder engagement across disciplines and sectors, communication, collaboration, team building, innovation, development of a safety culture and resource mobilization. However, good ideas need end user support by their active participation. Policies to encourage and maintain change should be applied.

4. CONCLUSION

An integrated framework facilitates the discussion and development of radiation protection actions for health care systems and end users by selecting appropriate measures, strategies and process improvements. Using a framework such as the one discussed, together with good teamwork, will overcome many of the emerging challenges and narrow the gaps between evidence and practice. These actions will improve patient care through doing the right procedure (justified) and doing the procedure right (optimized and without error), each time.

REFERENCES

[1] LAU, L.S., et al., Global quality imaging: Emerging issues, J. Am. Coll. Radiol. **8** 7 (2011) 508–512.

[2] PEARCE, M.S., et al., Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumors: A retrospective cohort study, Lancet **380** 9480 (2012) 499–505.
[3] LAU, L.S., et al., Global quality imaging: Improvement actions, J. Am. Coll. Radiol. **8** 5 (2011) 330–334.
[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection of Patients (RPOP), http://rpop.iaea.org
[5] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).
[6] WORLD HEALTH ORGANIZATION, WHO Global Initiative on Radiation Safety in Health Care Settings, Technical Meeting Report, WHO, Geneva (2008).
[7] WORLD HEALTH ORGANIZATION, Medical Imaging Specialists Call for Global Referral Guidelines, http://www.who.int/ionizing_radiation/about/med_exposure/en/index2.html.

ENSURING SAFETY IN TRANSITION TO DIGITAL RADIOGRAPHY IN PRACTICE

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Abstract

Many countries are currently transitioning from screen-film radiography to digital radiography. Most principles for dose reduction in screen-film radiography, including justification, are relevant to digital systems. However, digital systems have the potential to significantly increase patient dose, possibly due to lack of awareness among imaging personnel. Examination parameters, such as tube voltage, tube current and filtration, have been adopted from screen-film technology without further adjustments. The imaging parameters must be optimized according to the best performance of a particular system. Current safety issues with clinical digital radiography are discussed; these are technology factors, such as automatic exposure factors and exposure index; and human factors, such as inappropriate exposure, no collimation and overexposure. Digital techniques increasingly offer options for dose reduction. Therefore, implementation of dose indicators and dose monitoring is mandatory for digital radiography in practice. Finally, the advantages and challenges of radiographer performed fluoroscopy will also be discussed.

1. INTRODUCTION

Many countries are currently transitioning from screen-film radiography to digital radiography. Most principles for dose reduction in screen-film radiography, including justification, are still relevant to digital systems. However, in digital systems, different scenarios apply for dose reduction and optimization compared with screen-film radiography [1–3]. Publication 93 of the International Commission on Radiological Protection (ICRP) states that:

> "While digital techniques have the potential to reduce patient doses, they also have the potential to significantly increase them. This is a technology that is advancing rapidly and which will soon affect hundreds of millions of patients. If careful attention is not paid to the radiation protection issues of digital radiology, medical exposure

of patients will increase significantly and without concurrent benefit." [1]

2. ADVANTAGES OF GOING DIGITAL

The diagnostic information provided by modern digital detectors can be equal or superior to conventional screen-film systems with comparable patient doses. Digital imaging has practical technical advantages compared with film techniques, e.g. wide contrast dynamic range, post-processing functions, multiple image viewing options, and electronic transfer and archiving possibilities [3, 4].

3. ISSUES IN GOING DIGITAL

Digital X ray imaging involves several issues such as cost and productivity, skills training, radiation dose, overuse and image quality [2]. Digital imaging brings benefits but also demands changes in our ways of working.

3.1. Current safety issues with clinical digital radiography

3.1.1. Technology factors

3.1.1.1. Automatic exposure control [5]

The wide exposure dynamic range of such systems may have the disadvantage that if the X ray generator automatic exposure control (AEC) develops a fault or the output calibration drifts, the dose increase/decrease may not be readily identified. Also, the wide exposure dynamic range means that there is significant potential for the initial set-up of such systems not to be optimized. Digital radiography systems may have different X ray energy responses to screen-film systems. Thus, the generator's AEC compensation characteristics should be different from those used for screen-film systems. For existing systems which have been upgraded to computed radiography or digital radiography, the existing AEC compensation characteristics will need reprogramming. X ray equipment manufacturers should work with physicists on this.

3.1.1.2. Exposure (sensitivity) index [5, 6]

Each image should ideally have an associated number to indicate the level of exposure to the detector. Currently, all digital systems have an exposure

(sensitivity) index which is related to detector exposure (Fig. 1). Once digital radiography systems are in use, the constancy of applied exposure factors should be monitored on a regular basis.

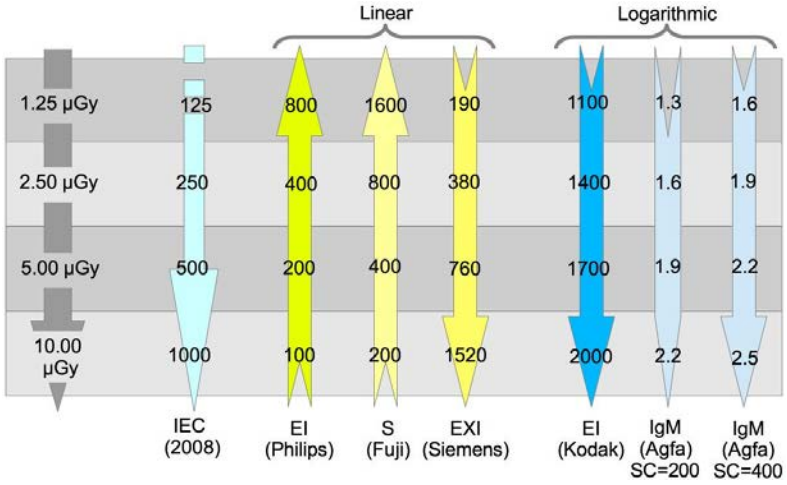


FIG. 1. A list of exposure indices terminology used by various digital systems and their relationship to traditional dose measure (in micrograys). In the second column, the proposal for an international standardization (International Electrotechnical Commission) is detailed [3].

Both the International Electrotechnical Commission (IEC) (IEC 62494-1 [7]) and the American Association of Physicists in Medicine (AAPM) (AAPM Task Group 116) have developed similar standards for monitoring exposure in digital radiography to eliminate proprietary and confusing terminology. Radiologists and technologists will need to learn three new terms — exposure index, target exposure index and deviation index — to understand the new standards [8].

3.1.2. Human factors

(a) Inappropriate exposure: With digital systems, overexposure can occur without an adverse impact on image quality. Overexposure may not be recognized by the radiologist or radiographer. In conventional radiography, excessive exposure produces a ‘black’ film and inadequate exposure produces a ‘white’ film, both with reduced contrast. In digital systems, image brightness can be adjusted post-processing independent of exposure level [9].

(b) Increase in the number of examinations: In several US hospitals, the number of examinations per in-patient day increased by 82% after a transition to film-less operation. Outpatient utilization (i.e. the number of examinations per visit) increased by 21%, compared with a net decrease of 19% nationally at film-based hospitals [10].

(c) No collimation: The lack of collimation remains a major issue in digital radiography. When collimation is poor, a large part of the body is being unnecessarily exposed, although it cannot be seen in digitally cropped images. An example is given in Fig. 2, where apparently 'perfect' radiographs of the paranasal sinuses are produced with post-examination cropping.

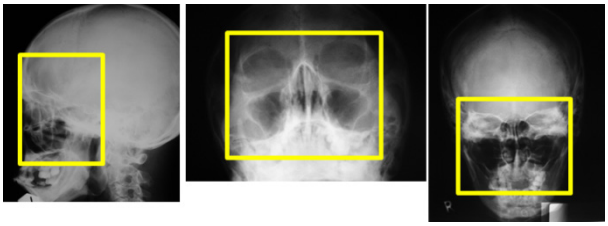


FIG. 2. A series of radiographs which were supposed to only image the paranasal sinuses (yellow collimation lines); instead, almost the whole head was X rayed. (Images courtesy of E. Ho, Sime Darby Medical Centre Park City, Malaysia.)

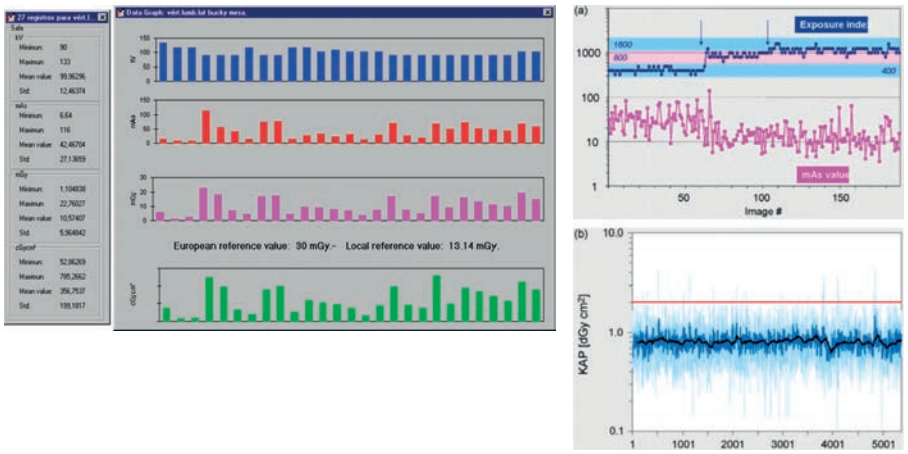
In a study on lumbar spine radiography, the proportion of the irradiated field outside the region of interest (ROI) was larger in digital than in analogue images (mean: 61.7% versus 42.4%, $p = 0.001$). The mean total field size was 46% larger in digital than in analogue images (791 versus 541 cm^2). Digital techniques have made it possible to mask areas irradiated outside the ROI, but have also caused patients to be unnecessarily exposed to high radiation doses [11].

A survey of 450 technologists by the American Society of Radiologic Technologists revealed that half of the respondents used electronic cropping after the exposure [12].

(d) Lack of compatibility between image quality and imaging task: Different imaging tasks require different levels of image quality; for example, a follow-up examination for a fracture does not require the same image quality as that required for its diagnosis. The objective is to avoid unnecessary dose exposure in patients, i.e. doses which have no additional benefit for the clinical purpose intended.

4. STRATEGIES IN MONITORING DOSE

There have been various attempts at automated data collection for dose monitoring and evaluation of longitudinal assessment of dose. Some examples are given in Fig. 3.



(a) (b)

FIG. 3. (a) An on-line patient dose monitoring system developed for computed radiography auditing [13]. (b) Top: anteroposterior lumbar spine radiograph exposure. Small alterations of the automated exposure control are indicated (arrows). Bottom: automated assessment of the kerma area product in posteroanterior chest radiographs. The majority of exposures are below the diagnostic reference level (red line) [3].

5. STRATEGIES IN DOSE MANAGEMENT

While digital techniques have the potential to reduce patient doses, they also have the potential to significantly increase them. There is a trade-off between radiation dose and image quality. Optimization does not mean simply maximizing image quality and minimizing patient dose; rather, it requires radiologists to determine the level of image quality that is necessary to make the clinical diagnosis and then for the dose to be minimized without compromising this image quality.

Diagnostic reference levels (DRLs) should be set up and refined for digital radiography, specific for clinical image quality and adjusted for body weight/size.

Table 1 from the ICRP [1] illustrates the different levels of image quality required in different medical imaging tasks.

TABLE 1. LEVELS OF IMAGE QUALITY REQUIRED IN DIFFERENT MEDICAL IMAGING TASKS

Clinical problem	Image quality class	Comment
Primary bone tumour	High	Image may characterize the lesion
Chronic back pain with no pointers to infection or neoplasm	Medium	Degenerative changes are common and non-specific. Mainly used for younger patients (e.g. below 20 years of age, spondylolisthesis) or older patients (above 55 years)
Pneumonia adults: follow-up	Low	To confirm clearing, etc. Also, not useful to re-examine patient in less than 10 day intervals as clearing can be slow (especially in the elderly)

5.1. Advantages and challenges of radiographer performed fluoroscopy

In some countries, radiographers perform fluoroscopy as part of the expansion of their role, in order to relieve the workload of busy radiologists. Radiographers generally handle routine cases, e.g. barium meals and enema, but may lack clinical knowledge and history of the patient, resulting in long screening time and repeat procedures by radiologists.

In one study, dose–area product measurements for over a thousand barium enema examinations performed by radiologists and radiographers were analysed and compared to ascertain whether there were significant differences in the radiation dose to the patient, depending on the category of staff performing the examination. All examinations were reported by a radiologist. The radiologist's reports were analysed against the known outcomes to compare the diagnostic value of the examination when carried out by the two categories of staff. The study shows that although radiographers are able to produce consistent diagnostic results, there is an increase in patient dose due to extra films taken for reporting, which may be difficult to justify [14].

6. SUMMARY

In ensuring safety when transitioning to digital radiography, attention should be paid to the following points:

(a) Appropriate training, particularly in the aspects of patient dose management, should be undertaken by radiologists, medical physicists and radiographers before and during the clinical use of digital techniques.
(b) National and local DRLs should be reviewed when new digital systems are introduced in a facility.
(c) All imaging procedures should be audited (evaluated) at least once a year.
(d) The original (raw) image data should be made available to the user not only for objective testing in a rigorous quality assurance programme but also for other types of independent tests of the performance of digital imaging systems.
(e) When a new digital system or new post-processing software is introduced, an optimization programme and continuing training should be conducted in parallel.
(f) Quality control in digital radiology requires new procedures and protocols. Acceptance and constancy tests should include aspects concerning visualization, transmission and archiving of the images.
(g) As digital images are easier to acquire and to transmit in communication networks, referring physicians should be fully conversant with the justification criteria for requesting medical X ray imaging procedures.
(h) Industry should promote tools to inform radiologists, radiographers and medical physicists about the exposure parameters and the resultant patient doses. The exposure parameters and the resultant patient doses should be standardized, displayed and recorded.
(i) Making use of radiographic and dosimetric data contained in DICOM (Digital Imaging and Communications in Medicine) header for dose management.
(j) Educate, educate, educate. Train, retrain, train, retrain.

REFERENCES

[1] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Managing Patient Dose in Digital Radiology, Publication 93, Pergamon Press, Oxford and New York (2004).
[2] NG, K.H., REHANI, M.M., X ray imaging goes digital, Br. Med. J. **333** (2006) 765–766.

[3] UFFMANN, M., SCHEFER-PROKOP, C., Digital radiography: The balance between image quality and required radiation dose, Eur. J. Radiol. **72** 2 (2009) 202–208.
[4] NG, K.H., McLEAN, I.D., Diagnostic radiology in the tropics: Technical considerations, Semin. Musculoskelet. Radiol. **15** 5 (2011) 441–445.
[5] ZHANG, M., Dose optimization for different medical imaging tasks from exposure index, exposure control factor, and mAs in digital radiography, Health Phys. **103** 3 (2012) 235–240.
[6] SCHAEFER-PROKOP, C., Digital chest radiography: An update on modern technology, dose containment and control of image quality, Eur. Radiol. **18** 9 (2008) 1818–1830.
[7] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment — Exposure Index of Digital X-ray Imaging Systems — Part 1: Definitions and Requirements for General Radiography, IEC 62494-1, IEC (2008).
[8] DON, S., WHITING, B.R., RUTZ, L.J., APGAR, B.K., New exposure indicators for digital radiography simplified for radiologists and technologists, AJR Am. J. Roentgenol. **199** 6 (2012) 1337–1341.
[9] SUN, Z., LIN, C., TYAN, Y., NG, K.H., Optimization of chest radiographic imaging parameters: A comparison of image quality and entrance skin dose for digital chest radiography systems, Clin. Imaging **36** 4 (2012) 279–286.
[10] REINER, B.I., Effect of filmless imaging on the utilization of radiologic services, Radiology **215** 1 (2000) 163–167.
[11] ZETTERBERG, L.G., ESPELAND, A., Lumbar spine radiography — Poor collimation practices after implementation of digital technology, Br. J. Radiol. **84** (2011) 566–569.
[12] MORRISON, G., Pediatric digital radiography education for radiologic technologists: Current state, Pediatr. Radiol. **41** 5 (2011) 602–610.
[13] VÁÑO, E., TEN, J.I., FERNANDEZ-SOTO, J.M., SANCHEZ-CASANUEVA, R.M., Experience on patient dosimetry and quality control on line for diagnostic and interventional radiology using DICOM services, AJR Am. J. Roentgenol. **200** 4 (2013) 783-790.
[14] CRAWLEY, M.T., SHINE, B., BOOTH, A., Radiation dose and diagnosticity of barium enema examinations by radiographers and radiologists: A comparative study, Br. J. Radiol. **71** 844 (1998) 399–405.

IMPACT OF TELERADIOLOGY ON RADIATION PROTECTION

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Abstract

Teleradiology has been in place for more than 25 years. It is probably the most developed and common telemedicine application. Many different kinds of benefits and also risks have been named over the years. The implication for radiation protection is, however, not mentioned very often. The improper use of teleradiology or scanning protocols could, of course, harm patients.

1. STATUS AND BENEFITS OF TELERADIOLOGY

Teleradiology is used in different scenarios. It is evident that on-line communication of radiological studies could improve the health care process for different situations, e.g. consultation of specialists ('second opinion'), clinical studies and central registries/repositories for regional eHealth projects. Different from these situations is teleradiology for primary reading of studies (this means that patient and responsible radiologists are in different places). For these use cases, different regulations are in place or are in discussion [1–4]. There are quality assurance programmes for teleradiology, which rely on different indicators, e.g. turn around time (TAT), double-reading and discrepancy rates [5, 6]. It has been published that teleradiology can improve the TAT; for example, Kennedy et al. [7] could prove a significant increase of reports in due time for teleradiology compared with in-house reporting.

Teleradiology for primary reading is accepted and requested due to different circumstances, for example, for regions with lower population rates, due to shortage of trained radiologists, and even the behaviour of radiologists, because many groups do not find partners for night-time reporting ('controllable lifestyle') [4, 8, 9]. Based on this, many commercial for-profit teleradiology providers are now in place, some with offices in different time zones for

international reporting to provide reading during daytime from another continent [8, 9].

2. POTENTIAL RISKS

Teleradiology, and especially international teleradiology, is criticized by many groups such as scientific societies, academic hospitals and others, because a radiological examination is a medical act and some risks are evident. Reporting, the only part which could be provided, is only part of a radiological procedure, which includes clear identification of medical problems and a patient history, a decision on the appropriate study and protocol, and reporting and communication with the patient and referring physician to avoid mistakes. The interaction of patient and radiologist does not occur in teleradiology; very often, there is no access to the medical record and/or former images, and there are limitations in communication with the referring physician [10]. Relevant medical malpractice due to these limitations has been described [11].

It is expected that teleradiology reporting is linked with more defensive, overcautious or vague reporting. This could lead to other, probably unnecessary imaging tests or even interventional procedures. Therefore, there is a risk of loss in diagnostic quality [3].

3. TELERADIOLOGY AND RADIATION PROTECTION

There is limited experience on the influence of teleradiology on radiation protection (e.g. a PubMed search with these terms resulted in only nine hits).

Access to previous imaging is one of the most important issues to reduce unnecessary imaging due to repeated studies. Sodickson et al. [12] proved a 17% reduction in follow-up studies based on CD-import (‘off-line teleradiology’) for emergency department transfer patients. Flanagen et al. [13] published a study on trauma patients transferred in a regional trauma network. They found a significant lower repeat rate for CT imaging (17%) with electronic image transfer compared to literature of conventional transfers (28–58%) [13].

4. PERSPECTIVE

Improvements in technical, organizational and legal aspects of eHealth platforms, especially the worldwide acceptance of solutions based on the IHE (Integrating the Healthcare Enterprise) initiative, could reduce unnecessary

repetition of imaging, which would have major impacts on radiation protection. Teleradiology will be part of this, but it should be considered that especially international and/or anonymous teleradiology could be a risk for lower quality. Proper imaging is a complex procedure requiring optimal equipment and choice of optimized protocols [14]. Thus, regional cooperation of referrers and radiologists should be considered.

REFERENCES

[1] LAU, L.S., Clinical teleradiology in Australia: Practice and standards, J. Am. Coll. Radiol. **3** 5 (2006) 377–381.

[2] MILDENBERGER, P., et al., Teleradiology with DICOM e-Mail: Recommendations of @GIT, Rofo **177** 5 (2005) 697–702 (in German).

[3] PATTYNAMA, P.M., Legal aspects of cross-border teleradiology, Eur. J. Radiol. **73** 1 (2010) 26–30.

[4] ROSENBERG, C., LANGNER, S., ROSENBERG, B., HOSTEN, N., Medical and legal aspects of teleradiology in Germany, Rofo **183** 9 (2011) 804–811 (in German).

[5] SCHILLEBEECKX, J., Quality assurance in teleradiology (Proc. 22nd EuroPACS-MIR Conf., Trieste, 2004), (2004) 179.

[6] WONG, W.S., et al., Outsourced teleradiology imaging services: An analysis of discordant interpretation in 124,870 cases, J. Am. Coll. Radiol. **2** 6 (2005) 478–484.

[7] KENNEDY, S., BHARGAVAN, M., SUNSHINE, J.H., FORMAN, H.P., The effect of teleradiology on time to interpretation for CT pulmonary angiographic studies, J. Am. Coll. Radiol. **6** 3 (2009) 180–189.

[8] BRANT-ZAWADZKI, M.N., Special focus — Outsourcing after hours radiology: One point of view — Outsourcing night call, J. Am. Coll. Radiol. **4** 10 (2007) 672–674.

[9] HILLMAN, B.J., International teleradiology and new workforce expectations, J. Am. Coll. Radiol. **2** 2 (2005) 103–104.

[10] ABRAMSON, R.G., Variability in radiology practice in the United States: A former teleradiologist's perspective, Radiology **263** 2 (2012) 318–322.

[11] BERLIN, L., Suboptimal radiologic examinations, AJR Am. J. Roentgenol. **196** 4 (2011) W482.

[12] SODICKSON, A., OPRASEUTH, J., LEDBETTER, S., Outside imaging in emergency department transfer patients: CD import reduces rates of subsequent imaging utilization, Radiology **260** 2 (2011) 408–413.

[13] FLANAGAN, P.T., RELYEA-CHEW, A., GROSS, J.A., GUNN, M.L., Using the Internet for image transfer in a regional trauma network: Effect on CT repeat rate, cost, and radiation exposure, J. Am. Coll. Radiol. **9** 9 (2012) 648–656.

[14] LAU, L.S., et al., Global quality imaging: Emerging issues, J. Am. Coll. Radiol. **8** 7 (2011) 508–512.

RADIATION PROTECTION ISSUES IN BREAST SCREENING

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Abstract

In X ray breast imaging, application of the ALARA (as low as reasonably achievable) principle makes us focus on the woman screened or the patients being diagnosed or investigated using X rays. The harm associated with X ray breast imaging is expressed via the concept of the mean glandular dose (MGD). We explain how the MGD is calculated for individual patients and for cohorts of patients, and how it relates to risk. Dose optimization studies should be driven by image quality assessment.

1. INTRODUCTION

This paper is not restricted to (classical) radiation protection of personnel. These challenges are not so difficult to meet and easy measures, such as the use of simple lead screens, allow for sufficient protection of the personnel. Whether extra precautions will be needed for newer applications, such as breast tomosynthesis, is currently being investigated at the level of the International Electrotechnical Commission. Radiation protection in a wider sense is discussed and the focus is on the appropriate use of X rays in patients undergoing X ray imaging of the breast and populations being screened for breast cancer by means of X ray mammography. We will first explain how doses to the breast are estimated and how they are used to ensure the best compromise in image quality and detriment from X rays.

2. DOSE TO THE BREAST

Most dosimetric applications of the breast distinguish between three tissues: glandular tissue, and adipose tissue in the breast and skin. Only the glandular tissue is known to be sensitive to X rays and it is, therefore, the tissue of interest in dosimetry. The glandular tissue can be distributed in very different ways in the

breast (scattered or more concentrated) and it can be abundant or nearly absent. In addition to the impact on the difficulty in reading of the mammogram, the distribution and amount of glandular tissue will also determine the absorbed doses in the glandular tissue from a mammographic examination. The first models of the breast for dosimetric calculations used a simple approximation, with the breast being a semicylinder with a layer of skin and a homogeneous mixture of glandular tissue and fat. The relative amount of glandular tissue was then a parameter that could be varied to a value between 0 and 100%. Monte Carlo techniques were applied to estimate the dose to the glandular tissue for given situations of beam quality and compressed breast thickness of the models. There are two groups of methods being used today: Dance's approach [1, 2] and Wu's approach [3]. Both authors calculate the mean glandular dose (MGD) from a set of input parameters and for a well described (simple) model of the breast.

The equation developed by Dance and largely applied in Europe is as follows [1, 2]:

$$\mathrm{MGD} = K \cdot g \cdot c \cdot s \cdot t$$

where

- K is the incident air kerma under the compression plate (also called 'tube output' and expressed in milligrays);
- g is the conversion factor from K to MGD for a breast that consists of 50% adipose tissue and 50% glandular tissue, and a skin layer;
- c is the conversion factor from a breast of 50% adipose tissue and 50% glandular tissue, and a skin layer, to another weight fraction of glandular tissue;
- s is the conversion factor from anode/filter Mo/Mo to other anode/filter materials;

and t is the conversion factor from the classical 2D mammographic geometry to current tomosynthesis acquisition strategies.

Wu et al. [3] also estimate the dose to the glandular tissue and have also tabulated conversion factors for that purpose. In the equations, MGD is obtained from the multiplication of a normalized dose D_{gn} with the incident air kerma K:

$$\mathrm{MGD} = D_{gn} \cdot K$$

The factor D_{gn} depends on the beam quality, the thickness of the compressed breast and the glandularity.

Recently, Sechopoulos et al. [4] also included the scatter from the breast to other organs as well as the backscatter of other organs back into the breast in their dosimetry calculations. These effects were found to be negligible.

3. DOSE TO THE SCREENED POPULATION

X ray doses delivered during breast cancer screening actions can be monitored via dedicated dose surveys, either manually or using automatic dose data collection software tools. For each woman, exposure parameters along with some patient related parameters (compressed breast thickness, fraction of glandular tissue, projection view) are to be collected. From a series of tables, the MGD can then be assessed. A large number of data can be used to construct dose histograms for further analysis. A practical difficulty is associated with the estimation of the glandular fraction.

Dance et al. [5] have studied the fractions of glandular tissue for the screened United Kingdom population and for younger women between 40 and 49 years. They obtained a glandularity distribution that depends on the thickness of the compressed breast. This curve was applied in the early United Kingdom population dose studies [6] and is still applied in most dose survey studies today. An example of dose distribution using these averaged glandularity coefficients is shown in Fig. 1.

In the present conference, Geeraert et al. [7] discuss a study of the glandularity based upon a specific parameter retrieved from the system and called ‘peak breast density’. The analysis was performed separately for Europe, Asia and North America, and showed that the glandularity estimate of Dance et al. [5] seems to be a reasonable average curve for the different populations.

An example of how these data can be used for creating awareness is shown in Figs 2 and 3. In our local network of mammography systems, we control the mammography systems following the European Guidelines for Quality Assurance [8] and the Belgian obligations of (3 yearly) patient dosimetry. Dosimetric data are automatically collected and processed (software tools by qaelum NV) and reported in comparison to data of other centres (Fig. 2). A more global analysis (Fig. 3) showed that our computed radiography (CR) systems use a considerably larger dose than our direct radiology (DR) systems [9].

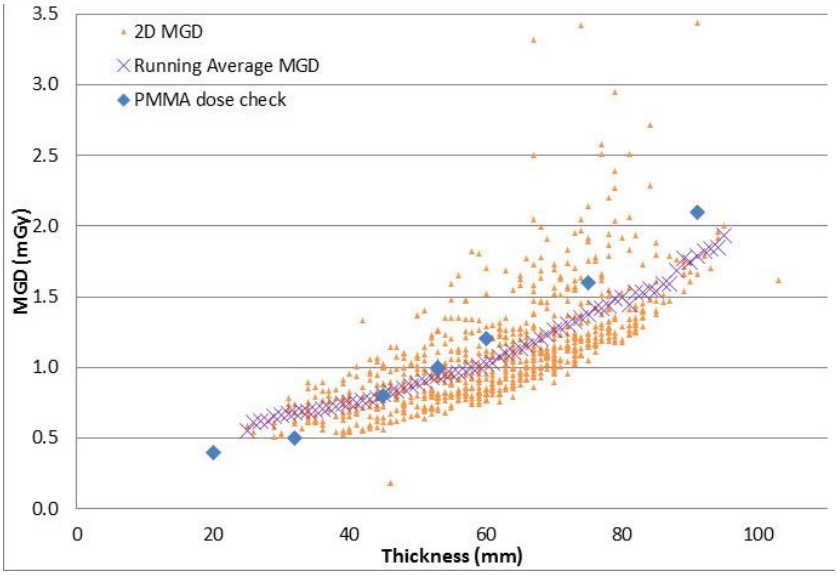

FIG. 1. Distribution of mean glandular doses (MGDs) for a large dose data survey using automated tools for data collection and MGD calculation assuming a thickness dependent glandularity distribution as in Ref. [5] for the age group 50–69 years. MGD estimates from acquisitions on polymethyl methacrylate (PMMA) are also indicated.

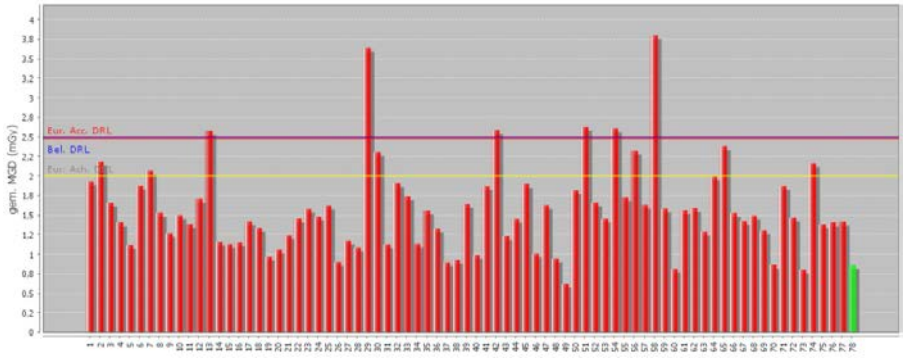

FIG. 2. Part of a feedback document as sent to centre 78 after a dose survey in 78 centres. Centre 78 is coloured in green and can, therefore, easily be compared to all the other centres. In the case of high doses, the feedback document can motivate a centre to start dose optimization studies.

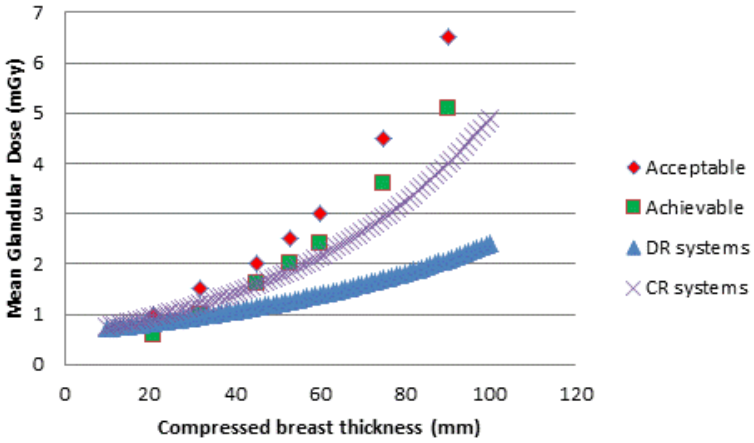

FIG. 3. Mean glandular dose (MGD) as a function of compressed breast thickness for a large patient dose sample examined with direct radiography (DR) and computed radiography (CR) technology, respectively. The achievable and acceptable dose levels for polymethyl methacrylate (PMMA) acquisitions (all of them corresponding to a specific compressed breast thickness) are plotted on top of this graph.

4. THE ALARA PRINCIPLE APPLIED TO BREAST IMAGING

The ALARA (as low as reasonably achievable) principle confronts risks and advantages associated with the use of X rays. In medical imaging, this translates into doses should be as low as possible, while images should be suitable for the radiological task. Breast imaging is well studied in this respect and should be considered an example for other imaging applications.

In Europe, the common approach to studying the suitability for the radiological task is translated into the measurements of the threshold gold thickness of discs with a diameter of 100 µm. In the European Guidelines, limiting values can be found for the minimal thickness required to detect a gold disc with a diameter of 100 µm. Some reports, such as the commissioning reports in the national health service in the United Kingdom, publish the required MGD for a 5 cm phantom (representing a 6 cm compressed breast) to achieve the quality criteria. The typical situation of image quality MGD is shown in Fig. 4 for our breast cancer network [10]. It shows, for a large set of systems, at what dose or quality level the systems are being set up and the limits being imposed by the European Guidelines.

The limiting values had been retrieved from values of film-screen systems used in screening programmes, by which it was proven that they had a reduced

mortality due to screening programmes. Analyses were performed on a large set of film-screen systems and the 5% percentile of quality (with only 5% of systems scoring worse) was set as the upper limit for the gold thicknesses. In the Flemish breast cancer screening programme, a large variety of mammography systems are being used, all of them with a dose setting adjusted to pass the threshold thickness criteria. It has been shown that both CR and DR systems provide similar screening parameters [9].

Warren et al. [11] explored the detectability of (simulated) microcalcifications for system conditions simulated to perform at different dose levels and system parameters. They obtained a link between the detectability of these microcalcifications and the threshold gold thicknesses of the corresponding system conditions (Fig. 5). This work is a step in the direction of virtual clinical trials that are being prepared. In the most extensive application, virtual breast phantoms with virtual lesions (software phantoms) are being projected for a virtual X ray system and are being analysed using mathematical measures of lesion detectability. The aim of these studies is to explore the breast imaging system performance for different system parameters, eventually beyond existing systems. It is an ultimate intitiative in the application of the ALARA principle, performed without any double exposure to any woman.

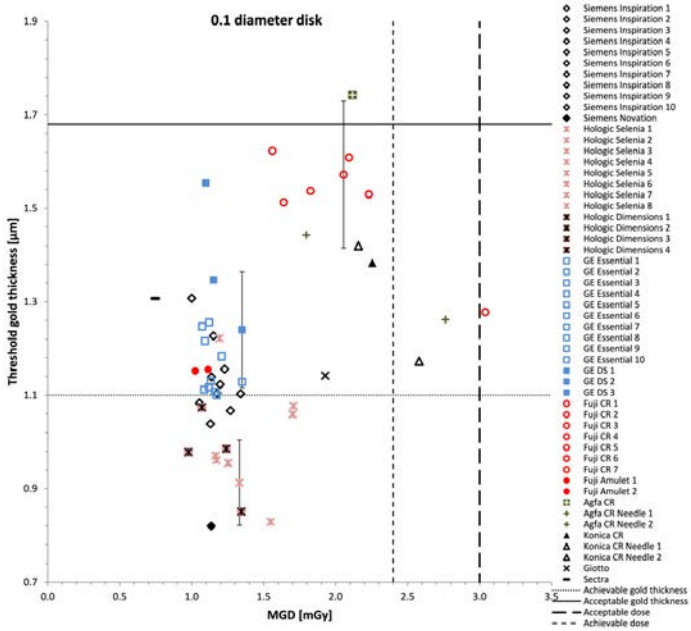

FIG. 4. Combined visualization of mean glandular dose (MGD) and threshold gold thickness to detect the 0.1 mm disc for a large set of systems [11].

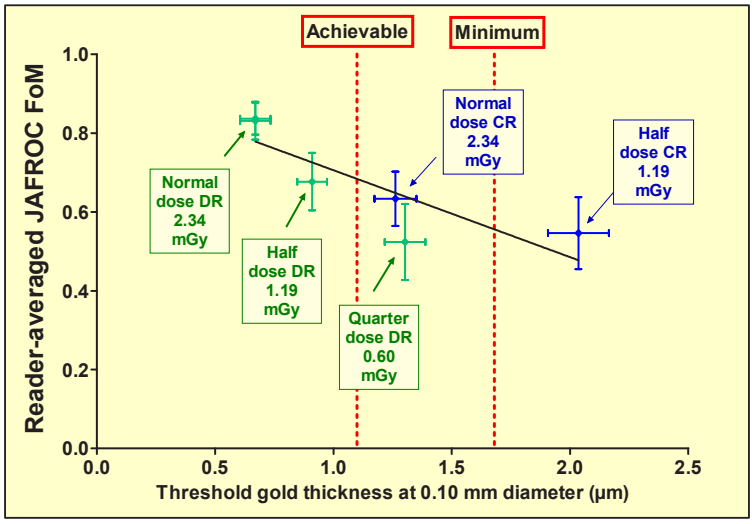

FIG. 5. Link between the threshold gold thickness retrieved from analysis of CDMAM images for different system simulations and a performance parameter retrieved from human reading of images of a virtual clinical trial of corresponding X ray systems (courtesy of K. Young, OPTIMAM project).

5. SUMMARY

Breast cancer screening has been shown to reduce mortality from breast cancer. This can be achieved at relatively low doses that are, in general, very well studied. This is certainly in part attributable to the fact that there is continuous (public) debate on radiation protection issues in screening. X ray doses delivered to the screened population require objective and quantitative data. There are different methods for breast dosimetry, retrieving either patient specific input data on glandularity or average values from larger cohorts (most common method).

The European summary of the use of X rays in the frame of screening was summarized in the European Council Recommendations of December 2003. Breast cancer screening is justified in the age group of 50–69 years but only if the quality is assured. In the United States of America and Canada, the benefits and risks of screening have been re-investigated recently [12]. Several authors show a benefit of screening over a larger age range, namely from 40 years, with annual screening up to 69 years or even older. This has been reinforced recently with a study entitled Saving dollars versus saving lives, with the aim of justifying breast cancer screening with X ray mammography [13].

REFERENCES

[1] DANCE, D.R., Monte Carlo calculation of conversion factors for the estimation of mean glandular breast dose, Phys. Med. Biol. **35** 9 (1990) 1211–1219.

[2] DANCE, D.R., YOUNG, K.C., VAN ENGEN, R.E., Estimation of mean glandular dose for breast tomosynthesis: Factors for use with the UK, European and IAEA breast dosimetry protocols, Phys. Med. Biol. **56** 2 (2011) 453–471.

[3] WU, X., BARNES, G.T., TUCKER, D.M., Spectral dependence of glandular tissue dose in screen-film mammography, Radiology **179** 1 (1991) 143–148.

[4] SECHOPOULOS, I., et al., Monte Carlo and phantom study of the radiation dose to the body from dedicated CT of the breast, Radiology **247** 1 (2008) 98–105.

[5] DANCE, D.R., et al., Additional factors for the estimation of mean glandular breast dose using the UK mammography dosimetry protocol, Phys. Med. Biol. **45** 11 (2000) 3225–3240.

[6] YOUNG, K.C., BURCH, M.A., ODUKO, J.M., Radiation doses received in the UK Breast Screening Programme in 2001 and 2002, Br. J. Radiol. **78** 927 (2005) 207–218.

[7] GEERAERT, N., et al., IAEA-CN-192, these Proceedings (CD-ROM).

[8] EUROPEAN COMMUNITIES, European Guidelines for Breast Cancer Screening and Diagnosis (PERRY, N., et al., Eds), Office for the Official Publications of the European Communities, Luxembourg (2006).

[9] BOSMANS, H., et al., Technical and clinical breast cancer screening performance indicators for computed radiography versus direct digital radiography, Eur. Radiol. **23** 10 (2013) 2891–2898.

[10] SALVAGNINI, E., et al., "Model observer detectability as a substitute for contrast detail analysis in routine digital mammography quality control", Medical Imaging 2013: Physics of Medical Imaging (Proc. SPIE, 2013), (2013).

[11] WARREN, L.M., et al., Effect of image quality on calcification detection in digital mammography, Med. Phys. **39** 6 (2012) 3202–3213.

[12] YAFFE, M.J., MAINPRIZE, J.G., Risk of radiation-induced breast cancer from mammographic screening, Radiology **258** 1 (2011) 98–105.

[13] LEWIS, T., et al., Saving dollars versus saving lives, Evaluation of the 2009 Revised United States Preventative Task Force Breast Cancer Screening Guidelines, Exhibits & Posters, LL-BRE3208 (Conf. RSNA 2012), (2012).

RADIATION PROTECTION OF PATIENTS AND STAFF WHERE PROCEDURES ARE PERFORMED OUTSIDE RADIOLOGY DEPARTMENTS

(Session 8)

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RADIATION PROTECTION OF PATIENTS AND STAFF WHERE PROCEDURES ARE PERFORMED OUTSIDE RADIOLOGY DEPARTMENTS

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Abstract

Nowadays, many diagnostic or interventional procedures using X rays are performed outside radiology departments: in operating rooms for X ray guided procedures or for control purposes, at the bedside and in dentistry. The variety of procedures, actors and installations in this area leads to a heterogeneous situation in terms of radiation protection. To improve radiation protection, important issues should be considered: the education and training in radiation protection of medical staff, the adaptation of the equipment to the complexity of the procedure, including the optimization process and the improvement of staff dose monitoring. Special care should be taken to repeated exposure of children, especially in neonatology and in dental radiology.

1. INTRODUCTION: A VARIETY OF PROCEDURES, ACTORS AND INSTALLATIONS

Procedures using ionizing radiation performed outside radiology departments are either interventional or diagnostic procedures.

First developed by radiologists in their own departments, interventional radiology nowadays is a technique used in many operating rooms, in various fields of medicine, such as cardiology, vascular surgery, gastroenterology, urology, gynaecology, orthopaedics and neurology. For diagnostic purposes, X rays are also used on a daily basis at the bedside, mainly in intensive care units and in neonatology. Dental radiology, including intra-oral, panoramic and computed tomography (CT) examinations, must also be included among the procedures performed outside radiology departments. This variety of procedures leads to very different levels of exposure, and levels of risk, for patients and staff.

Actors involved in X ray use, and consequently in radiation protection, are, thus, numerous. In operating rooms, the main actors are surgeons or cardiologists. However, anaesthetists and nurses are also concerned. In some

cases, radiographers are members of staff. Dental surgeons must also be included in this list.

There are various installations that can perform these types of procedure. Many conventional C-arms and mobile units equipped with image intensifiers are still being used, but digital detectors are becoming more common. Mobile CTs, called 'O-arm', have also been installed in operating rooms for the past few years. In dental care, cone beam CT was developed recently.

Very little data related to the frequency of procedures, patient doses or staff doses are available in this area at European level [1]. Furthermore, no diagnostic reference levels have been established for most of these procedures, at least in Europe. It is, thus, difficult to have an overview of patient or staff exposures related to these procedures.

2. MAIN RADIATION PROTECTION ISSUES FOR PROCEDURES PERFORMED OUTSIDE RADIOLOGY DEPARTMENTS

This variety of procedures, actors and installations explains that challenges will have to be faced to improve radiation protection outside radiology departments.

2.1. Education and training

One of the main issues regarding procedures performed outside radiology departments concerns staff education and training in radiation protection. As initial education varies, staff knowledge in radiation protection is very heterogeneous and, sometimes, even absent. Without sufficient education and training, basic radiation protection rules (applying justification and optimization principles) may not be implemented in daily practice, neither for the patients nor the staff.

Although radiation protection officers are designated, their missions are not recognized sufficiently in the different areas listed above. Moreover, medical physicists are rarely involved. The contribution of these professionals in dose optimization and radiation protection training would be very valuable.

2.2. Equipment characteristics

Another important issue concerns the equipment characteristics. This is particularly obvious in interventional radiology performed in operating rooms. This activity is being used for more types of procedure and for patients presenting with more complex clinical circumstances. In some cases, the

turnover of the X ray equipment is not in line with medical progress and the X ray installations might not be adapted to the complexity of the procedures undertaken. However, the optimization capacities of the equipment are all the more useful as the procedures get more complex and could lead to important patient and staff exposure reductions.

To allow patient dose monitoring and establishment of dose alert values, the equipment must provide the kerma area product of the procedure.

Finally, the equipment must be equipped with adequate collective shielding for staff protection. In operating rooms, where X ray units are mobile C-arms, no protective screen is systematically available. Hospitals must provide protection adapted to the types of procedure and to the operational work conditions. This protection could be ceiling screens, mobile screens or table curtains. Protection of the entire staff (operators, nurses, etc.) must be ensured.

2.3. Staff dose monitoring

Another point to be considered is the improvement of staff dose monitoring, especially in operating rooms.

It is well known that personal dosimeters are not regularly worn in operating rooms. Additional monitoring for the eyes and hands, using ring rather than wrist dosimeters, is sometimes necessary, according to the risk analysis. Operators, surgeons or cardiologists are not always convinced of the use of dose monitoring and sometimes consider dose monitoring a ‘constraint’ and refuse it. Hand monitoring has often been refused on hygiene grounds even though dosimeters can now be sterilized.

Staff dose monitoring in operating theatres is not harmonized at the international level. Some countries require active dosimetry in addition to passive dosimetry. Dose measurement above the apron is sometimes associated with the dose measurement under the apron to calculate the effective dose.

2.4. Repeated paediatric procedures

The last important issue concerns procedures performed on children. Owing to the fact that their organs are in development and due to their long life span, the paediatric population is sensitive to ionizing radiation. Special care must be taken in justification and optimization when exposing children, especially in the case of repeated procedures.

In neonatology, daily chest and abdomen X rays can be performed on very young children, often on premature babies, for weeks. These repeated X rays must be justified, optimized and monitored.

Dental radiology is also a major source of child exposure. Doses are small but the frequency of these procedures is high [2, 3]. In France in 2010, 50% of diagnostic procedures performed on children were dental examinations.

3. CONCLUSIONS

Radiation protection in the medical field has clearly improved over the past years. Many international recommendations have been implemented at the national level. Professional bodies have worked to enhance radiation protection in their field. Finally, the daily work of radiation protection actors has practically improved the situation in the medical field.

Nevertheless, operating rooms remain places where basic radiation protection rules are rarely integrated into daily practice. Guidelines have already been developed [2, 4] and recommendations are available [5], but work still has to be done, in the near future, to practically improve radiation protection in operating rooms.

Moreover, special attention should be paid to procedures performed on children, especially at the bedside and in dental radiology.

REFERENCES

[1] EUROPEAN MEDICAL ALARA NETWORK, European Workshop on Optimisation of Radiation Protection in Medicine, Vienna, 2012, http://eman-network.eu/IMG/pdf/3_EMAN_Workshopps4__WG3_workinggroup_Padovani.pdf

[2] EUROPEAN COMMISSION, European Guidelines on Radiation Protection in Dental Radiology, Radiation Protection Publication 136, Directorate-General for Energy and Transport, European Commission, Luxembourg (2004), http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/136_en.pdf

[3] ETARD, C., et al., French population exposure to ionizing radiations from diagnostic medical procedures in 2007, Health Phys. **102** 6 (2012) 670–679.

[4] WORLD GASTROENTEROLOGY ORGANISATION, Radiation Protection in the Endoscopy Suite — Minimizing Radiation Exposure for Patients and Staff in Endoscopy: A Joint ASGE/IAEA/WGO Guideline (2009), http://www.worldgastroenterology.org/radiation_protection_in_the_endoscopy_suite.html

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection of Patients (RPOP), http://rpop.iaea.org

MINIMIZING PATIENT EXPOSURE TO RADIATION IN GASTROINTESTINAL IMAGING

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Abstract

Many diagnostic imaging examinations in gastroenterology involve exposure to ionizing radiation. These procedures include plain radiography, barium studies, nuclear medicine studies, computed tomography (CT), interventional radiology procedures, and procedures performed under fluoroscopy guidance in an endoscopy suite (e.g. endoscopic retrograde cholangiopancreatography). Radiation protection is vital for all procedures performed under fluoroscopy guidance, including those performed in the endoscopy suite. Radiation protection in the endoscopy suite should follow published guidelines from the International Commission on Radiological Protection and the World Gastroenterology Organisation, which specifically address the issue of radiation protection for fluoroscopically guided procedures performed outside imaging departments and in the endoscopy suite. Recent studies have examined the issue of lifetime cumulative effective doses received by patients attending hospital with gastrointestinal disorders and have shown potential for substantial radiation exposures from gastrointestinal imaging, especially in small groups of patients with chronic gastrointestinal disorders such as Crohn's disease. In these studies, CT is the major contributor to cumulative dose. In these patients, radiation dose optimization is necessary and should follow the principles of justification, optimization and limitation.

1. RADIATION PROTECTION AND THE ENDOSCOPY SUITE

The background information and recommendations described below are based on Publication 117 of the International Commission on Radiological Protection (IRCP) [1] and the World Gastroenterology Organisation (WGO) guidelines [2].

Currently, there are increasing numbers of medical specialists using fluoroscopy outside imaging departments and the use of fluoroscopy is currently greater than at any time in the past. Studies have shown that there is greater likelihood of neglect of radiation protection procedures in fluoroscopy suites

located outside imaging departments. This is partly explained by lack of education and training in radiation protection in this setting, and can result in increased radiation risk to patients and staff.

1.1. Radiation protection and fluoroscopy facilities separate from radiology departments

The extent of the problem with radiation protection in endoscopy suites can vary greatly from one jurisdiction to another [1, 2]. In some countries, there is no database of fluoroscopic equipment located outside radiology departments. Radiation dose to staff in all fluoroscopy suites can potentially be much higher when compared to radiotherapy, computed tomography (CT) and nuclear medicine facilities. Selected procedures (e.g. therapeutic endoscopic retrograde cholangiopancreatography (ERCP)) can result in very substantial radiation exposures. As a result, staff in endoscopy suites need enhanced radiation protection education and need to routinely utilize radiation protection tools (e.g. lead aprons, thyroid and eye shields). There is huge variation, between institutions and between countries, in the level of involvement of radiologists and medical physicists in radiation protection for endoscopic procedures.

1.2. Potential risk areas

In some hospitals and in some jurisdictions, there may be a lack of radiation protection culture, with a paucity of patient and staff dose monitoring [1, 2]. There may be poor quality control of fluoroscopic equipment with risk for incidental accidental high exposures or routine overexposures affecting patients and staff. Poor radiation shielding, including lead flaps and poor maintenance of radiation protection equipment, can also be associated with additional risks.

1.3. Radiation dose to patients in endoscopic procedures

Shielding systems to protect staff should be optimized to reduce dose, but must not interfere with performance of clinical tasks. Scheduled periodic testing of fluoroscopic equipment can provide confidence in equipment safety [1, 2].

1.4. Patient factors

Factors which can impact the dose received by patients or the effects of radiation exposure include:

— Body mass or thickness of body part in the fluoroscopic field, i.e. the greater the thickness, the greater the radiation dose.
— Young age: Tissues in children (including thyroid, gonads and breasts) are more susceptible to effects of ionizing radiation.
— Patient's disease and indication for procedure: Complex diseases requiring complex procedures are associated with higher doses.
— Previous radiation exposure: may increase risk of radiation injury.
— Radiosensitivity of tissues and organs in some patients, including ataxia-telangiectasia syndrome, connective tissue disorders (discoid lupus) and diabetes mellitus, is increased.

1.5. Equipment factors

— Under-couch tubes reduce scattered radiation and exposure to operators, staff and patients.
— The use of pulsed fluoroscopy reduces dose, and operators should use the lowest possible pulsed rate in an effort to reduce radiation exposure. Image hold and image capture options also represent very important features of modern fluoroscopy which can reduce dose and should be used where feasible.
— Appropriate quality control of fluoroscopy equipment: Properly functioning fluoroscopy equipment and personnel protection equipment represent vitally important components of radiation safety.
— Alarm levels for excessive fluoroscopy time and higher dose can help reduce fluoroscopy time and radiation dose.
— Poor radiation shielding, including lead flaps and poor maintenance of all radiation protection components, can be a major problem.

1.6. Procedure related factors

There are many important steps which can be taken to reduce radiation exposure, including the careful use of collimation to reduce area of exposure, limiting the number of radiographic images, using magnification only when really necessary and avoiding steep angulations of the X ray tube [1, 2]. The X ray tube should be as far as possible and image receptor as close as possible to the patient. In addition, the radiation field should be limited carefully to the parts of the body being investigated.

2. RADIATION PROTECTION AND THE GASTROENTEROLOGY AND HEPATOBILIARY SYSTEMS

ERCP represents 8.5% of all fluoroscopic guided diagnostic and interventional procedures in the United States of America [1, 2]. ERCP represents the procedure which accounts for the most radiation exposure in interventional gastroenterology. The mean effective dose for ERCP is 4 mSv and ERCP contributes 4–5% of total collective dose from all fluoroscopy guided interventions [1, 2]. Most ERCP studies involve 2–16 min of fluoroscopy, but fluoroscopy time can be much longer when therapeutic interventions such as stent placement are performed. The mean effective doses of therapeutic ERCP (12–20 mSv) are, therefore, much higher than diagnostic ERCP (2–6 mSv).

2.1. Staff doses at endoscopic retrograde cholangiopancreatography

Average effective doses of 2–70 μSv per procedure have been reported for endoscopists wearing a lead apron [1, 2]. The major source of radiation exposure to endoscopists is scattered radiation. Lead aprons provide protection; however, there can be substantial doses to unshielded parts such as the fingers and eyes. Busy physicians can potentially receive substantial annual effective doses. Doses to assisting personnel (e.g. nurses and radiographers/technologists) are usually considerably lower.

2.2. Recommendations: Patient doses

To reduce patient doses at ERCP, the following measures should be implemented:

— Replace diagnostic ERCP with magnetic resonance cholangiopancreatography and reserve ERCP for cases where intervention is required.
— Use C-arm fluoroscopy units with pulsed fluoroscopy. Use of grid controlled fluoroscopy also significantly reduces patient doses.
— Reduce fluoroscopy (screening) time, limit radiographic images, collimate beam and reduce the use of magnification.
— Record and audit patient exposure factors (fluoroscopy time, dose area product).

2.3. Recommendations: Staff doses

To reduce staff doses, the following measures should be followed:

— The fluoroscopy facility should be licensed by an appropriate radiation regulatory authority.
— ERCP requires the same attention to radiation protection as all other interventional radiology (IR) procedures.
— All staff working in endoscopy suites must follow similar radiation protection procedures to those in IR suites inside radiology departments.
— Staff participation in institutional radiation protection programmes should be mandatory.
— Basic principles of radiation protection should be remembered: time, distance and shielding should be followed.
— All staff should wear appropriate protective lead apron, thyroid shields and leaded eyewear. Use of ceiling mounted shielding, and lead rubber flaps mounted on pedestals that are mobile, should be mandatory and staff should be educated in how to use them effectively.
— Shielding devices should be regularly inspected and maintained.
— Personnel dosimetry badges should be mandatory to estimate and monitor dose.
— Training and experience are powerful dose reduction tools. Procedures performed by highly experienced and trained staff usually result in much lower patient and staff exposures — every 10 years of experience has been reported to be associated with 20% reduced fluoroscopy time.

3. RADIATION DOSE IN GASTROINTESTINAL IMAGING

Recently published papers have shown increasing lifetime cumulative effective doses (CEDs) of radiation as a result of diagnostic imaging in patients with chronic gastrointestinal disorders, such as inflammatory bowel disease [3–6]. These studies have documented increased performance of CT scanning and reduced performance of barium studies in recent years [3]. There has been continued high utilization of plain radiographs, in spite of the fact that other studies have questioned the diagnostic value of these studies and their ability to influence patient management [3]. Small groups of patients (and especially subgroups of Crohn's patients) can be exposed to substantial cumulative effective doses of ionizing radiation [3]. In most studies, CT is the biggest contributor to CED [3, 4]. The authors of these papers have argued that if CED is to be reduced in patients presenting to gastrointestinal clinics, an initial focus on reducing the dose from CT scanning would have a major impact. In addition, limiting the use of plain abdominal radiography in Crohn's disease and other chronic gastrointestinal disorders should be considered, as performance of these studies usually has little impact on patient management.

3.1. Strategies for reducing radiation dose from CT in gastroenterology patients

Briefly, strategies for reducing radiation exposure associated with CT scanning in gastroenterology patients should follow three basic principles [7, 8]:

(a) Justification: Use CT and other studies which involve exposure to ionizing radiation only when necessary.
(b) Substitute CT with ultrasound and magnetic resonance imaging when possible.
(c) Optimization: When CT and other studies which involve exposure to ionizing radiation are necessary, perform them at the lowest achievable dose. An example to highlight this strategy would be the use of magnetic resonance enterography (MRE) in place of CT enterography (CTE) in Crohn's disease patients. MRE is an excellent alternative to CTE and offers the additional value of cine sequences which can give additional information regarding the severity of strictures. MRE, however, is technically more challenging and image quality is more prone to variability, when compared to CTE. It is also less available than CTE, takes longer and may not be suitable for acutely unwell patients.

3.2. Reducing radiation dose associated with CT scanning of the gastrointestinal tract

Radiation dose optimization in the performance of CT scanning can be summarized as "Achieving a diagnostic-quality image at lowest possible radiation dose" [6]. The major obstacle to substantially reducing radiation dose at CT scanning is that low dose CT images may have increased image noise, which reduces image quality and may result in missed diagnoses. There is, therefore, a fine balance between reducing radiation exposure and maintaining sufficient image quality to ensure accurate detection of pathology.

3.3. Major technological developments which assist dose optimization at CT

3.3.1. Automatic exposure control techniques

Practically all CT systems have automatic exposure control (AEC) systems operating with tube current modulation [9]. Each of these systems has different specifications and operates somewhat differently. The challenge is to ensure

that all CT centres use this technology optimally. Studies which have critically examined the ability of AEC to reduce radiation exposure during CT scanning have reported a 34–41% reduction in the mean tube current time product during CT scanning of the abdomen and pelvis. AEC resulted in reduction in the mean tube current time product in 87% of patients [9].

3.3.2. Iterative reconstruction

In recent years, the industry has focused much of its efforts in research and development on iterative reconstruction techniques as a means of reducing noise or 'mottle' from CT images acquired with the use of low dose protocols [10–13]. These iterative reconstruction techniques are replacing filtered back projection, which has been the standard method of image reconstruction on most commercial CT scanners. Iterative reconstruction is a method which models photon statistics and, thus, extracts noise in the final image. Recently published studies have shown that iterative reconstruction techniques can achieve substantial radiation dose reductions in gastrointestinal imaging, with particularly low dose CT protocols being described for inflammatory bowel disease and Crohn's disease patients [6, 10, 11]. Reports are now emerging of submillisievert CT abdomen and pelvis protocols in these patients and radiation dose reductions of 70–80% for selected clinical indications.

4. OTHER DEVELOPMENTS

4.1. Patient dose tracking

Radiation dose tracking is a new development, which has recently been made available by the industry [14]. Its aim is to create an institutional database of radiation exposures which can be used for a number of applications. It consists of a workstation, which is installed between the individual imaging modalities (i.e. CT, fluoroscopy, nuclear medicine, etc.) and the picture archiving and communication system (PACS). Radiation exposures associated with diagnostic imaging procedures are calculated from Digital Imaging and Communications in Medicine (DICOM) headers and are recorded in the database. From this database, accurate radiation dose estimations can be made for each imaging procedure, and this information may be included in the patient's radiology report, if appropriate. Patient lifetime CED can be made available instantaneously and this can be made available to the ordering physician or radiologist before a CT scan is performed. This information, if freely available, could potentially result in another study (involving less or no radiation exposure) being performed or a

lower dose CT protocol being employed. In addition, this radiation database could result in robust radiology department quality assurance in radiation protection. Valuable data including mean radiation doses per radiology technician, modality (CT, nuclear medicine) and/or radiologist could be collected and analysed and compared to international best standards. A recent paper assessed the current status of patient radiation exposure tracking internationally and showed that no country has yet implemented a patient exposure tracking programme at a national level [14]. Eight countries (11%) indicated that a national patient tracking programme was being actively planned. There were some successfully established programmes at subnational or regional level.

4.2. Education in radiation protection

Education in radiation protection is a key priority and is important for all physicians including radiologists and other physicians who perform fluoroscopically guided procedures and other procedures which involve exposure to ionizing radiation. It is also important for physicians who order imaging studies including plain radiography, CT, barium studies and nuclear medicine examinations. Radiation protection should, therefore, be introduced as a core competency in the undergraduate medical curriculum [15]. Organizations such as the WGO are now advocating that radiation protection should be part of specialist training in gastroenterology and should also be highlighted as an important issue in continuous medical education for gastroenterologists.

5. CONCLUSIONS

Radiation protection in endoscopy suites should follow ICRP and WGO guidelines in all jurisdictions. ERCP requires the same attention to radiation protection as all other IR procedures. With regard to gastrointestinal imaging, recent studies have demonstrated that there is potential for substantial cumulative radiation doses from gastrointestinal imaging in groups of patients with chronic gastrointestinal disorders, e.g. Crohn's disease patients. In these patient cohorts, CT is the major contributor to cumulative exposure. If the potential for high cumulative effective radiation doses is to be reduced in these patients, focusing efforts initially on optimizing radiation exposure associated with CT scanning is likely to have a major impact.

REFERENCES

[1] INTERNATIIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Fluoroscopically Guided Procedures Performed outside the Imaging Department, Publication 117, Elsevier (2010).

[2] WORLD GASTROENTEROLOGY ORGANISATION, Radiation Protection in the Endoscopy Suite — Minimizing Radiation Exposure for Patients and Staff in Endoscopy: A Joint ASGE/IAEA/WGO Guideline (2009), http://www.worldgastroenterology.org/radiation_protection_in_the_endoscopy_suite.html

[3] DESMOND, A.N., et al., Crohn's disease: Factors associated with exposure to high levels of diagnostic radiation, Gut **57** 11 (2008) 1524–1529.

[4] LEVI, Z., et al., Factors associated with radiation exposure in patients with inflammatory bowel disease, Aliment. Pharmacol. Ther. **30** 11–12 (2009) 1128–1136.

[5] DESMOND, A.N., et al., Radiation exposure from diagnostic imaging among patients with gastrointestinal disorders, Clin. Gastroenterol. Hepatol. **10** 3 (2012) 259–265.

[6] CRAIG, O., et al., Diagnostic accuracy of computed tomography using lower doses of radiation for patients with Crohn's disease, Clin. Gastroenterol. Hepatol. **10** 8 (2012) 886–892.

[7] KALRA, M.K., et al., Strategies for CT radiation dose optimization, Radiology **230** 6 (2004) 619–628.

[8] COAKLEY, F.V., GOULD, R., YEH, B.M., ARENSON, R.L., CT radiation dose: What can you do right now in your practice? AJR Am. J. Roentgenol. **196** 3 (2011) 619–625.

[9] KALRA, M.K., et al., Comparison of Z-axis automatic tube current modulation technique with fixed tube current CT scanning of abdomen and pelvis, Radiology **232** 2 (2004) 347–353.

[10] KAMBADAKONE, A.R., et al., Low-dose MDCT and CT enterography of patients with Crohn disease: Feasibility of adaptive statistical iterative reconstruction, AJR Am. J. Roentgenol. **196** 6 (2011) W743–W752.

[11] KAMBADAKONE, A.R., PRAKASH, P., HAHN, P.F., SAHANI, D.V., Low-dose CT examinations in Crohn's disease: Impact on image quality, diagnostic performance, and radiation dose, AJR Am. J. Roentgenol. **195** 1 (2010) 78–88.

[12] SILVA, A.C., et al., Innovations in CT dose reduction strategy: Application of the adaptive statistical iterative reconstruction algorithm, AJR Am. J. Roentgenol. **194** 1 (2010) 191–199.

[13] SINGH, S., et al., Abdominal CT: Comparison of adaptive statistical iterative and filtered back projection reconstruction techniques, Radiology **257** 2 (2010) 373–383.

[14] REHANI, M.M., FRUSH, D.P., BERRIS, T., EINSTEIN, A.J., Patient radiation exposure tracking: Worldwide programs and needs — Results from the first IAEA survey, Eur. J. Radiol. **81** 10 (2012) 968–976.

[15] LEONG, S., et al., An assessment of the feasibility and effectiveness of an e-learning module in delivering a curriculum in radiation protection to undergraduate medical students, J. Am. Coll. Radiol. **9** 3 (2012) 203–209.

RADIATION PROTECTION IN DENTAL RADIOLOGY

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Abstract

Dentists undertake large numbers of diagnostic X ray examinations, but the generally accepted view is that radiation doses are low. Nonetheless, most dental radiology is performed outside radiology departments in independent practices, where self-referral is normal, paediatric patients form a large proportion of those exposed and quality assurance procedures may be lacking. While dental radiology encompasses a small range of techniques, the recent introduction of cone beam computed tomography (CBCT) promises to increase collective doses attributable to dental radiology in the future. While effective doses in well controlled research studies are quite low, dose audits suggest that the 'real world' situation is not so straightforward. In terms of justification, dentists are influenced in their use of diagnostic X rays by non-clinical factors. Referral criteria are available, but evidence for compliance is low. In terms of optimization, newer equipment and modified techniques should lead to lower doses, but their adoption is slow. There are particular optimization issues with CBCT, where some equipment gives little scope for exposure adjustment. The difficult challenges of radiation protection in dental radiology require efforts in education of dentists and increased awareness of evidence based guidelines, including audit of compliance with good practice. Regular dose audits and the setting of diagnostic reference levels are valuable tools, as long as they are followed by individualized feedback to dentists on optimization strategies.

1. INTRODUCTION

In their 2008 report, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) estimated that there were approximately half a billion diagnostic dental X ray examinations perfomed annually worldwide, representing about 15% of all diagnostic X ray examinations [1]. This is probably an underestimate, because most are performed by dentists in primary care outside public health care systems. Most diagnostic dental X ray examinations are perfomed in health care level I countries and, according to UNSCEAR, the level of use has been steady over recent decades. In health care level II and below countries, use is much lower, but increasing. Despite the quite high number of diagnostic dental X ray examinations, the associated radiation doses are quite low, with an estimated

global collective effective dose of 11 000 manSv [1]. In other words, dental radiology could be described as a high volume, low dose procedure.

If the collective doses are so low, despite the relatively high numbers, then it could be argued that dental radiology has a trivial importance as far as radiation protection is concerned. It would be wrong, however, to be complacent about dental radiology. This is for several reasons. First, as has already been said, most dental radiology takes place in primary care facilities without the supportive framework of medical physicist support and robust quality assurance programmes; this raises concerns about optimization of exposures. Second, unlike the rest of medicine, the use of X rays tends to be high in children and younger people for whom the risks are highest. Finally, dentists usually perform their own radiographic procedures; self-referral and the financial pressures to make X ray equipment pay for itself inevitably challenge the justification process [2].

The aim of this paper is to review the challenges around radiation protection in dental radiology and to highlight strategies for improvement.

2. SCOPE OF DENTAL RADIOLOGICAL PRACTICE

The basic form of diagnostic X ray examination is intraoral radiography, which serves the overwhelming majority of a general dentist's needs: the detection of decay, the demonstration of the supporting bone and the diagnosis of inflammatory lesions around the roots of teeth. Supplementing this is panoramic radiography, developed in the 1940s–1950s, but which has grown substantially in use since the 1970s, with particular applications in assessing the developing dentition and in surgical procedures. Facial bone imaging using cephalography is mainly used as part of orthodontic assessment. Although analogue (film based) imaging is still widespread, digital systems are increasingly widespread and have become predominant in some developed countries. Beyond these techniques, computed tomography (CT) has been widely used in implant planning although, recently, dental cone beam CT (CBCT) has begun to replace CT. It was reported that 1 in 10 dental practices in the Republic of Korea had CBCT in 2009 [3].

2.1. Radiation doses

Radiation doses of diagnostic dental X ray examinations are, as described by UNSCEAR, low relative to many medical uses of radiation. A recent review of the literature has confirmed this, at least for the simple radiographic techniques [4]. These figures must be viewed with caution; dosimetry performed as part of scientific studies presents results from modern equipment in carefully controlled situations. In the 'real world', the truth is often very different

and is revealed by dose audits. Where large studies have been performed on equipment in primary dental care, a wide range of radiation doses is revealed with an elongated tail at the high dose end [3, 5–12].

3. JUSTIFICATION ISSUES

As self-referral is the normal situation for dentists, there are potential concerns with regard to justification of exposures [2]. Payment, whether by the patient directly, through private insurance or public health service systems, is a motivation for intervention. While evidence for this is often anecdotal, recent research has shown the impact on prescription of radiography when a public health service payment system changed [13]. X ray equipment suppliers can, and sometimes do, argue that the purchase cost of a panoramic or CBCT system can be covered by taking a specified number of examinations per week. There are other, more subtle, pressures on dentists to use radiography; in particular, there can be fears of missing something and facing consequent medico-legal problems [14]. Dentists are strongly influenced by peer pressure to use X rays, patient expectations and by the teaching received in undergraduate training.

How can these issues be addressed? As with medical radiology generally, there have been efforts to introduce guidelines (referral criteria) on prescription of diagnostic dental X ray examinations, for example, in Europe and in the United States of America [14, 15]. The quality of such guidelines varies, ranging from expert opinion of a small self-selected panel of individuals, through consensus statements of larger groups, to evidence based guidelines produced using robust methodologies. Guidelines are useless if they are not adopted and incorporated into the education of clinicians (undergraduate and continuing professional education). There is a paucity of current evidence for awareness of and adherence to published referral criteria. The evidence that does exist is not reassuring [16, 17]. ‘Screening’ radiography, especially using panoramic radiographs, is difficult to justify in unselected patient groups. Intraoral radiography for detection of dental caries (decay) is the most commonly performed X ray examination in dentistry, but intervals between examinations should be matched to clinical criteria of risk of disease [15, 18].

In terms of potential collective effective dose impact in the future, the growing use of CBCT presents important justification challenges. There is a perception, sometimes implicit in manufacturers’ literature and among clinicians, that ‘three dimensions’ (i.e. cross-sectional imaging using CBCT) are always better than two. Thus, where dentists have access to CBCT, it has become practice to use it instead of conventional radiography for some clinical applications. In the context of orthodontic treatments in children, this is highly controversial because

there is a paucity of evidence at the higher levels of diagnostic efficacy for a positive effect of using CBCT [4]. In particular, there has been no well designed randomized controlled trial to compare the outcomes of treatments using CBCT with treatments using conventional imaging. At present, the evidence suggests that CBCT should be considered as a secondary line of diagnostic X ray examination, to be used when conventional radiography fails to provide the information essential for management of the patient's problem [4].

4. OPTIMIZATION ISSUES

The 2008 UNSCEAR survey indicated that there had been a fall in collective effective dose attributable to dental radiology over the period since the previous survey [1]. They ascribed this finding to the introduction of improved films and film-screen combinations. While these factors undoubtedly contributed to a lowering of doses, the situation is somewhat more complex. With intraoral radiology, there has been a shift over the past 20 years by manufacturers from low operating potentials (50 kVp or less) to higher operating potentials (65–70 kVp) and constant potential equipment. In parallel, there has been a shift from round to rectangular collimation of the X ray beam. These features of newer equipment reduce doses substantially. The long working lifespan of dental X ray equipment means that the changes do not occur overnight, but emerge gradually as old equipment is phased out. It is important to remember, however, that these changes in equipment may not yet have had an impact in many countries, where there is evidence of continuing use of older, higher dose, equipment [19–21]. Even in the wealthiest countries, there is sometimes a reluctance to adopt even low (or zero) net economic cost methods of optimization, such as faster film speeds [22]. For panoramic radiography, analagous improvements in equipment design have contributed to lower individual patient doses, notably through field size limitation. Digital technology offers the potential of lowering patient doses, although the wide exposure latitude of digital systems, along with the absence of medical physics support, means that there is a risk of dentists not taking advantage of such opportunities. In the case of CBCT, as with other dental digital imaging, evidence suggests a substantial scope for optimization of dose by adjustment of exposures [4]. Matching the field of view to the diagnostic task permits significant dose reductions to be achieved, not least by taking organs of importance (e.g. the thyroid gland) out of the primary beam. Some CBCT systems, however, have no scope for adjustment of mAs and little or no way of changing the field of view. While manufacturers seem to be responding to calls for improvements in these deficiencies, it is likely that existing equipment will continue in clinical use for many years.

There is ample evidence of poor quality of images produced in dental practices [15]. Quality assurance programmes are often non-existent. Working in isolation means that dentists can become inured to sub-optimal quality. The growing use of digital imaging has had a positive impact by removing chemical processing, deficiencies of which are a common cause of poor image quality.

As pointed out above, 'real world' radiation doses from dental diagnostic X ray examinations often do not reflect those quoted in the scientific literature. Wide ranges of dose have been revealed in national dose audits. Diagnostic reference levels (DRLs), also known as 'guidance levels' or 'reference levels', based on third quartile values have been recommended in some countries [3, 5–12]. In the United Kingdom, for example, dental reference doses have been reduced over the years since their introduction [23], suggesting that when dentists are alerted to a possibility of lowering dose to patients they respond positively to external advice. In many countries, however, there are no widespread dose audits of dental X ray equipment and no mechanism of facilitating optimization of exposures.

5. DISCUSSION AND CONCLUSIONS

The impact of dental radiology on radiation protection of patients may be perceived as minor in view of the generally low individual and collective doses. Nonetheless, the large number of examinations, the high paediatric use, the primary care location, inconsistent or complete lack of interaction with medical physics support, self-referral and the long working lifespan of dental X ray equipment all suggest that complacency is not appropriate. Managing this challenge requires a coordinated response involving several groups. First, education in radiation protection must be part of the undergraduate dental curriculum and reinforced through lifelong learning. Education in dental aspects of radiation protection issues is also desirable for other groups, including medical physicists and dental X ray equipment manufacturers. Second, there is an important role to be played by guidelines; these should be evidence based and their development should involve all stakeholders (including dentists, medical physicists and dental radiologists), and compliance should be assessed through clinical audit. Finally, wherever feasible, dose audit with the development of DRLs including constructive feedback to dentists on dose optimization possibilities is needed.

REFERENCES

[1] UNITED NATIONS, Sources and Effects of Ionizing Radiation. Volume 1: Annex A: Medical Radiation Exposures (Report to the General Assembly), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).

[2] HORNER, K., "Dental radiology: The forgotten problem?", Justification of Medical Exposure in Diagnostic Imaging (Proc. Int. Workshop Brussels, 2009), IAEA, Vienna (2011) 139–147.

[3] HAN, S., et al., Dose area product measurement for diagnostic reference levels and analysis of patient dose in dental radiography, Radiat. Prot. Dosimetry **150** 4 (2012) 523–531.

[4] EUROPEAN COMMISSION, Cone Beam CT for Dental and Maxillofacial Radiology, Evidence Based Guidelines, Radiation Protection 172, Directorate-General for Energy, European Commission, Luxembourg (2012).

[5] HAVUKAINEN, R., Survey of dental radiographic equipment and radiation doses in Finland, Acta Radiol. **29** 4 (1988) 481–485.

[6] NAPIER, I.D., Reference doses for dental radiography, Br. Dent. J. **186** (1999) 392–396.

[7] GONZÁLEZ, L., VAÑÓ, E., FERNÁNDEZ, R., Reference doses in dental radiodiagnostic facilities, Br. J. Radiol. **74** 878 (2001) 153–156.

[8] HATZIIOANNOU, K., et al., Quality control and diagnostic reference levels in intraoral dental radiographic facilities, Dentomaxillofac. Radiol. **34** (2005) 304–307.

[9] POPPE, B., et al., Radiation exposure and dose evaluation in intraoral dental radiology, Radiat. Prot. Dosimetry **123** 2 (2007) 262–267.

[10] HOLROYD, J.R., National reference doses for dental cephalometric radiography, Br. J. Radiol. **84** 1008 (2011) 1121–1124.

[11] WALKER, C., VAN DER PUTTEN, W., Patient dosimetry and a novel approach to establishing Diagnostic Reference Levels in dental radiology, Phys. Med. **28 1** (2012) 7–12.

[12] ALCARAZ, M., et al., Evolution of diagnostic reference levels in Spanish intraoral radiology, Radiat. Prot. Dosimetry 151 1 (2012) 166–171.

[13] TICKLE, M., et al., Paying for the wrong kind of performance? Financial incentives and behaviour changes in National Health Service dentistry 1992–2009, Community Dent. Oral Epidemiol. **39** 5 (2011) 465–473.

[14] RUSHTON, V.E., HORNER, K., WORTHINGTON, H.V., Factors influencing the frequency of bitewing radiography in general dental practice, Community Dent. Oral Epidemiol. **24** 4 (1996) 272–276.

[15] EUROPEAN COMMISSION, European Guidelines on Radiation Protection in Dental Radiology. The Safe Use of Radiographs in Dental Practice, Radiation Protection 136, Directorate-General for Energy and Transport, European Commission, Luxembourg (2004),
http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/136_en.pdf

[16] KIM, I.H., MUPPARAPU, M., Dental radiographic guidelines: A review, Quintessence Int. **40** 5 (2009) 389–398.

[17] METTES, T.G., et al., Impact of guideline implementation on patient care: A cluster RCT, J. Dent. Res. **89** 1 (2010) 71–76.
[18] AMERICAN DENTAL ASSOCIATION COUNCIL ON SCIENTIFIC AFFAIRS, The use of dental radiographs: Update and recommendations, J. Am. Dent. Assoc. **137** 9 (2006) 1304–1312.
[19] SALTI, L., WHAITES, E., Survey of dental radiographic services in private dental clinics in Damascus, Syria, Dentomaxillofac. Radiol. **31** 2 (2002) 100–105.
[20] ILGÜY, D., et al., Survey of dental radiological practice in Turkey, Dentomaxillofac. Radiol. **34** 4 (2005) 222–227.
[21] SHAHAB, S., et al., Compliance of Iranian dentists with safety standards of oral radiology, Dentomaxillofac. Radiol. **41** 2 (2012) 159–164.
[22] GALLAGHER, A., et al., European survey of dental x-ray equipment, Radiat. Prot. Dosimetry **129** 1–3 (2008) 284–287.
[23] HART, D., HILLIER, M.C., WALL, B.F., National reference doses for common radiographic, fluoroscopic and dental X-ray examinations in the UK, Br. J. Radiol. **82** 973 (2009) 1–12.

BENEFIT–RISK DIALOGUE WITH PATIENTS AND PUBLIC

(Round Table 1)

Chairpersons

M. PEREZ
WHO

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BENEFIT–RISK DIALOGUE WITH PATIENTS AND PUBLIC

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The round table was dedicated to public and patient information.

From one available abstract on Image Wisely, it was highlighted that professional commitment and the quality of the content were of the utmost importance for the success of this public campaign.

The talks pointed out that patients wish to be appropriately informed by physicians and especially by the radiologist, although available on-line information (i.e. web sites, social media) significantly contributes to better awareness. Professional organizations should develop on-line evidence based material for patients and the media. If properly informed, the media can be a champion of public interest and a means of accountability to the public. We should learn how to 'tell them a story'.

Risk perception by the public and media may be different from the risk assessment. Media and social media have to be monitored to see what people actually perceive.

There is nothing 'general' about communicating with the general public: different strategies tailored to specific public audiences have to be developed.

Health professionals, in general, have poor communication skills. Empathetic communication means taking into account the patient's values and beliefs. Physician education and training in communication with the patient and the media should be included in training charters; however, the workload of radiologists and the current organization of imaging departments pose strong limitations. The potential role of radiographers in this matter was mentioned.

Information on dose is often delicate, especially when one keeps up with the technological advances that can reduce exposure by 70%: former low dose protocols, used a few years ago, are actually high dose protocols today!

Information on the risks versus the benefit was a bit disputed. Some were of the opinion that an appropriate indication is by definition beneficial, while others expressed that given the precautionary principle, there was a need

to provide an estimate of the risk. It must be noted that papers extrapolating the number of deaths from population exposure are highly questionable when they are used for individual risk estimation. However, our vision of the individual risk will probably be influenced by advances in the field of individual radiosensitivity assessment and detection.

Knowledge gaps prevent patients from assessing options. The justification conversation between the doctor and the patient is important to bridge these gaps. This goes beyond the concept of informed consent, towards a shared informed decision making process. Patient education and information has to avoid creating a disproportionate level of anxiety about radiation.

The family doctor/general practitioner is trusted by the patients and can be a first gate-keeper.

Beyond these considerations, the development of a culture of transparency, dedication, collaboration and partnership certainly represents the way forward for the development of patient and public information.

MANUFACTURERS' ROLE IN MEDICAL RADIATION PROTECTION

(Round Table 2)

Chairpersons

S. EBDON-JACKSON
United Kingdom

J. GRIEBEL
Germany

MANUFACTURERS' ROLE IN MEDICAL RADIATION PROTECTION

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Abstract

The availability and complexity of medical equipment continues to increase and from its use, the dose to the population from medical exposures has also risen. Optimization of exposures requires that operators understand the equipment they use and that the image quality is consistent with the clinical need. Educating operators on optimization is a responsibility of professional bodies and manufacturers alike, and this should be updated throughout the lifetime of the equipment. The role of regulators is more limited.

The development of medical equipment over the past 40 years has been startling, with the introduction of new modalities such as ultrasound, computed tomography (CT) and magnetic resonance imaging. The enhanced capabilities of equipment in the last 10 years, since the Malaga conference, are astounding.

CT provides an excellent example. Multidetector technology has revolutionized the role of this modality within the clinical setting, with single breath-hold chest scans providing previously unavailable information regarding the lungs, and the possibility of single beat cardiac scans being achievable.

The increased availability of medical equipment and its use in new clinical settings means that the number of examinations an individual may experience in a lifetime has increased dramatically. Even in the United Kingdom, the use of cross-sectional imaging has risen in excess of 10% per annum over the past 10 years and shows little sign of reaching a plateau. Rapid CT scanning provides an excellent example of this and although, like for like, there is some evidence that the dose per examination is falling, there is more compelling evidence that the total dose per individual is rising. Well publicized data from the United States of America have shown that the population dose from medical exposures is now around half of that from all exposures.

Appropriate and effective radiation protection in medicine can only be achieved if there is transparency and understanding between manufacturers,

suppliers and users. Dose reduction now drives many of the new innovations associated with CT and has become a major selling point for manufacturers. However, there is some evidence that users are not always fully aware of all the dose saving technology available and how it works. The range of doses delivered at different clinics for the same examination demonstrates this. Without a thorough knowledge of how modern equipment works, it is possible to increase rather than decrease the dose delivered to the patient.

In the past few years, justification has been the major focus within medical radiation protection circles and there is no doubt that there is scope for considerable dose saving when only justified procedures are undertaken. Nevertheless, optimization also has a role and there is a need for more attention to be paid regarding the impact of image quality on dose. The capability of modern CT scanners to produce images of exquisite quality can seduce the user. The view that the image quality needed is that to adequately demonstrate the clinical problem and no more, is often unseen within conferences, the scientific literature and in manufacturers' training and publicity material. The community as a whole has a responsibility to address both image quality and dose when considering optimization and to aim for a satisfactory diagnosis rather than the best possible image quality.

Finally, regulators have a role to play, by providing platforms and frameworks, for and with users and manufacturers. Again, better understanding and cooperation will help, but ultimately, the regulator relies on the professionals in the field to work with the manufacturers in order to optimize exposures. On a day to day basis, the regulator only has a limited impact.

MANUFACTURERS' ROLE IN MEDICAL RADIATION PROTECTION

The end users' perspective

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The human body anatomy and disease pattern is universal. The clinical methods for disease diagnosis and treatment are also universal. Physicians all over the world can discuss any disease process without physical contact with the patient.

The essence of radiological imaging in health care is to accrue maximum benefits against the radiation risk. The advance in technology has resulted in improved imaging information acquisition and a great desire for good quality diagnostic images. Radiologists play a crucial role as gate-keepers for radiological protection of patients, personnel and the public. The gate-keeper role is between justification and optimization of radiation protection of patients.

Radiological imaging does not obey the socioeconomic status of the patient, nor the economic dynamics of the times. Once you are declared as a patient or you need an investigation due to altered body physiology, then you become a subject of different types of imaging.

A radiological survey in Kenya has revealed that the majority of patients undergo a general radiography examination. The statistics indicate that per million people, there are 26 sets of X ray equipment, 5 radiographers, 3 radiologists and 0.41 medical physicists. One set of equipment would be used to perform 4000 examinations annually. Thus, each radiographer and each radiologist would perform 189 300 and 325 000 examinations per year. An X ray procedure would be performed on 82 per 1000 in the population per year.

These figures send an alarming message about the percentage of the population exposed to radiation risk and calls for an urgent international response to protect the patient, imaging personnel and the general public.

There are other factors that enhance the upsurge in radiation risk: the inadequacy or non-existence of quality assurance programmes, unskilled or inadequately trained personnel, a poorly funded health sector with no funds allocated for dosimetry studies, and the high cost of imaging, leading to the mushrooming of imaging facilities that acquire refurbished or cheap equipment that is not assessed for compliance.

The manufacturers of radiation equipment have an important role to play:

— Manufacturers should own their branded equipment and track it through country regulatory bodies until it is decommissioned.
— The majority of countries have an inadequate number of medical physicists to establish quality assurance/quality control programmes.
— Manufactures should universally fit all equipment with dosimetry meters for real-time patient dose recording. They should provide guidelines on how to assess the accuracy of PACS and DICOM structures in high dose procedures. This will enable imaging professionals, biomedical/ maintenance engineers and technologists to be involved in patient dose research, tracking and monitoring.
— Manufacturers should participate and provide adequate training of users in handling and understanding application functions of the equipment.

Proper training and a good understanding of patient dose monitoring by imaging professionals will enhance the optimization of radiation protection in medicine.

MEETING RADIATION PROTECTION NEEDS IN HEALTH CARE SETTINGS WITH LIMITED INFRASTRUCTURE

(Round Table 3)

Chairpersons

P. JIMENEZ
PAHO

A. NADER
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MEETING RADIATION PROTECTION NEEDS IN HEALTH CARE SETTINGS WITH LIMITED INFRASTRUCTURE

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Abstract

Developing countries are facing both the prevalence of communicable diseases, and a swift rise in non-communicable diseases. Lack of preventive care, diagnosis and access to adequate health services are among the major factors responsible for this. In recent years, the world has observed major growth in the number and in the applications of medical imaging and radiotherapy technologies. This growth has had an impact on reducing disease mortality and increasing prevention in high income countries. Low income countries have difficulties in obtaining the benefits of such technological developments. Multiple factors, such as infrastructure, health technology assessment and management, human resources, quality of care and safety, economic constraints and cultural aspects, contribute to the challenge. In particular, the lack of an appropriate regulatory infrastructure, well maintained equipment, trained staff and physical infrastructures, threatens the safety of patients and health workers. A more widespread use of medical imaging and radiotherapy technologies and improvement in treatment approaches will lead to a reduction in mortality and help to combat many diseases and conditions of public health concern, as well as to improved quality of life for people in developing countries.

1. INTRODUCTION

The radiological health programme of the Pan American Health Organization (PAHO) was officially established in 1960 and has been in continuous operation ever since [1]. PAHO co-sponsored the International Conference on Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy held in Malaga, Spain, in 2001. PAHO advocates ministries of health to be fully involved in the development and implementation of national policies regarding radiation safety, and the 28th Pan American Sanitary Conference approved Resolution CSP28.R15 endorsing the revised Basic Safety Standards [2] on 20 September 2012.

The services of radiation medicine encompass a wide spectrum of clinical applications. Modalities such as ultrasound and X ray examinations alone can solve around 80% of diagnostic problems in developing countries. Radiotherapy is used today for the treatment of many kinds of tumours, and is frequently administered in combination with surgery, chemotherapy or both. Demand for radiation medicine services has increased worldwide due to the global increase of diseases, new clinical applications, the increase in world population, an ageing population, lifestyle changes and worldwide health care programmes and reforms.

The lack of appropriate infrastructure and technologies, well maintained equipment, trained staff, and governmental regulations, among other factors, threatens the safety of patients and health workers in low income countries. Even where the technology is available, both the quality and safety of the procedures may be questionable or even dangerous for the patient and health workers.

2. DISEASES OF PUBLIC HEALTH CONCERN WHERE RADIATION MEDICINE HAS AN IMPACT

Low income countries experience more than 500 000 maternal deaths annually, making maternal mortality the leading cause of death for women of childbearing age (15–44 years). Most of the mortality causes are conditions for which timely ultrasound imaging could increase survival rates [3].

Acute lower respiratory infection, mostly pneumonia, is the leading cause of childhood mortality, accounting for about 4 million deaths per year in low income countries. Appropriate case management, focusing on early detection and treatment of the disease, has been challenging to implement, especially in low income countries that often face poor access to basic health care. Radiography would appear to be the best available method for diagnosing pneumonia if relevant health professionals knew how to interpret the images, and these met the necessary quality standards [4].

In 2010, there were an estimated 8.8 million cases of tuberculosis (TB) in the world and 1.4 million deaths. In addition, TB is a leading killer of people living with HIV, causing one quarter of all deaths [5]. Chest radiography is a highly sensitive technique for diagnosing pulmonary TB in immunocompetent individuals. Chest radiography plays a significant role in shortening delays in diagnosis and should be performed early in the course of investigation of TB among seriously ill patients infected with HIV. On the other hand, computed tomography is the modality of choice for the evaluation of primary and post-primary pulmonary TB.

The World Health Organization estimated that 17.3 million people died of cardiovascular diseases (CVDs) in 2008, while over 80% of CVD deaths are

in low and middle income countries [6]. By 2030, almost 23.6 million people will die of CVDs. Cardiac ultrasound has diagnostic applications that are particularly suited to the developing world because of its non-invasive nature. The diagnosis of CVDs is possible thanks to diagnostic imaging, while some of the elective treatments for these pathologies are based on image guided radiology procedures, which permit patients to be treated as outpatients instead of requiring long hospital stays.

The International Agency for Research on Cancer estimated that 12.7 million new cancer cases occurred in 2008 worldwide, of which 7.1 million were in low and middle income countries with 4.8 million deaths. By 2030, the global burden is expected to grow to 21.4 million new cancer cases and 13.2 million cancer deaths. Internationally, it is believed that radiotherapy will continue to be key for the treatment of cancer in the coming decades for its curative function, which is particularly important for tumours of the head and neck, cervix–uterus, breast and prostate, and for its palliative function and effectiveness. Breast cancer is the most common malignant tumour in women. Early detection methods for breast cancer, such as clinical exploration, ultrasound or mammography, improve the outcome of treatment. In addition, ultrasound is an essential component of the diagnosis and staging of breast cancer.

Injury is the ninth most common cause of premature death worldwide and the third most common cause of years lived with disability. Each year, road traffic accidents kill 1.2 million people and injure or disable tens of millions. Most traffic related deaths take place in low and middle income countries among young men 15–44 years old. Road traffic deaths are likely to increase by more than 80% in developing countries by 2030 [7]. Low income countries are also particularly vulnerable to intentional or non-intentional injuries, including natural disasters and war. Much of the mortality due to injuries and trauma could be avoided by timely stabilization and medical care, and timely use of emergency equipment, including basic diagnostic tests. Easy to use ultrasound devices for diagnosis of internal, especially intra-abdominal, bleeding would also be a useful development. Emergency care, including imaging techniques to diagnose bone trauma in health care facilities, is necessary for immediately addressing urgent health issues and to prevent long term disability. Standard radiology remains the major diagnostic tool for trauma and some types of injury.

3. CURRENT CHALLENGES IN DEVELOPING COUNTRIES

3.1. Organization of health systems and services

PAHO is promoting the Integrated Health Service Delivery Networks as a way to address the approach of primary health care based health systems at the health services level. However, health systems in many developing countries are highly segmented and the provision of health services is very fragmented. Experience to date demonstrates that excessive fragmentation leads to difficulties in access to services, delivery of services of poor technical quality, irrational and inefficient use of available resources, unnecessary increases in production costs and low user satisfaction with services received [8].

However, many patients in low income settings do not have access to early detection methods for breast cancer or TB. The specialized training needed to diagnose such diseases is a challenge for low and middle income countries. On the other hand, the lack of comprehensive cancer control programmes, including access to treatment services with radiotherapy, represents the major obstacle for reducing cancer mortality in developing countries.

3.2. Technology and infrastructure

Radiation medicine technology is associated with high costs from the acquisition to the functional phase, including maintenance needs and environmental conditions. The costs of these services, considering both the initial investment and operating costs, make careful planning and management of their development necessary, but the latter are not always adequate. Frequently, the costs of procuring and maintaining equipment are much higher than in industrialized countries. All these aspects become more critical with the incorporation of more complex and costly technologies. Almost two thirds of all low income countries do not have a national health technology policy in the national health programmes to guide the planning, assessment, acquisition and management of medical equipment. As a result, inappropriate medical devices that do not meet the priority needs of the population, are not suited to the existing infrastructure and are too costly to maintain are incorporated, draining funds needed for essential health services [9].

The technology is often unreliable in those settings. Much of the most complex equipment imported from industrialized regions does not work when it reaches low income countries. Maintenance of diagnostic equipment plays a very significant role in the longevity and effectiveness of diagnostic machines, as well as in safety and quality. Unfortunately, most of the equipment is poorly, if at all, maintained. Many facilities in resource poor settings also do not have

appropriate room design to minimize radiation scattering, and lack a reliable and stable electricity supply and proper environmental conditions for the technology. Better technology policy in countries will lead to an increase in the quality, effectiveness and coverage of health care with regard to medical devices.

In some countries, the low demand for medical technology often derives from deep rooted culture and social norms. At the beginning of the symptoms, people tend to solve their problems with traditional medical services or even magic–religious approaches. Many prefer traditional over modern therapies, and it is very common to use a of combination of both. Often, when appropriate results are not produced, the patient then seeks modern medicine. Although the introduction of new technologies and techniques is necessary in some countries, awareness of the traditions and beliefs may be crucial to the success of any project. Some beliefs and culture can affect radiation medicine's acceptability and accessibility.

3.3. Human resources

Most low income countries face challenges in radiation medicine services because of the lack of skilled human resources. As a consequence, general practitioners often have to interpret the radiological images; nurses or technical personnel, without adequate education and training, carry out the diagnostic examinations or the treatment delivery; and inappropriately trained physicists or engineers assume quality aspects, safety and maintenance responsibilities [10]. On the other hand, there is a lack of mechanisms for the necessary certification or recognition of these professionals [11]. In some countries, these human resources are so scarce that it is not possible to include formal education programmes at the national level; and in those that do have these programmes, they are not of sufficient quality. The possibilities for continuing education for professionals are also very limited in developing countries. Many professionals choose to migrate due to a lack of opportunities for education and training; underfunding of health services; lack of established posts and career opportunities; health service management shortcomings; civil unrest or personal security.

3.4. Radiation protection and quality assurance

Although radiation doses to patients in radiographic examinations are generally considered to be small in comparison with the immense benefits derived from these examinations, it is necessary to optimize the dose to the amount that is necessary to produce the image quality required for a diagnosis. There is also a tremendous amount of waste of resources with regard to the image quality produced in radiographic examinations. Poor quality images result in unnecessary

radiation exposure to patients through repeated radiographic examinations, loss of diagnostic information and increased costs of health care. On the other hand, an examination that does not help medical management is unjustified, no matter how small the dose is. Many factors influence the effectiveness and safety of radiotherapy treatments, such as accurate diagnosis and the stage of the disease, good therapeutic decisions, the precise location of the tumour, and the planning and delivery of treatment. This complexity points to the essential need to introduce quality assurance (QA) programmes to improve the effectiveness and safety of treatments [12].

QA is a management tool which aims to ensure that every examination or treatment in a radiation medicine service is necessary and appropriate for the medical problem, and is performed with the utmost level of quality and safety for the patient. These procedures should be performed according to previously accepted clinical protocols by adequately trained personnel, with properly selected and functioning equipment, to the satisfaction of patients and referring physicians, in safe conditions and at minimum cost. Thus, a QA programme should include periodic reviews of referral patterns, clinical protocols, continuing education for staff, facility inspections, equipment testing, and administrative procedures related to the purchase of supplies and billing. The ultimate goal of QA is to improve patient care.

4. CONCLUSION

Owing to increasing technological advancement and the use of radiation medicine technologies globally, low income countries ought to benefit from such trends. Many low income countries face an increase in incidence and mortality of many diseases, which are potentially curable if early diagnosis and appropriate treatment are available. Diagnostic imaging and radiotherapy can provide public health programmes with tools to screen, diagnose, treat and palliate many diseases. The incorporation of such technology in developing countries requires a careful study of feasibility that ensures its appropriateness and sustainability. Additionally, it is essential for the human resources working in these services to be trained in the use of the respective technologies. Relevant authorities should be committed to incorporating and maintaining the technology, as well as to ensuring the quality of care and safety. A more widespread and proper use of radiation medicine will lead to a reduction in mortality and help to combat many diseases and conditions of public health concern, as well as to improved quality of life for people in developing countries.

REFERENCES

[1] PAN AMERICAN HEALTH ORGANIZATION, History of the Radiological Health Program of the Pan American Health Organization: 1960–2010 (2010), http://www2.paho.org/hq/dmdocuments/2010/English%20document%20Radiologia.pdf

[2] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[3] WORLD HEALTH ORGANIZATION, UNITED NATIONS CHILDREN'S FUND, UNITED NATIONS POPULATION FUND, THE WORLD BANK, Trends in Maternal Mortality: 1990 to 2010 (2012), http://whqlibdoc.who.int/publications/2012/9789241503631_eng.pdf

[4] WORLD HEALTH ORGANIZATION, Pneumonia Vaccine Trial Investigators' Group, Standardization of Interpretation of Chest Radiographs for the Diagnosis of Pneumonia in Children (2001), http://apps.who.int/iris/bitstream/10665/66956/1/WHO_V_and_B_01.35.pdf?ua=1

[5] WORLD HEALTH ORGANIZATION (2011), Who Report 2011: Global Tuberculosis Control (2011), http://www.who.int/tb/publications/global_report/2011/gtbr11_main.pdf

[6] WORLD HEALTH ORGANIZATION, Global Atlas on Cardiovascular Disease Prevention and Control (2011), http://www.who.int/cardiovascular_diseases/publications/atlas_cvd/en/index.html

[7] WORLD HEALTH ORGANIZATION, Global Impact: World Report on Road Traffic Injury Prevention, http://www.who.int/violence_injury_prevention/publications/road_traffic/world_report/en/

[8] PAN AMERICAN HEALTH ORGANIZATION, Integrated Health Service Delivery Networks: Concepts, Policy Options and a Road Map for Implementation in the Americas (2011), http://new.paho.org/hq/dmdocuments/2011/PHC_IHSD-2011Serie4.pdf

[9] WORLD HEALTH ORGANIZATION, First WHO Global Forum on Medical Devices: Context, Outcomes, and Future Actions (2011), http://www.who.int/medical_devices/gfmd_report_final.pdf

[10] JIMENEZ, P., "Emerging challenges in the management of medical exposures", Strengthening Radiation Protection Worldwide — Highlights, Global Perspective and Future Trends (Proc. 12th Congr. of the Int. Radiation Protection Association (IRPA12)), IAEA, Vienna (2010).

[11] ROONEY, A., VAN OSTENBERG, P., Licensure, Accreditation, and Certification: Approaches to Health Services Quality (1999), http://pdf.usaid.gov/pdf_docs/PNACF510.pdf

[12] PAN AMERICAN HEALTH ORGANIZATION, Health in the Americas: 2012 Edition, Regional Outlook and Country Profiles, PAHO, Washington, DC (2012), http://new.paho.org/saludenlasamericas/index.php?option=com_content&view=article&id=9&Itemid=14&lang=en

CHALLENGES AND OPPORTUNITIES WITH REFURBISHED/SECOND HAND EQUIPMENT

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Abstract

The issues related to the transfer (via purchase or donation) of second hand equipment (mainly, but not exclusively, from industrialized to developing countries) and the problems associated with its use and sustainability are explored. Emphasis is placed on the needs of the recipient facility; the provision of tools, accessories, spare parts and manuals; the arrangements for acceptance testing, commissioning and maintenance of the equipment; and the training of staff and service technicians regarding equipment operation and maintenance.

1. INTRODUCTION

Introducing and sustaining radiological equipment, especially high-technology equipment, is expensive, particularly in resource limited settings. Ideally, equipment should be bought new, but to minimize capital costs, developing countries may consider acquiring pre-owned machines, either directly from donors or refurbished from manufacturers. The acquisition may be through purchase or through donations. Guidelines regarding health care equipment donations — mostly new equipment — have been addressed extensively by the World Health Organization (WHO) [1]. The guidelines include financial considerations.

Other costs in addition to capital costs need to be taken into account: installation and siting costs, which involve potential room modifications, equipment transport and custom fees when applicable; operational costs, which include registration and licence fees, utility consumption such as electricity and water, supplies and consumables; and human resources costs that encompass salaries and training of operators, maintenance staff and consultants — if needed. There are also indirect costs, such as facility and equipment depreciation, as well as unexpected fees arising from legal, accounting, clinical, architectural, engineering and medical physics consultations. The procurement issues involved in equipment acquisition should be carefully analysed.

2. PROCUREMENT ISSUES IN THE ACQUISITION OF SECOND HAND/REFURBISHED EQUIPMENT

Radiological equipment is only one component of a medical imaging or radiotherapy department. The type of radiological equipment that facilities need should depend on the types of services that the facility offers or plans to offer and the staff available or budgeted for to operate and maintain the equipment. The number, characteristics and technical specifications should depend on the population to be served, the availability of resources in the respective health care system, and the volume of procedures to be carried out in a given unit of time [2]. The very first issue the facility should consider is whether the type of equipment to be acquired is really needed and whether it will require additional staff to operate it. There are certain procurement considerations that should be taken into account.

2.1. Radiation safety requirements

The design of radiation emitting equipment and equipment to be used with radioactive materials, such as a gamma camera, should comply with national or international radiation protection and safety standards [3].

2.2. Compliance with manufacturer's specifications

Second hand equipment should maintain the original manufacturer's specifications. Proof of compliance should be obtained before the equipment is acquired. If an original feature is no longer functional, but the equipment could still be used, this should be clearly indicated in the documentation provided by the donor/seller.

2.3. Warranties

Refurbished equipment should be sold with warranties, at least for one year of operation. It is important to establish exactly whether it includes parts (X ray tubes are very costly, for example) and when the warranty actually starts. It should not be at installation, but after acceptance testing.

2.4. Obsolescence

Even in good operating conditions and meeting the manufacturer's specifications, equipment should not be acquired if deemed to be obsolete; i.e. if a type that allows diagnoses or treatments that before could not

be achieved has replaced it. The fact that a unit is old does not mean it is obsolete. For example, a cobalt therapy unit with an adequate radioactive source is not obsolete, but a mammography unit with a tungsten target and an aluminum filter is, because the image quality that is produced is substandard. Acquiring obsolete equipment may have detrimental effects on the health care system. Furthermore, such an acquisition may delay the purchase of a better unit.

2.5. Availability of operation and service manuals

No piece of equipment should be acquired without operation and service manuals. These should be available in a local language acceptable to the user. This may be difficult if the language of the original equipment owner was different from that of the intended recipient and the equipment is no longer being manufactured. In such cases, the manuals should be translated and such costs budgeted for.

2.6. Availability of accessories and replacement parts

When acquiring second hand equipment, it is important to assess whether the original accessories come with the main unit. Examples of potential problems are wedges for cobalt therapy machines, image receptors for mammography units and collimators for gamma cameras.

It is essential that replacement parts be available from the original manufacturer or a reputable distributor for the length of the intended use of the equipment. WHO recommends that the manufacturer's support — including spare parts and accessories — be available for a minimum of two years and preferably four [1]. The recipient institution should investigate from the original manufacturer the length of time they can support the equipment and whether local distributors and/or third party maintenance organizations have spare parts and accessories in stock, for how long and at what cost.

2.7. Availability of software upgrades

Nowadays, software is as important as hardware. Equipment which uses some kind of software, especially if it is no longer manufactured, may have old software versions that may be out of date, or if nothing else, awkward to use. Before acquiring any equipment, the availability of software upgrades should be explored from the original manufacturer and budgeted for.

2.8. Environmental (facility) conditions

There are several types of environmental concerns that need to be addressed when installing a piece of equipment in a new facility built to house it. First, the facility needs to comply with local building codes regarding space, accessibility, floor loading capacity, electrical power (voltage, frequency, phase and heat dissipation), water volume, pressure and drainage, etc. If the equipment emits radiation, the structural shielding needs to be calculated and its adequacy tested — preferably before the unit is installed, but certainly before it is put into clinical use — taking into account patient, staff and public dose constraints [3]. If the second hand equipment to be acquired is to be placed in an already existing building, to comply with local regulations may be more difficult, as there may be structural limitations. Furthermore, if open radioactive sources, such as those used in nuclear medicine, are included, there should be a plan for disposal of the radioactive waste that will be generated.

Most types of radiological equipment can only function well with a stable power supply. The need to purchase additional generators and/or UPS units should be addressed and budgeted for. Another problem is the need of many units to have air-conditioning. This is particularly true for old computed tomography scanners, which cannot function unless the room temperature is very low.

The biggest problem, however, especially in tropical countries, is humidity. Electrical equipment just does not work well without proper humidity control. The requirements for both temperature and humidity should be known before the equipment is acquired. Room modifications should be implemented and plans for daily monitoring of the temperature and the humidity established, before the equipment is put into clinical use.

2.9. Sustainability considerations

Prior to equipment acquisition, facilities should ensure, through appropriate budgeting, that there is adequate and properly trained staff for its operation and that the equipment can be maintained during its projected lifetime. Second hand equipment may require more corrective maintenance than new equipment. If the equipment is technically complex, it may be less expensive to outsource maintenance services than to train local maintenance personnel. Discarding the equipment at the end of its life cycle should also be contemplated and disposal costs budgeted.

3. THE PROCESS OF ACQUIRING SECOND HAND RADIOLOGICAL EQUIPMENT

3.1. Obtaining authorization from the regulatory authorities

Facilities of countries with radiation protection legislation/regulations need to seek approval of the regulatory authority before acquiring radiological equipment. The authorization process may require registering the equipment or licensing the installation [3]. Most refurbishing companies will not sell any piece of equipment to a foreign country until such documentation is produced. Facilities which plan to introduce new practices will need to produce more documentation than facilities which only replace a unit and usually require permits from other governmental entities such as the ministry of health, which regulates medical practices.

In facilities of countries which do not have any radiation safety legislation, it is the responsibility of the facility manager to ensure that the equipment and its use comply with international safety standards. The compliance should be documented in writing and be made available to the staff and to the patients and public, if required. Such documentation is important for both moral and legal purposes.

3.2. Site preparation

Good coordination should exist between equipment acquisition and site preparation. The room in which the equipment is to be housed needs to be ready before the equipment arrives, so that its installation can proceed smoothly.

3.3. Clearing customs

If the equipment comes from a foreign country, import permits are required. The facility manager must ensure that the documentation required in customs clearing processes is ready well before the equipment arrives.

3.4. Installation

Arrangements for installation, including the need for cranes and other heavy machinery, should be made in advance of radiological equipment arrival. Contractors and local staff must be properly protected and monitored if they can be exposed to ionizing radiation during their work, for example when a cobalt source is exchanged. Accessories and supplies should be available at the time

of installation to ensure that they are compatible and that the equipment can be operated in a safe manner.

3.5. Acceptance testing

Acceptance testing is the process of determining whether the unit meets acquisition specifications. The responsibility rests with the buyer. Acceptance tests are normally done between a person of the institution (preferably a medical physicist) and an engineer or technical representative of the manufacturer. For second hand equipment, compliance with the original manufacturer's specifications can be tricky, unless it has been specified in the acquisition agreement. Safety tests are of paramount importance. Previous service records should be examined in detail, and repaired or replaced components should be tested very carefully to assess whether they may compromise safety. Adjustment costs may have to be borne by the user, unless clearly indicated in the acquisition agreement that the responsibility is the institution's or the company's providing the equipment.

Consumables, such as X ray film or printing paper, should be available at acceptance testing, to ensure that the tests can be performed and documented.

3.6. Commissioning

Commissioning is the process in which the necessary clinical data are acquired so that the unit can be used clinically. Second hand equipment may come with the originally acquired data. If so, these data should be consulted and verified before allowing patient examinations or treatments. Verification should be performed by a knowledgeable and competent medical physicist and should be more or less extensive depending on the complexity of the equipment.

3.7. Establishment of quality control/quality assurance programmes

Based on the acceptance testing and on the acquired data during commissioning, it is important to develop a set of tests and establish compliance criteria to check that the unit continues to perform adequately. The institution's medical physicist should assume responsibility that the unit always functions within the established tolerances. External audits are recommended [3].

REFERENCES

[1] WORLD HEALTH ORGANIZATION, Guidelines for Health Care Equipment Donations, (2000), www.who.int/entity/medical_devices/publications/en/Donation_Guidelines.pdf

[2] PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, Organization, Development, Quality Assurance and Radiation Protection in Radiological Services: Imaging and Radiation Therapy (BORRÁS, C., Ed.), PAHO, Washington, DC (1997).

[3] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

GOALS FOR MEDICAL RADIATION PROTECTION IN 2020

(Round Table 4)

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GOALS FOR MEDICAL RADIATION PROTECTION IN 2020

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Abstract

The key issues covered during the round table discussion addressed the means necessary to narrow the gap between evidence and practice, the need to develop improved tools for radiation dosimetry and protection, the improvement of safety education and training, and subsequently the establishment of specialists, as well as improving criteria for individual and population screening (heart, lung, colon, breast). Specific attention was given to: (i) the situation in developing countries, where access to proper imaging must be improved; (ii) the fact that training in diagnostic imaging and radiation protection is part of the safety culture; and (iii) the need to normalize education requirements for radiation, which is a high priority.

1. INTRODUCTION

The purpose of this roundtable discussion was to identify benefit–risk goals to be achieved by 2020, and strategies to reach these goals, applicable to the medical uses of radiation. The areas covered were the need for dose reduction as a result of standardized quality assurance procedures, education and training, and the development and implementation of a sustainable safety culture, research needs to improve the knowledge in individual radiosensitivity of patients, as well as the access to proper imaging techniques and training in diagnostic imaging and radiation protection in developing countries. Altogether, 14 papers contributed to the discussion of these issues.

2. MAIN RADIATION PROTECTION ISSUES

The following thematic areas were addressed during the discussion:

— Integration of radiation protection and safety;
— Dose assessment and national registries;
— Clinical audits;
— Individual sensitivity to ionizing radiation;
— Education and training.

2.1. Integration of radiation protection and safety

It is important to include radiation protection and safety plans in management control systems in hospitals. This can best be achieved by involvement of key managers, authority given to radiation protection experts and transparent internal audits. Key challenges within such a process include effective communication within the organization and adoption of a graded approach towards radiation and safety.

2.2. Dose assessment and national registries

It is important to assess effective collective doses from diagnostic X ray and nuclear medicine examinations. This can be best achieved by establishing national registration systems to monitor frequency and doses, with the aim of identifying long term trends. The results can be used to select priorities for clinical audit and optimization actions.

2.3. Clinical audits

Clinical audits are required by Euratom Directive 97/43 [1]. Experience shows that it is beneficial to engage stakeholders (professionals, institutional representatives, users) in developing methodology for clinical audits focusing on processes and outcomes. Of equal importance is the cooperation between authorities and professionals when establishing clinical audits.

2.4. Quality assurance, education and training, and the development of a radiation safety culture

Radiation protection is embedded in everyday clinical practice and is part of overall standard procedures. Events occurring in areas of radiotherapy and interventional radiology, as well as events resulting from accidental overexposures

in the medical environment, have shown that radiation protection practices need to be embedded in good medical practices within a common and sustainable safety culture. Radiographers have an important role in medical radiation protection; it is important that their education and training meets high standards. In this context, it was noted that the MEDRAPET[1] project is developing new European guidelines on education and training in radiation protection for medical exposures. There is a strong need for increased cooperation between education and training organizations and employers. Adherence to dose reduction should be rewarded through accreditation and communication. Behavioural changes should be advocated to referring physician societies.

Education to achieve a culture of radiation protection should go hand in hand with promoting justified use of radiation based examination. Risk management measures reduce the potential or even prevent unintended exposures and they are, therefore, a critical component of radiation protection culture. There is a need to demonstrate, through standard health technology assessment, that radiation protection measures, such as technological development, meet clinical cost–benefit requirements. The establishment of a safety culture is a focus area within the efforts of the International Radiation Protection Association to develop and enhance a strong radiation protection culture.

2.5. The implementation of the Basic Safety Standards in health care at the global level

Access to high quality and safe radiotherapy is particularly essential for developing countries. Medical physicists are the gatekeepers to high quality and safe radiotherapy. The implementation of the International Basic Safety Standards (BSS) [2] in health care at the global level is a high priority. Specific attention should be given to developing countries, where access to proper imaging should be improved and training in diagnostic imaging and radiation protection should be a high priority. This could be best achieved by partnership between the IAEA and WHO in the context of medical physics capacity building as part of cancer control programmes in developing countries.

2.6. Individual sensitivity

One of the key future impacts on medical radiation protection from advances in radiobiology is the specific consideration of the individual sensitivity of patients to ionizing radiation. Individual sensitivity may affect as much

[1] http://www.medrapet.eu/

as 5–15% of the population. It is a key issue in the context of medical exposures. There is an increasing opportunity to take into account the variability of the individual sensitivity of patients in diagnostic applications of ionizing radiation. Specific emphasis is on the most sensitive patients, the most sensitive tissues, the examinations with the highest dose and the most frequent examinations. Repeated medical exposures of young patients that are hypersensitive to ionizing radiation are a major concern for radiation protection.

If fully established, the system of radiation protection may need to be revised to take into account individual sensitivity to ionizing radiation. In order to improve our knowledge of this important question, individual sensitivity and hypersensitivity to low doses of medical imaging and consequences for radiation protection systems and practices have to be explored further by targeted research activities.

3. CONCLUSIONS AND RECOMMENDATIONS

There is no doubt that radiation protection in the medical field as well as our knowledge about radiation risk has improved over the last decade. Moreover, the technical development in diagnosis and therapy has increased the capabilities for more targeted and individual approaches. There are, however, still opportunities for improvement. Radiation protection and safety issues are closely linked to patient safety issues, and management control systems must include radiation protection and safety. Consideration should be give to make maximum dose reduction techniques mandatory in new acquisition techniques. It is recommended to replicate the best practices that have been applied to the nuclear industry and adjust them to the medical sector. As the ultimate goal is to arrive at a situation where medical radiation protection is evidence based, there is a need to narrow the gap between evidence and practice. For this purpose, more emphasis has to be devoted to risk assessment, long term follow-up and risk management.

Concern has been raised about the fact that there is little to no access to imaging techniques in developing countries. Access to high quality and safe radiotherapy is particularly essential for countries with low and medium income. Low and medium income countries represent 85% of the world's population but only one third of radiotherapy treatment facilities are operated in these countries. Owing to improvements in hygiene and life expectancy, it is assumed that over the next decade the increase in cancer incidence in low and medium income countries will be about twice as high as in high income countries. There is an urgent need to develop and provide these countries with equipment for basic imaging and treatment. Training opportunities should be adjusted to the needs of basic radiology. Training activities should be coordinated by professional bodies

(e.g. the International Society of Radiology, the World Federation for Ultrasound in Medicine and Biology, and the International Society of Radiographers and Radiological Technologists) and disseminated with the help of the IAEA and WHO. Training must go hand in hand with improvements in access to proper/basic medical imaging. The implementation of the BSS in health care at the global level is a high priority.

REFERENCES

[1] EUROPEAN COMMISSION, Council Directive 97/43/EURATOM of 30 June 1997 on Health Protection of Individuals against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/EURATOM, Official Journal of the European Communities No L 180/22-27, 9.7.1997.

[2] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

REVISION OF THE EURATOM BASIC SAFETY STANDARDS AND BEYOND

(EC Breakout Session)

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REVISION OF THE EURATOM BASIC SAFETY STANDARDS AND BEYOND

Transposition and implementation challenges

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Abstract

The recently proposed revised Euratom Basic Safety Standards, while based on existing legislation in Europe, provide several important amendments in the area of radiation protection in medicine. These include, among others, strengthening the implementation of the justification principle and expanding it to medically exposed asymptomatic individuals, more attention to interventional radiology, new requirements for dose recording and reporting, an increased role of the medical physics expert in imaging and a whole new set of requirements for preventing and following up on accidents. The changes will bring further advances in radiation protection of patients across Europe but may pose some challenges to Member States, regulators and clinical professionals, who have to transpose them into national law and everyday practice. Those challenges are discussed in this paper and some suggestions for dealing with them are made, wherever allowed by the format of the relevant meeting. The need for further developments going beyond the revision of the Euratom (European Atomic Energy Community) legislation and requiring cooperation on national and European level has been clearly identified.

1. INTRODUCTION

The treaty that established the European Atomic Energy Community (Euratom), commonly referred to as the Euratom Treaty [1], was adopted in 1957 and is nowadays binding primary law for the 27 Member States of the European Union (EU) with more than 500 million inhabitants. The Euratom Treaty offers

the legal framework for the establishment, as a secondary law, of the Euratom Basic Safety Standards (Euratom BSS) for the protection of the health of workers and the general public. The Euratom BSS were first adopted in 1959 and the latest version, Council Directive 96/29/Euratom [2], was published in 1996. The first Euratom legislation with respect to medical exposure was established in the 1980s [3] and further revised in the 1990s by the publication of Council Directive 97/43/Euratom: Medical Exposures Directive [4]. In May 2012, the European Commission published its proposal to EU Member States for a revised radiation protection Directive ('revised Euratom BSS') [5], which should replace the current Euratom BSS, the Medical Exposures Directive and three other pieces of existing Euratom legislation. This paper describes the main changes in the revised Euratom BSS with regard to radiation protection in medicine and discusses some of the challenges that EU Member States and professional groups concerned may face when implementing those changes.

2. MEDICAL EXPOSURE IN THE REVISED EURATOM BASIC SAFETY STANDARDS

The revised Euratom BSS maintain the main principles for protection of patients and other medically exposed individuals, proposing changes in a few cases where a need to emphasize, strengthen or clarify requirements has been identified and introducing several new requirements in areas where there have been obvious gaps. The main changes are described below.

2.1. Justification

The revised Euratom BSS introduce new requirements in relation to exposure of asymptomatic individuals which shall either: (i) be part of an approved health screening programme; or (ii) require specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines from relevant medical scientific societies and competent authorities. The radiology practitioner shall inform patients about the benefits and risks associated with the medical exposure, with special attention required in the case of asymptomatic individuals. In addition to patient exposure, staff exposure shall also be taken into account in justifying a type of medical procedure.

2.2. Optimization

The requirements in this area remain substantially unchanged, except that interventional radiology is explicitly mentioned in several requirements,

including those for establishment, regular review and use of diagnostic reference levels (DRLs).

2.3. Dose recording and reporting

Any system used for interventional radiology and computed tomography (CT) shall have a device or feature informing the radiology practitioner of the quantity of radiation produced by the equipment during the procedure. Any other medical radiodiagnostic equipment shall have such a device/feature or equivalent means. The dose shall be part of the examination report, the intent being to raise awareness among prescribers and practitioners of the doses associated with an examination.

2.4. Medical physics expert

The proposed new definition and detailed description of the medical physics expert's responsibilities aim to provide a link between their required competences and the assigned responsibilities. A greater level of medical physics expert involvement in imaging examinations is now required.

2.5. Education and training

The introduction of radiation protection in medical and dental schools was proposed as a mandatory requirement. A new legal provision requires mechanisms for timely dissemination of information on lessons learned from significant events involving unintended or accidental medical exposures.

2.6. Accidental and unintended exposures

The revised Euratom BSS introduce several new requirements on accidental and unintended exposures. In radiotherapy, the quality assurance programmes shall include a study of risks of accidental or unintended exposures. The operators of radiological equipment shall implement a registration and analysis system of events involving or potentially involving accidental or unintended exposures. The operators shall declare to the authorities the occurrence of significant events including the results of their investigation and the associated corrective measures. The referrer and the patient shall be informed about such exposures.

2.7. Occupational dose limit for the eye

The proposed limit on the equivalent dose for the lens of the eye is 20 mSv in a year or, where applicable, the same value as specified for the limit on effective dose. This may be compared to the annual dose limit in the existing Euratom BSS of 150 mSv to the lens of the eye. In addition, it is proposed that those liable to receive in excess of 15 mSv/a to the eye should be classified as Category A workers. The impact of these changes will be most relevant in medicine, for example, for interventional fluoroscopy guided practices in radiology and cardiology, where the proper use of radiation protection tools and rules will need to be reinforced, especially for professionals with a high workload.

2.8. Population dose

The requirement to estimate population dose from medical exposure remains, but there is now a requirement to take into account the age and gender of the exposed population.

3. AREAS OF SPECIFIC INTEREST AND IMPLEMENTATION CHALLENGES

The following sections reflect the presentations and discussion that took place during a dedicated breakout session held on 5 December 2012 as part of the conference programme. They seek to capture inputs from the panellists as well as from the session participants.

3.1. Medical exposure of asymptomatic individuals

The situation in which an asymptomatic, i.e. apparently healthy, individual is referred for a diagnostic test involving exposure to ionizing radiation is often referred to as ‘opportunistic screening’ or ‘individual health assessment’ (IHA). This situation deviates considerably from the basic assumption of a direct health benefit to a medically exposed patient and is also different from approved screening programmes in that the risk:benefit ratio is not clearly established for a targeted population. In addition, IHA practices are currently not subject to the same level of quality assurance, education and training, and other requirements applicable to the exposure of patients and health screening.

An area of special concern is the use of CT for IHA, practised mostly in economically developed countries, for example, for early detection of lung or colon cancer or as whole body CT. It should be noted that CT organ doses

may reach values for which there is sufficient scientific evidence to confirm a statistically significant increase in radiation induced cancer. Several statements from reputable sources show a lack of benefit from whole body [6, 7] or colon cancer [7] CT screening; as for lung CT, positive results from one prospective randomized trial [8] have not been widely accepted as sufficient to recommend low dose CT lung screening [9].

Recently, the network of the Heads of the European Radiological protection Competent Authorities (HERCA) published a position paper on IHA [10] containing, among others, recommendations on the future implementation of the revised Euratom BSS. The paper concluded that: "it is a remarkable progress, that the Euratom Basic Safety Standards Directive…clearly addresses this issue" and "to transform this requirement into national legislation in the EU member states, a thorough discussion is needed…".

3.2. Accidental and unintended medical exposures

Radiotherapy is an important element of the fight against cancer worldwide, with an estimated 6.5 million patients needing radiotherapy each year. Radiotherapy has proven to be a safe treatment method. Data from the United Kingdom demonstrate that about one in ten thousand treatment episodes would be associated with a reportable event. At the same time, the consequences could be significant when errors occurred.

There is a considerable body of information accumulated in different countries regarding the occurrence of accidents in radiotherapy. In the United Kingdom, where a highly developed reporting culture exists, radiotherapy accidents involving single or multiple patients have been caused mainly by equipment or human error, and the potential for error is evident throughout the entire pathway. A similar situation was encountered in France in relation to radiotherapy accidents occurring in the past 20 years.

National approaches and initiatives have been developed to address accident prevention, reporting and follow-up. Examples include quality management systems [11, 12]; regulations defining professional responsibility within management frameworks [13–15] or requiring, for example, prior risk assessment, internal reporting, feedback committees and training of personnel [16]; professional initiatives providing consistent terminology and classification of events [17]; notification systems [18, 19]; incident rating for public communication [20]; and regulatory initiatives [21, 22].

International initiatives have been undertaken in this area. These include Publication 112 of the International Commission on Radiological Protection [23], the international conference held in Versailles in 2009 [24] and the recent launch of the SAFRON reporting and learning system by the IAEA [25]. The ongoing

European ACCIRAD project [26] will develop guidelines on risk analysis of events involving or potentially involving accidental or unintended exposures (adverse events and near misses) in external beam radiotherapy.

The new requirements in the revised Euratom BSS will help consolidate European efforts and advances in this area. The following points have to be taken into account and/or may represent specific challenges: systems to record and follow-up accidents have to be commensurate with the risk from the practice; dissemination of information about accidents is crucial to avoid repetition; trust between operators and regulators and a no-blame culture stimulating reporting shall be developed; defining a 'significant event' in radiotherapy may be challenging; for instance, numerical criteria seem insufficient to address cases of delivery to wrong volumes; developments in individual sensitivity have to be followed and factored into classification of events in radiotherapy. ACCIRAD and HERCA work on defining criteria for reporting accidents, and there may be further European guidance in this area following the adoption of the revised Euratom BSS.

3.3. Other issues and concerns

The revised Euratom BSS place a much greater role on dose constraints and evaluation of organ doses as part of the optimization for all practices. This will have an influence on medical practices with regard to occupational and patient exposures.

The new requirement to monitor the dose to the lens of the eye for all staff liable to exceed the public limit (15 mSv) poses practical difficulties. The new dose limit of 20 mSv may be challenging for some busy cardiologists and there is a need to reinforce protective measures.

A standardized set of dose quantities and units has to be developed and implemented on all equipment to allow recording and reporting of patient dose. Automatic transfer, storage and retrieval of dose data to/from a picture archiving and communication system (PACS)/radiology information system (RIS) needs to be reliable and user friendly. The same applies to patient specific data needed for radiation protection purposes, e.g. age and sex.

A qualitative approach is needed for communicating risk and benefit to patients rather than reporting individual doses or risk. Clear assignment of responsibility has to be made on the national level, and this may be procedure dependent. There is a need for further guidance in this area.

There is still uncertainty among professionals about what are the most appropriate dose quantities in diagnostic radiology. Effective dose is needed for comparison between different procedures but is not appropriate for optimization. Modality specific quantities have been developed for optimization and setting

of DRLs. European guidelines [27] provide uniform methodology for converting machine displayed or directly measurable dose quantities into effective dose.

In the EU, medical equipment design is regulated under EU legislation for medical devices [28] and is, in practice, implemented through 'harmonized standards'. Euratom has a limited role in this area and would place additional legal requirements on equipment in use only when considered of crucial importance for radiation protection. In Europe, HERCA launched an initiative to discuss radiation protection issues with CT manufacturers and cooperates with the US Food and Drug Administration in this area [10].

Other issues mentioned during the panel discussion and worth mentioning but not fully discussed include ongoing chest X ray screening for tuberculosis, which is not subject to the scrutiny applied, for instance, to mammography screening in some countries, second hand equipment where action may be needed to better control or limit use, and hand-held equipment where safety issues have recently been encountered.

4. CONCLUSIONS

The European Union has almost a 30 year history of regulating radiation protection of patients and other medically exposed individuals. The Euratom legislation in this area has provided for considerable progress in ensuring a high level of radiation safety of patients in Europe. Nevertheless, technological and societal developments in the past decade or so have shown that there is a need to update European medical exposure legislation. This update has been done in the framework of the recently undertaken overhaul of the overall Euratom radiation protection legislation, which brings the additional advantage of providing for a consistent and consolidated legal framework covering all categories of exposure and exposure situations. The updated Euratom BSS maintain the existing principles and most of the requirements for radiation protection in medicine and provide further advances in several key areas.

The amendments of the legal requirements will require transposition into the national law of EU Member States and some changes in established national systems and arrangements. This has to be followed by focused efforts to implement the new requirements into everyday practice. Such efforts should be collaborative by nature, and have to be based on dialogue and partnership between national regulators, professional groups and industry. Collaboration across Europe is needed to fully benefit from the advances in the common European legal basis for radiation protection; it is even more important and, indeed, unavoidable in today's conditions of highly integrated European markets. The European Commission will continue supporting Member States in the

implementation of Euratom legislation, including through active collaboration with the European regulatory, professional and industry groups and networks.

REFERENCES

[1] THE COUNCIL OF THE EUROPEAN UNION, THE HIGH CONTRACTING PARTIES OF EURATOM (1957), Consolidated Version of the Treaty Establishing the European Atomic Energy Community, Official Journal of the European Union No. 2010/C 84/01 (2010).

[2] THE COUNCIL OF THE EUROPEAN UNION, Council Directive 96/29/Euratom of 13 May 1996: Laying Down Basic Safety Standards for the Health Protection of the General Public and Workers against the Dangers of Ionizing Radiation, Official Journal of the European Union No. 1996/L 159/1 (1996).

[3] THE COUNCIL OF THE EUROPEAN UNION, Council Directive 84/466/Euratom of 3 September 1984: Laying Down Basic Measures for the Radiation Protection of Persons Undergoing Medical Examination or Treatment, Official Journal of the European Union No. 1984/L 265/1 (1984).

[4] THE COUNCIL OF THE EUROPEAN UNION, Council Directive 97/43/Euratom of 30 June 1997: On Health Protection of Individuals against the Dangers of Ionizing Radiation in Relation to Medical Exposure, and Repealing Directive 84/466/EURATOM, Official Journal of the European Union No. 1997/L 180/22 (1997).

[5] EUROPEAN COMMISSION, Proposal for a Council Directive Laying Down Basic Safety Standards for Protection against the Dangers Arising from Exposure to Ionising Radiation (2012), http://ec.europa.eu/energy/nuclear/radiation_protection/doc/2012_com_242.pdf

[6] UNITED STATES FOOD AND DRUG ADMINISTRATION, Full-Body CT Scans — What You Need to Know (2010), http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115340.htm

[7] COMMITTEE ON MEDICAL ASPECTS OF RADIATION IN THE ENVIRONMENT (COMARE), COMARE 12th Report: The Impact of Personally Initiated X-ray Computed Tomography Scanning for the Health Assessment of Asymptomatic Individuals (2007), http://www.comare.org.uk/documents/COMARE12thReport.pdf

[8] THE NATIONAL LUNG SCREENING TRIAL RESEARCH TEAM, Reduced lung-cancer mortality with low-dose computed tomographic screening, N. Engl. J. Med. **365** (2011) 395–409.

[9] THE EUROPEAN RANDOMIZED CT SCREENING (EUCT) INVESTIGATORS, The PISA Position Statement (2011).

[10] HEADS OF EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES (HERCA), (2013), http://www.herca.org/
[11] BLEEHEN, N., Quality Assurance in Radiotherapy, Report of a Working Party of the Standing Subcommittee on Cancer of the Standing Medical Advisory Committee, Department of Health, London (1991).
[12] FRENCH NUCLEAR SAFETY AUTHORITY, Contribution by the French Nuclear Safety Authority (ASN) to the Ministry of Health's National Action Plan for Radiotherapy Established in 2007, Assessment of Actions (2012).
[13] SECRETARY OF STATE (UK), The Ionising Radiation (Medical Exposure) Regulations 2000, No. 1059 (2000), http://www.legislation.gov.uk/uksi/2000/1059/contents/made
[14] FRENCH NUCLEAR SAFETY AUTHORITY, Management Guidelines for Safety and Quality in Radiotherapy, ASN Guide No. 5, ASN, Paris (2009) (in French).
[15] FRENCH NUCLEAR SAFETY AUTHORITY, ASN Resolution on Healthcare Safety Management, Management Guidelines for Safety and Quality in Radiotherapy, ASN Guide No. 5, ASN, Paris (2009) 99 (in French).
[16] FRENCH NUCLEAR SAFETY AUTHORITY, ASN Guide for the Self-assessment of Risks Incurred by Patients in External Beam Radiotherapy, ASN Guide No. 4, ASN, Paris (2009) (in French).
[17] BRITISH INSTITUTE OF RADIOLOGY, INSTITUTE OF PHYSICS AND ENGINEERING IN MEDICINE, NATIONAL PATIENT SAFETY AGENCY, SOCIETY AND COLLEGE OF RADIOGRAPHERS, ROYAL COLLEGE OF RADIOLOGISTS, Towards Safer Radiotherapy, The Royal College of Radiologists, London (2008), http://www.rcr.ac.uk/docs/oncology/pdf/Towards_saferRT_final.pdf
[18] FRENCH NUCLEAR SAFETY AUTHORITY, Significant Radiation Protection Events Affecting Patients in Radiotherapy (Criterion 2.1), ASN Guide No. 16, ASN, Paris (2010) (in French).
[19] FRENCH NUCLEAR SAFETY AUTHORITY, ASN Reports on Radiotherapy Events (Rangueil Hospital, Epinal), Notifications Received by ASN and AFSSAPS Regarding Radiation Protection and Medical Device Vigilance in Radiotherapy, ASN, Paris (2008/2009).
[20] FRENCH NUCLEAR SAFETY AUTHORITY, ASN-SFRO Incident Rating Scale, ASN, Paris (2008).
[21] PUBLIC HEALTH ENGLAND, Radiotherapy, Public Health England, London (2013), http://www.hpa.org.uk/radiotherapy
[22] FRENCH NUCLEAR SAFETY AUTHORITY, News Bulletin on the Safety of the Patients Elaborated together with Professionals, ASN, Paris (2012).
[23] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, Publication 112, Elsevier (2009).

[24] FRENCH NUCLEAR SAFETY AUTHORITY, International Conference on Modern Radiotherapy: Advances and Challenges in Radiation Protection of Patients, Versailles, (2009).
[25] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Reporting and Learning System for Radiotherapy (SAFRON), IAEA, Vienna (2013), https://rpop.iaea.org/SAFRON/
[26] ACCIRAD project web site (2013), http://www.accirad.eu/
[27] EUROPEAN COMMISSION, European Guidance on Estimating Population Doses from Medical X-Ray Procedures, Radiation Protection No. 154, Directorate-General for Energy and Transport, European Commission, Luxembourg (2008).
[28] THE COUNCIL OF THE EUROPEAN UNION, Council Directive 93/42/EEC of 14 June 1993: Concerning Medical Devices, Official Journal of the European Union No. 2007/L 247/21 (2007).

UNSCEAR'S SURVEYS ON MEDICAL EXPOSURES: HOW TO ASSESS GLOBAL LEVELS AND TRENDS, AND INTERPRET THE RISKS

(UNSCEAR Breakout Session)

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UNSCEAR'S SURVEYS ON MEDICAL EXPOSURES

How to assess global levels and trends, and interpret the risks

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Abstract

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was established in 1955 to systematically collect, evaluate, publish and share data on the global levels and effects of ionizing radiation from natural and artificial sources. Regular surveys have been conducted on the frequencies of medical radiological procedures and levels of exposure, equipment and staffing to monitor evolving trends. Two thirds of diagnostic radiological procedures and over 90% of all nuclear medicine procedures are performed in industrialized countries. The global average annual per caput effective dose from diagnostic radiological procedures nearly doubled between 1988 and 2007, from 0.35 to 0.62 mSv. A major challenge relating to the interpretation, analysis and use of radiation exposure data of a population is the uncertainty when attributing cancer risk to ionizing radiation exposure. The uncertainty of cancer risk after exposure to ionizing radiation is often underestimated. For solid cancer risk after an exposure of 100 mSv, upper and lower boundaries of the 95% confidence interval differ by a factor of 5. It is important to distinguish between a manifest 'health effect' and 'health risk', when describing such health implications for an individual or a population. A manifest health effect in an individual (such as skin burns) can be unequivocally attributed to radiation exposure only if other possible causes for an observable tissue reaction are excluded. Cancer cannot be unequivocally attributed to radiation exposure because radiation is not the only possible cause and there are, at present, no known biomarkers that are specific to radiation exposure. Therefore, when estimating radiation induced health effects in a population exposed to incremental doses at levels equivalent to or below natural background,

it is *not* recommended to do this simply by multiplying the very low doses by a large number of individuals. However, it is recognized that there is a need for such estimations by health authorities to allocate resources or to compare health risks. This is valid if applied consistently and the uncertainties in the estimations are fully taken into account, and the projected health effects are notional.

1. INTRODUCTION

In 1955, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was established by the United Nations General Assembly to collect and evaluate information on the levels and effects of ionizing radiation from natural and artificial sources. UNSCEAR has systematically reviewed and evaluated the global and regional levels and trends of medical exposure, as well as exposures to the public and workers. It has also regularly evaluated the evidence for radiation induced health effects from studies of Japanese atomic bombing survivors and other exposed groups, and has reviewed advances in the mechanisms of radiation induced health effects.

An important source of evidence is population based surveys of radiation use and exposure in medicine, as such surveys identify the levels and trends of exposure, and highlight the procedures requiring intervention by virtue of doses or frequency of procedures. Gaps in treatment capabilities and possible unwarranted dose variations for the same procedure are also identified. This paper describes and discusses UNSCEAR surveys, including some findings and the challenges to interpreting the risks from medical radiological exposures.

2. UNSCEAR MEDICAL EXPOSURE SURVEYS

UNSCEAR has conducted global surveys for assessments and trend analyses on the medical use of ionizing radiation for many years, covering the three types of medical exposure defined by the International Commission on Radiological Protection: (i) patients as part of medical diagnosis or treatment; (ii) individuals as part of health screening programmes; and (iii) individuals or patients voluntarily participating in medical radiation research programmes [1].

As early as in its first report in 1958, UNSCEAR recognized that medical diagnostic and therapeutic exposures were a major component of artificial radiation exposures worldwide, a fact that remains true today [2]. UNSCEAR surveys revealed an absence of data on the frequency and doses of radiological procedures from more than half of the world's countries as most of the data came from industrialized countries [2, 3].

Based on the good correlation between the 'physician to population ratio' and the annual frequency of diagnostic radiological procedures, an analytical model was developed to enable the estimation of medical radiation exposure on a worldwide basis by grouping countries with similar resources under a certain health care level (HCL)[1]. This enables the estimation of the number and type of procedures for a given country where specific data were unavailable, by applying an average annual frequency of these procedures from other countries under the same HCL [4]. The UNSCEAR 1988 Report presented, for the first time, an estimate of the global dose to patients from medical diagnostic procedures using this extrapolation model [5]. Since the UNSCEAR 2000 Report, the collective effective dose (man sievert) and the per caput effective dose (millisievert) were used to express population dose estimates in general [3].

The UNSCEAR 2008 Report evaluated the global use of medical exposures from 1997 to 2007. According to this report, approximately 3.6 billion diagnostic radiological procedures (including approximately 0.5 billion dental procedures) were performed annually worldwide. The annual frequency of diagnostic medical procedures (including dental procedures) in HCL I countries increased from 1200 per 1000 inhabitants in the 1991–1996 period to 1650 in the 1997–2007 period [2, 3]. The annual frequency of diagnostic medical procedures in HCL III and IV countries remained fairly constant over the same periods, although since there were limited data for these countries, there is considerable uncertainty associated with this estimate. Only 1.5% of all worldwide diagnostic radiological procedures were estimated to be performed in HCL III and IV countries, which together cover 27% of the global population. This imbalance in health care provision is also reflected in the availability of radiological equipment and of practitioners.

Since the UNSCEAR 2000 Report, the total number of diagnostic radiological procedures and per caput effective dose has increased by approximately 50% and the total collective effective dose from medical diagnostic procedures has nearly doubled from about 2.3 million man Sv to about 4 million man Sv. The global average annual per caput effective dose increased from 0.35 mSv in 1988 to 0.62 mSv in 2007 [2, 3, 5].

The utilization of nuclear medicine procedures around the world is also quite uneven, with 90% of procedures performed in HCL I countries [2]. The estimated annual collective effective dose from diagnostic nuclear medicine procedures increased by 34% from 150 000 to 202 000 man Sv between the periods

[1] Under this model, a country is assigned to one of the four HCLs. Countries in HCL I have more than 1000 physicians per million people; HCL II between 333 and 1000; HCL III between 100 and 332; and HCL IV less than 100 [2–4].

1991–1996 and 1997–2007, and by a factor of ~3 compared to 74 000 man Sv in the evaluation conducted for the period 1980–1984 [2, 3, 5].

The main results of the UNSCEAR 2008 Report are summarized in Table 1 [2].

TABLE 1. GLOBAL AND HEALTH CARE LEVEL ESTIMATIONS OF ANNUAL FREQUENCIES OF RADIOLOGICAL DIAGNOSTIC PROCEDURES (DENTAL IN BRACKETS) AND COLLECTIVE EFFECTIVE DOSES FOR THE PERIOD 1997–2007 [2]

Health care level	Population (in millions)	Annual frequency per 1000 inhabitants	Annual collective effective dose (man Sv)	Annual per caput effective dose (man Sv)
I	1 540	1 332 (275)	2 900 000 (9 900)	1.91
II	3 153	332 (16)	1 000 000 (1 300)	0.32
III	1 009	20 (2.6)	33 000 (51)	0.03
IV	744	20 (2.6)	24 000 (38)	0.03
Global	6 446	488 (74)	4 000 000 (11 000)	0.62

3. INTERPRETATION OF MEDICAL EXPOSURE DATA

One of the major challenges relating to the interpretation, analysis and use of radiation exposure data of populations is the uncertainty when attributing cancer risk to ionizing radiation exposure. In epidemiological surveys of populations exposed to radiation, there are statistical fluctuations and uncertainties due to selection and information bias, exposure and dose assessment, and model assumptions used when evaluating data. In addition, transferring the risk estimate based on data from an epidemiological study to a population of interest needs to take into account differences in location, setting, data collection period, age and gender profile, genetic disposition, doses, type of radiation and acute versus protracted exposures [6]. The uncertainty of cancer risk after exposure to ionizing radiation is, therefore, often underestimated. For solid cancer risk after an exposure of 100 mSv, upper and lower boundaries of the 95% confidence interval differ by a factor of 5. The uncertainty of excess risk for a specific cancer type is considerably higher than for all solid cancers [6]. These uncertainties

in estimating cancer risk from ionizing radiation exposure need to be addressed when assessing the health implications of medical radiation exposures.

It is important to distinguish between a manifest 'health effect' and 'health risk' (likelihood of a future health effect to occur), when describing such health implications for an individual or a population. A manifest health effect in an individual could be unequivocally attributed to radiation exposure only if other possible causes for an observable tissue reaction (such as skin burns; deterministic effect) were excluded. Cancer (stochastic effects) in individuals cannot be unequivocally attributed to radiation exposure because radiation is not the only possible cause and there are, at present, no known biomarkers that are specific to radiation exposure. An increased incidence of stochastic effects in a population could be attributed to radiation exposure through epidemiological analysis, provided the increased incidence is sufficient to overcome the inherent statistical uncertainties [6].

In general, a manifest increased incidence of health effects in a population cannot reliably be attributed to radiation exposures at levels that are typical of the global average background levels of radiation or the levels applied at medical radiological diagnostics. The reasons are: (i) the uncertainties associated with risk assessment at low doses; (ii) the absence of radiation specific biomarkers; and (iii) the insufficient statistical power of epidemiological studies [6].

When estimating radiation induced health effects in a population exposed to incremental doses at levels equivalent to or below natural background, it is not recommended to do this simply by multiplying the very low doses by a large number of individuals. However, it is recognized that there is a need for such estimations by health authorities to allocate resources or to compare health risks. This is valid if applied consistently and the uncertainties in the estimations are fully taken into account, and the projected health effects are notional [6].

4. CONCLUSION

Medical exposure remains by far the largest artificial source of exposure and it continues to grow significantly. The distribution of medical exposures is uneven between countries. A quarter of the world's population lives in HCL I countries, and receives 66% of all diagnostic radiology and 90% of nuclear medicine procedures. While data are available from HCL I countries on which UNSCEAR's assessments are mainly based, data from HCL II to IV countries are scarce. In collaboration with the IAEA and the World Health Organization, an improvement strategy has been developed to address deficiencies in data quality and collection, and to improve participation in future surveys [7]. This includes the revision of the HCL model for better data extrapolation and the focus

on those procedures with significant contribution to the collective effective dose similar to the methodology used by the European Commission's Dose Datamed project [8, 9].

While the magnitude of medical exposures can be assessed, it is very difficult to estimate the health risks from such uses as there are still many uncertainties in estimating cancer risk due to ionizing radiation and in attributing other health effects to and inferring risk from medical radiation exposure. The lower the dose, the higher is the uncertainty. Thus, the uncertainty increases when extrapolating risk estimates from moderate dose to low dose. Therefore, it is not surprising to note that a statistically significant increase in radiation induced cancer is seen only when the exposure is 100 mSv or above [6]. Therefore, UNSCEAR does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation induced health effects within a population exposed to incremental doses at levels equivalent to or lower than natural background levels [6].

REFERENCES

[1] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the ICRP, Publication 60, Pergamon Press, Oxford and New York (1991).

[2] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2008 Report to the General Assembly, with Scientific Annexes A and B), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).

[3] UNITED NATIONS, Sources and Effects of Ionizing Radiation (2000 Report to the General Assembly, with Scientific Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2000).

[4] METTLER, F.A., Jr., et al., Analytical modeling of worldwide medical radiation use, Health Phys. **52** 2 (1987) 133–141.

[5] UNITED NATIONS, Sources, Effects and Risks of Ionizing Radiation (1988 Report to the General Assembly, with Annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (1988).

[6] UNITED NATIONS, Sources, Effects and Risks of Ionizing Radiation (2012 Report to the General Assembly, with annexes), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2012).

[7] CRICK, M., et al., "Opportunities to improve the global assessment of medical radiation exposures", Radiation Protection in Medicine (Proc. Int. Conf. Varna, 2010), National Centre of Radiobiology and Radiation Protection, Varna (2010).

[8] SHANNOUN, F., "A comparison of classification methodologies of Health Care Levels used by UNSCEAR and WHO", Dose Datamed II Project Workshop on European Population Doses from Medical Exposure, Greek Atomic Energy Commission, Athens (2012).
[9] EUROPEAN COMMISSION, European Guidance on Estimating Population Doses from Medical X-Ray Procedures, Radiation Protection No. 154, Directorate-General for Energy and Transport, European Commission, Luxembourg (2008).

MOBILIZING FOR FUTURE EFFECTIVE WORK AND CONCLUSIONS

(Closing Session)

Chairpersons

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World Health Organization

A SUMMARY OF CONCLUSIONS FROM SESSIONS AND ROUND TABLES OF THE CONFERENCE

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This paper provides a brief summary of the major conclusions of the scientific sessions and discussion round tables constituting the International Conference on Radiation Protection in Medicine held in Bonn, Germany on 3–7 December 2012. It highlights some of the more important presentations at the conference as well as issues that arose during discussion and that require further investigation and action.

At the conference, the necessity of a commitment to a safety culture within institutions and organizations providing health care to patients was emphasized. The safety culture must support and reinforce efforts to provide adequate protective measures for patients and staff exposed to ionizing radiation used for diagnosis of disease and injury, and for the treatment of cancer. Elements of a safety culture are: (i) leadership; (ii) evidence based practice; (iii) teamwork; (iv) accountability; (v) communication; (vi) continuous learning; and (vii) justice. These elements are essential to a safety culture and must, therefore, be present in any organization that reinforces radiation protection.

Over 25 years (1982–2006) in the United States of America alone, the average individual dose from medical radiation increased by a factor of 5.5, and the collective population dose increased sevenfold. These increases occurred even though the actual dose delivered to individual patients decreased for many imaging procedures. The increases in average and collective dose reflect the growing usefulness of medical imaging as a consequence of improved technologies, new procedures and applications, and increased access to imaging. This is encouraging news, because it demonstrates that increasing numbers of patients are receiving the medical benefits of imaging and therapeutic procedures employing ionizing radiation. However, these trends also reinforce the need for careful justification of procedures employing ionizing radiation, and

diligence in their deployment, to ensure that the benefits far outweigh the risks of the procedures in every case.

At the conference, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) announced its resolution concerning low exposure levels from medical imaging. The resolution states:

> "Therefore the Scientific Committee (of UNSCEAR) does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation induced health effects within a population exposed to incremental doses and levels equivalent to or lower than natural background levels."

This statement will be helpful in establishing priorities for the allocation of efforts and resources, so that real challenges are not ignored in an effort to deal with less important and perhaps imaginary problems.

The tracking of imaging procedures and radiation doses is recommended as a way for institutions and agencies to monitor trends in procedures and radiation doses delivered collectively to patients. It is also possible for patients to track their individual exposures by use of a tracking card available from agencies such as the IAEA and, in the USA, the Food and Drug Administration. This process lends a sense of personal empowerment to individuals, but may also mislead patients into thinking that their collective exposure can be estimated by adding doses to different body regions from separate modalities. In any event, the decision to administer an imaging procedure to a patient should always be based on the benefits/risks of the procedure without regard to previous exposures the patient may have received.

There was considerable discussion about justification and optimization of imaging procedures at the conference, while less attention was paid to proper implementation and evaluation of the procedures. The four elements collectively comprise the continuous quality improvement cycle for imaging procedures shown in Fig. 1. It was recognized that both overutilization and underutilization of medical imaging compromise the concept of justification of imaging procedures. However, these shortcomings can be addressed relatively successfully through the use of decision support systems to guide the referring physician in selecting the proper imaging examination for the patient. In institutions with computerized physician order entry (CPOE), decision support software can be added as an integral part of CPOE. In institutions without CPOE and with limited resources for information management, guidance to referring physicians can be provided in printed guidelines and by personal communication with a radiologist.

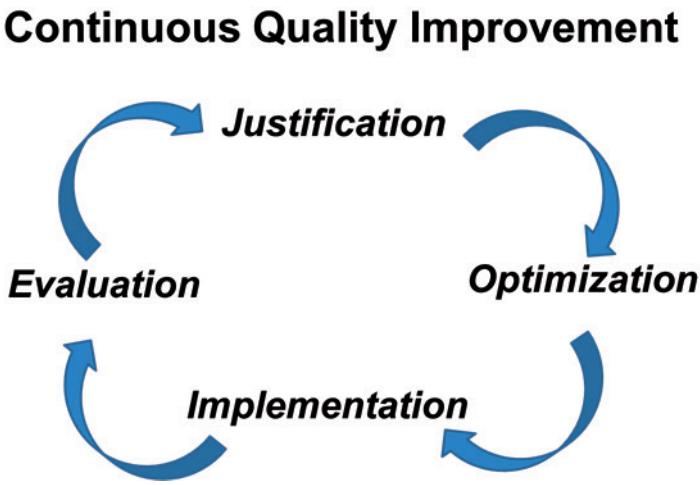

FIG. 1. Elements constituting continuous quality improvement.

The usefulness of diagnostic reference levels (DRLs) was recognized by the participants in the conference, and expansion of their use to additional geographic regions and newer imaging modalities was encouraged.

Digital radiography presents a number of challenges with regard to patient protection and procedure optimization. Among these challenges are: (i) automatic exposure controls must be recalibrated when a radiographic system is upgraded to digital, and DRLs should be adjusted in accordance with the sensitivity of the digital system; (ii) some operators use wide collimation during patient exposures and then crop the images after exposure to display only the region of interest — this approach exposes the patient to unnecessary radiation and should be discouraged; (iii) as digital systems have a wide dynamic range, it is possible to overexpose patients and still recover diagnostic images — operators must be educated to avoid this problem; and (iv) operators of digital systems should identify the minimum acceptable quality of images for a diagnostic procedure, and then reduce the dose to a level consistent with those images.

Interventional procedures have increased remarkably over the past couple of decades, and have improved patient outcomes and reduced patient mortality and morbidity as a consequence. They have contributed to the rise in average and collective patient exposures in the USA and other developed countries. Several technical features were described at the conference to improve the benefit and limit the exposure to patients and staff during interventional procedures, including:

— Software programs for accurately co-registering data from multiple imaging techniques;
— Robotic systems and magnetic steering of catheters to reduce exposures by increasing the distance of the staff from the X ray unit;
— Dynamic flat panel detectors of greater spatial and temporal resolution;
— Improved shielding and wearable dosimeters to help operators protect themselves from exposures.

It was also agreed that formulating DRLs for interventional procedures is a challenge that should be addressed in the near future.

The Image Wisely campaign has been launched to improve quality and reduce dose in adult imaging in the manner so successfully achieved by the Image Gently campaign for paediatric imaging. The Image Wisely campaign focused its initial efforts on computed tomography (CT) imaging, but now has extended the campaign to nuclear medicine, with guidelines such as weight based dosing, single examinations when possible (e.g. cardiac imaging under stress without non-stress imaging), and development and implementation of guidelines for nuclear imaging.

The rapid increase in average and population doses in the USA and other developed countries is primarily the product of increased applications of CT resulting from the evolution of spiral CT. Advances in CT are continuing, and were described at the conference as:

— Optimized X ray spectra generated at lower kVp for both adult and paediatric examinations;
— More efficient X ray detectors;
— Careful beam collimation;
— Dose management with techniques such as tube current modulation and automatic exposure control;
— CT units designed for specialized imaging applications such as CT mammography, dental cone beam computed tomography and orthopaedic surgery;
— Use of iterative reconstruction which provides faster and higher quality images compared with filtered back projection reconstruction techniques.

The provision of many routine CT examinations with doses at or below 1 mSv is approaching feasibility. Considerable effort has been expended in the USA to develop recommended protocols for specific imaging applications for CT scanners manufactured by different companies. These protocols are accessible

free from the American Association of Physicists in Medicine[1], together with a lexicon for translating CT terms among different manufacturers, and educational materials to explain recent advances in CT imaging. Collaboration in this effort with organizations concerned with similar issues in other countries was encouraged.

Limitations in the definition of the computed tomography dose index $(CTDI)_{vol}$ as a measure of dose in computed tomography were discussed, with the recognition that organ dose from CT examinations is a preferred dose quantity. Although some approximate methods for estimating organ dose from $(CTDI)_{vol}$ are available, they are less satisfactory than actual organ doses calculated by Monte Carlo methods. Anatomically correct phantoms for validation of Monte Carlo methods for organ dose calculations are being developed. Also of concern is the use of adjectives such as 'low', 'very low' and 'ultra low' as adjectives preceding dose in articles published in the literature. These terms are relative and vary with time, geographic location and patient size. The journal Radiology has stated that it will not accept these modifiers of dose in submitted papers, and the journal Medical Physics will take a similar position in the near future.

Radiation oncology has changed radically over the past 2–3 decades, and today is a highly complex field dominated by software as well as sophisticated hardware. Non-standard photon and particle beams are widely used under conditions that can cause major errors if commissioning and ongoing quality control are inadequate. Several examples of such inadequacies were described in which patients were severely injured or killed by improper physics procedures. At the conference, the IAEA announced that SAFRON[2], a web based system for reporting significant events in radiation therapy, would be released during the week following the meeting. SAFRON is expected to play a major role in providing information leading to reductions in the likelihood of an adverse event in participating institutions.

Other challenges of the modern era of radiation oncology include improved methods for in vivo dosimetry, better compensation for patient motion, increased biological understanding of individual differences in radiation sensitivity, and the propensity for developing second cancers, especially in children. New unsealed sources that target tumours through the use of antibodies, nanoparticles and tumour specific agents constitute an exciting arena for future developments. One observation made at the conference was that as the complexity of diagnostic and therapeutic devices increases, quality assurance measures must be simplified

[1] www.aapm.org
[2] https://rpop.iaea.org/SAFRON/

and automated to ensure that hardware, software and operator components function properly.

The challenge of improving the care of patients in countries with greatly limited resources was raised several times during the conference, and was recognized as a great and unfulfilled need across the globe.

It was widely recognized that health care is a collaborative partnership between those who provide care and those who receive it, and that true collaboration requires: (i) truthfulness and directness; (ii) partnership and collaboration; (iii) openness and transparency; (iv) understanding of benefits, risks and options; and (v) engagement and involvement of all parties. As stated by World Health Organization patient advocate M. Murphy, "Patients don't care what you know until they know that you care."

Patients should be imaged wisely and gently, and the following guidelines should always be followed:

— An imaging study should use as little radiation as possible, while still meeting the image quality needs of the examination.
— Concerns for special groups (children, pregnant women, persons with a family history of disease, hypersensitive individuals) should be paramount.
— An imaging study that is non-diagnostic because the radiation dose is too low may require re-imaging the patient, thereby increasing the patient's dose.
— In every appropriate imaging study, the benefits far outweigh the risks.

It was recognized that all medical procedures employing ionizing radiation should be provided within a culture of safety. Such a culture requires active leadership from the top, but is everyone's responsibility if it is to be fulfilled.

THE REVISED INTERNATIONAL BASIC SAFETY STANDARDS AND THEIR POTENTIAL IMPACT ON RADIATION PROTECTION IN MEDICINE

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Abstract

The Revised International Basic Safety Standards (international BSS) were published as an interim edition in November 2011. The international BSS cover radiation protection in all uses of radiation and have an important role in many countries, especially in the developing world. Issues of particular relevance for the next decade, addressed in the international BSS include responsibilities for patient radiation protection, justification for medical exposure of individual patients, imaging of asymptomatic individuals for the early detection of disease, software that can influence the delivery of medical exposure, diagnostic reference levels, voluntary safety reporting systems, radiological reviews, personal monitoring and the dose limit for the lens of the eye. The international BSS should provide an effective regulatory basis for radiation protection in medicine for the next decade, but effective implementation is needed. Further, the international BSS not only set the basic requirements but also provide the foundation for enabling additional actions to continuously improve radiation protection in medicine.

1. INTRODUCTION

The IAEA has a United Nations mandate that includes, inter alia, developing international safety standards and providing for their application. One of these safety standards is the international Basic Safety Standards (BSS). These standards have a long pedigree, with the 1996 edition entitled International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety

of Radiation Sources[1] arguably having the highest profile to date around the world, especially in the developing world. This edition has been superseded. The BSS cover radiation protection in all uses of radiation, including uses in medicine.

The BSS periodically undergo review and, if needed, revision. This process commenced for the 1996 edition with a review in 2006, followed by the decision to revise, commencing in 2007. This resulted in many drafting meetings being held, in conjunction with the potential co-sponsors, and the production of successive iterations of the revised BSS. The IAEA has its own formal processes for the development of its safety standards, with the draft progressing through the Safety Standards Committees, formal Member State comment, Commission of Safety Standards and, finally, Board of Governors approval. This process was completed in September 2011, and an interim edition of the international BSS was published in November 2011[2] — the 'interim' indicating that the formal approval or adoption of the BSS by each of the co-sponsors had, at that stage, yet to take place. This edition has also been superseded. During the course of 2012, each of the co-sponsors, the European Commission, Food and Agriculture Organization of the United Nations, International Labour Organization, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environment Programme and the World Health Organization, completed their respective formal processes with respect to the BSS. The final version of the international BSS is set for 2013.

The BSS has an important role in many countries — compliance with its requirements is mandatory in those countries receiving technical assistance from the IAEA and, in many other countries, it acts as a template for national regulations.

This paper discusses some aspects of how the international BSS should provide an adequate basis, for the next decade, for radiation protection in medicine — for the patient and for personnel.

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[1] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards — Interim Edition, IAEA Safety Standards Series No. GSR Part 3 (Interim), IAEA, Vienna (2011).

2. RESPONSIBILITIES FOR MEDICAL EXPOSURE

Regardless of the regulatory framework in a given country and the way in which authorizations to use ionizing radiation in medicine are granted, radiation protection of the patient depends primarily on three key health professional groups — the radiological medical practitioners (e.g. radiologist, nuclear medicine physician, radiation oncologist, interventional cardiologist, dentist), the medical radiation technologists (e.g. radiographer, radiological technologist) and the medical physicists. It is crucial that only persons who meet particular requirements are allowed to act in these roles. In this respect, the BSS are quite clear that the regulatory body in a given country must ensure that persons can act in these roles only if they are specialized in the appropriate area and meet the respective education, training and competence requirements in radiation protection [1]. Appropriately trained personnel will continue to underpin radiation protection in medicine in the next decade.

3. JUSTIFICATION OF MEDICAL EXPOSURES IN THE BASIC SAFETY STANDARDS

The requirements in the international BSS for justification of medical exposures are based on the recommendations of the International Commission on Radiological Protection [2] and the 'three levels' approach. It could be argued that, in the past, the level of implementation of the radiation protection principle of justification in medical exposure was not as good as it should have been, partly due to lack of clarity about who is responsible. The international BSS clearly assign responsibilities, including for 'level 3' justification — justification for individual patients. Imaging is the area of medical uses of radiation where this is particularly a problem. On the one hand, the referring medical practitioner knows the patient, the medical history and the clinical context, while, on the other, the radiological medical practitioner has specialist knowledge about the proposed procedure — its benefits, risks and limitations. However, the practice of defensive medicine may lead to the referring medical practitioner requesting more procedures than necessary. In some countries, there may be a financial conflict of interest for the radiological medical practitioner — the more procedures performed, the greater the income. In summary, two parties, each with strengths and potential weaknesses.

Fortunately there is a growing body of knowledge about the appropriateness of given examinations or procedures for given conditions — the so-called referral guidelines [3] or criteria of appropriateness [4] — and these act as a bridge between the referring and the radiological medical practitioner.

The international BSS, recognizing that both parties have a role to play, require that the 'level 3' justification take place through consultation between the referring medical practitioner and the radiological medical practitioner — a joint responsibility. Further, the international BSS require the use of national or international referral guidelines. The next decade will see the increasing role of software for referrals, with the incorporation of appropriateness criteria into such systems. The international BSS also require that relevant information from the patient's previous radiological procedures be taken into account in the justification. This is not a new requirement, but rather one that is becoming increasingly realizable as information technology continues to advance. Information technology, hardware and software will provide tools to help with the implementation of the justification requirements in the international BSS.

An issue that needed to be addressed in the international BSS was the imaging of asymptomatic individuals, intended for the early detection of disease, but not as part of an approved health screening programme. Such imaging is effectively occurring in the area of medicine between biomedical research programmes and established medical practice. It is complicated by the presence of entrepreneurial medicine and by self-presenting patients who have been reached by the media. In addition to the joint responsibility for justification by the referring medical practitioner and the radiological medical practitioner, the international BSS place responsibilities on the relevant professional bodies to provide guidance on such procedures and for the individual to be informed in advance of not only the benefits but also of the risks and limitations of the procedure being considered.

4. OPTIMIZATION OF PROTECTION AND SAFETY

The international BSS contain an overarching requirement that there is optimization of protection and safety for each and every medical exposure. There are many components in the process of optimization — design considerations, operational considerations, calibration, patient dosimetry, diagnostic reference levels (DRLs), quality assurance and dose constraints. Discussion in this paper only covers design considerations and DRLs.

There are two aspects of design considerations in the international BSS — medical radiological equipment, and software that could influence the delivery of medical exposure. It is the latter that is new to the international BSS and reflects the ever increasing role of software in the control and planning of radiation delivery — a trend that is set to continue in the next decade. The quality and robustness of such software is crucial to radiation safety and, clearly, software must meet acceptable standards.

DRLs are a concept that has been around for some 20 years and are an important tool in the optimization 'tool box' for imaging procedures. There is clear evidence for their effectiveness, such as that reported by the United Kingdom experience, where DRL values are now typically less than half of their original values [5]. However, the level of implementation around the world remains poor. The international BSS clearly require governments to establish DRLs, and mandate the use of DRLs by medical radiation facilities, linking their use with a requirement for dosimetry of patients. It is hoped that this structured approach to DRLs will improve their establishment and utilization around the world.

5. UNINTENDED AND ACCIDENTAL MEDICAL EXPOSURES

Sometimes, things go awry, resulting in unintended or accidental medical exposures. The international BSS specify what is meant by such events, and require that they be investigated and improvements implemented to minimize the likelihood of recurrence. Safety culture is at the heart of the international BSS, and learning from mistakes is part of this approach. Making use of voluntary safety reporting systems, such as the IAEA's SAFRON [6], is seen as a proactive step in this direction.

6. RADIOLOGICAL REVIEWS

A new requirement in the international BSS is that in each medical radiation facility there is a periodic review of the current practical implementation in the facility of the radiation protection principles of justification and optimization. The review is to be performed by the radiological medical practitioners, the medical radiation technologists and the medical physicists, and they would essentially ask themselves the questions: 'How are we really doing?' and 'What can we do better?' This questioning approach paves the way for continuous improvement in the implementation of radiation protection.

7. OCCUPATIONAL EXPOSURE

The uses of radiation in medicine account for by far the largest number of occupationally exposed workers and the largest occupational collective dose [7]. Requirements for occupational radiation protection are mature and well established, resulting in few changes in the international BSS. Two issues

of particular importance in medical uses of radiation are individual monitoring and the new dose limit for the lens of the eye.

While requirements for individual monitoring are well established for medical uses of radiation, there is an almost inverse relationship between compliance in being monitored and the likelihood of occupational exposure. Those persons unlikely to receive much dose wear their dosimeters as required, while those with a high likelihood of significant occupational exposure seem to not regularly wear their dosimeters. For example, there is strong evidence that personnel performing interventional cardiology procedures are not being effectively monitored [8]. This situation will only improve, using current types of dosimetry, if monitoring is clearly seen as adding value. One way that this can occur is to use the monitoring results to improve occupational radiation protection in the facility. The IAEA international ISEMIR (Information System for Occupational Exposure in Medicine, Industry and Research) database under development is a tool that will be able to be used by any interventional cardiology facility to perform statistical analyses and benchmarking to improve their own radiation safety performance [9].

The new dose limit for the lens of the eye, recommended by the International Commission on Radiological Protection in 2011 [10], has been incorporated into the international BSS. Without good radiation protection practice, some health professionals could easily exceed the new dose limit. There is a clear need for education and training, provision of appropriate protective tools and, again, monitoring to ensure acceptable occupational radiation protection for the more at risk occupationally exposed personnel for the next decade.

8. CONCLUSION

The international BSS should provide an effective regulatory basis for radiation protection in medicine for the next decade, but effective implementation is needed. It not only sets the basic requirements, it also provides the foundation for enabling further actions.

As a final comment, a new Safety Guide is being developed with the co-sponsors to elaborate on the requirements of the international BSS with respect to radiation in medicine — covering medical exposure, occupational exposure and public exposure. The results of this conference will provide input for the Safety Guide.

REFERENCES

[1] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[2] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, Publication 103, Elsevier (2007).

[3] ROYAL COLLEGE OF RADIOLOGISTS, iRefer: Making the Best Use of Clinical Radiology, 7th edn, The Royal College of Radiologists, London (2012).

[4] AMERICAN COLLEGE OF RADIOLOGY, ACR Appropriateness Criteria (2013), http://www.acr.org/Quality-Safety/Appropriateness-Criteria

[5] HART, D., HILLIER, M.C., SHRIMPTON, P.C., Doses to Patients from Radiographic and Fluoroscopic X-ray Imaging Procedures in the UK — 2010 Review, Rep. HPA-CRCE-034, HPA (2012).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY, SAFRON — Safety in Radiation Oncology,
https://rpop.iaea.org/SAFRON/

[7] UNITED NATIONS, Sources and Effects of Ionizing Radiation, Volume 1 (Report to the General Assembly), Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).

[8] PADOVANI, R., et al., International project on individual monitoring and radiation exposure levels in interventional cardiology, Radiat. Prot. Dosimetry **144** 1–4 (2011) 437–441.

[9] LE HERON, J.C., IAEA-CN-192, these Proceedings.

[10] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Statement on Tissue Reactions (2011),
http://www.icrp.org/page.asp?id=123

WORKING TOWARDS AN APPROPRIATE LEVEL OF RADIATION PROTECTION IN MEDICINE IN THE NEXT DECADE

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Abstract

In October 1999, at the General Conference of the IAEA, the Board of Governors requested the Secretariat to organize an international conference on radiological protection of patients. The conference, which was held in March 2001 in Malaga, Spain, involved most of the international organizations (including the International Commission on Radiological Protection (ICRP)) as well as the scientific societies concerned with the use of ionizing radiation in medicine. An action plan derived from that conference was later approved by the IAEA. The ICRP cooperated closely in the Action Plan by producing 18 reports about recommendations on radiological protection in medicine and by promoting open interactions between the scientific medical community and stakeholders. In the coming years, specific guidance on radiation could be provided on the following topics: optimization of radiological protection for new technology in medicine; management of patient and staff protection as a global approach; occupational lens doses and extremity doses; radiation risk communication to patients; justification of some medical procedures including the impact of external factors; tissue reactions during complex interventional procedures; patient dose recording and tracking in imaging; expanding the use of diagnostic reference levels; radiation risk assessment in radiotherapy; requirement for sufficient trained staff to support radiological protection in medical installations. The ICRP is determined to improve the standards and the system of radiological protection in medicine using scientifically based evidence. It is also prepared to cooperate with other international organizations and to encourage the use of the best possible science as the foundation for radiological protection in medicine.

1. THE 2001 MALAGA CONFERENCE AND THE INTERNATIONAL ACTION PLAN FOR THE RADIOLOGICAL PROTECTION OF PATIENTS

In October 1999, at the General Conference of the IAEA, the Board of Governors requested the Secretariat:

> "to organize as soon as feasible, in close collaboration with the World Health Organization and within the Agency's current budgetary resources, an international meeting on the radiological protection of patients for the purpose of an exchange of information and the development of recommendations, as appropriate, regarding the radiological protection of patients" [1].

In response to the General Conference's request, the IAEA organized the International Conference on Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy, in March 2001 in Malaga, Spain.

The conference was hosted by the Spanish Government, co-sponsored by the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the European Commission, and organized with the cooperation of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP), the International Organization for Medical Physics (IOMP), the International Radiation Protection Association (IRPA), the International Society for Radiation Oncology (ISRO), the International Society of Radiographers and Radiological Technologists (ISRRT), the International Society of Radiology (ISR) and the World Federation of Nuclear Medicine and Biology (WFNMB).

The proceedings of the conference were published by the IAEA in 2001 [2]. In September 2001, the Board requested the Secretariat to convene a group of experts to formulate — on the basis of the conference's findings, conclusions and recommendations — an Action Plan for future international work related to radiological protection of patients, and to submit the Action Plan for approval.

The Secretariat convened a technical committee consisting of senior experts from a number of Member States and representatives of the WHO, PAHO, the European Commission, UNSCEAR, ICRP, the International Commission on Radiation Units and Measurements, the International Organization for Standardization, the International Electrotechnical Commission, IOMP, ISRO, ISRRT, ISR and the WFNMB. The technical committee met from 28 January to 1 February 2002 and recommended the International Action Plan for the

Radiological Protection of Patients. The Board of Governors approved the Action Plan in July 2002 [1].

The objective of the International Action Plan was to improve patient safety as a whole. The involvement of international organizations and professional bodies was considered crucial to performing the actions and achieving the goals outlined in the Action Plan.

The relevant actions considered were: (i) education and training (including transition from conventional to digital radiology, computed tomography (CT), interventional procedures, positron emission tomography and new techniques in radiotherapy); (ii) information exchange (including codes of practice for dosimetry, and collection and dissemination of information about accidental medical exposures, and events that did not have clinical consequences but from which prevention relevant lessons can be drawn); (iii) assistance (including formal recognition of the role of medical physicists and the impact of technologists, involved in day to day procedures, on the radiological protection of patients and audit services); (iv) guidance (including cooperation with the radiology industry and commissioning of equipment and accessories involved); (v) appraisal and other services (including development of local diagnostic reference levels and development of infrastructure for the radiological protection of patients and quality assurance); and (vi) coordinated research activities.

2. THE ICRP AND THE ACTION PLAN ON RADIOLOGICAL PROTECTION OF PATIENTS IN THE PAST 10 YEARS

Most of the actions suggested in the Action Plan were addressed by the IAEA and by other organizations or scientific societies involved. The ICRP also contributed to several items and was involved in all the follow-up meetings of the Action Plan.

2.1. The contribution of the ICRP with its documents and recommendations

The ICRP has published the following 18 reports dealing with radiological protection in medicine over the past 12 years[1]:

— Publication 121, Radiological Protection in Paediatric Diagnostic and Interventional Radiology (2013) [3];
— Publication 120, Radiological Protection in Cardiology (2013) [4];

[1] Abstracts are available at: http://www.icrp.org/publications.asp

— Publication 117, Radiological Protection in Fluoroscopically Guided Procedures Performed outside the Imaging Department (2010) [5];
— Publication 113, Education and Training in Radiological Protection for Diagnostic and Interventional Procedures (2009) [6];
— Publication 112, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies (2009) [7];
— Publication 106, Dose to Patients from Radiopharmaceuticals: Addendum 3 to ICRP Publication 53 (2008) [8];
— Publication 105, Radiological Protection in Medicine (2007) [9];
— Publication 102, Managing Patient Dose in Multi-detector Computed Tomography (2007) [10];
— Publication 98, Radiation Safety Aspects of Brachytherapy for Prostate Cancer Using Permanently Implanted Sources (2005) [11];
— Publication 97, Prevention of High-dose-rate Brachytherapy Accidents (2005) [12];
— Publication 94, Release of Patients after Therapy with Unsealed Radionuclides (2004) [13];
— Publication 93, Managing Patient Dose in Digital Radiology (2004) [14];
— Supporting Guidance 1, Radiation and Your Patient: A Guide for Medical Practitioners (2001) [15];
— Supporting Guidance 2, Reference Levels in Medical Imaging: Review and Additional Advice (2001) [16];
— Publication 87, Managing Patient Dose in Computed Tomography (2000) [17];
— Publication 86, Prevention of Accidents to Patients Undergoing Radiation Therapy (2000) [18];
— Publication 85, Avoidance of Radiation Injuries from Medical Interventional Procedures (2000) [19];
— Publication 84, Pregnancy and Medical Radiation (2000) [20].

Committee 3 (Protection in Medicine) of the ICRP is currently working on documents on:

— Radiation dose to patients from radiopharmaceuticals (update);
— Practical radiological protection recommendations on mitigating secondary cancer risks in modern radiation oncology;
— Radiological protection in ion beam radiotherapy;
— Radiological protection in cone beam computed tomography;
— Occupational radiological protection in brachytherapy;
— Framework for justification in medical uses of ionizing radiation;

— Occupational protection issues in interventional procedures (fluoroscopy guided);
— Radiological protection in therapy with radiopharmaceuticals;
— Diagnostic reference levels for diagnostic and interventional imaging;
— Contribution to the new report on effective dose (in the application in medicine) in cooperation with ICRP Committees 2 and 4.

2.2. Interaction and cooperation of the ICRP with other international organizations and scientific societies

The ICRP and particularly Committee 3 are trying to interact with other international organizations and scientific societies (diagnostic radiology, radiotherapy, nuclear medicine, medical physics, radiographers, etc.) related to the use of radiation in medicine. The presence of the ICRP in medical scientific congresses provides the opportunity to discuss and receive suggestions about topics that may need appropriate radiological protection recommendations.

When the ICRP and its committees hold annual meetings in different countries, it also organizes scientific symposia or seminars. External experts are invited to discuss the ICRP programme of work and are given the opportunity of interacting with local experts, authorities and scientific societies.

In addition, external experts are invited to participate as members of the task groups or working parties that produce the documents on radiological protection recommendations. This is also a means of preselecting candidates who may become members of the ICRP in future years. The Main Commission posts draft documents on the ICRP web site for public consultation 3 to 4 months before approval: this represents another open opportunity for the ICRP to interact with the scientific community and stakeholders. In recent years, this open review has allowed the ICRP to improve its publications and to take into account diverse points of view.

3. TOWARDS THE NEXT DECADE: WHAT IS STILL ABSENT FROM RADIATION PROTECTION IN MEDICINE?

Which topics does the ICRP consider to be of interest for radiological protection in medicine for the next decade? Technology in medicine is evolving very rapidly and the use of ionizing radiation is likely to increase in the coming years. The ICRP will address the requirement for radiological protection advice in medicine by producing recommendations and cooperating with other international organizations and scientific societies. In the coming years, specific guidance on radiological protection could be provided in the following topics:

— Optimization of radiological protection for new technology in medicine: The very rapid introduction of new technology using ionizing radiation in medicine with not enough time to train operators on aspects of radiation safety is a challenge. Not only medical and paramedical personnel but also industry engineers and maintenance professionals are to be considered in this issue.
— Management of patient and staff protection as a global approach: Good protection of the patient can sometimes involve an increase in the staff exposure.
— Occupational lens doses and extremity doses: All the procedures to reduce occupational lens doses (for interventionists) and extremity doses (for nuclear medicine operators) and to improve the methodology to measure or to estimate these doses should be implemented.
— Radiation risk communication to patients: Communicating radiological risks along with medical risks is of benefit to patients.
— Justification of some medical procedures: The impact of external factors, such as existing infrastructure of equipment, dedicated protocols and professionals properly trained for specific procedures (e.g. CT in paediatrics), should be considered.
— Tissue reactions: During some complex interventional procedures, organ doses can be higher than the new thresholds proposed by the ICRP for tissue reactions. Strategies for optimization in reducing organ doses in the cardiovascular and cerebrovascular systems need to be implemented. More attention to the lens doses in patients during some neuroradiology and CT procedures will be needed.
— Patient dose value recording and tracking in imaging, with special attention to paediatrics.
— Expanding the use of diagnostic reference levels for optimization using the full distribution of doses and using these distributions to select trigger levels for individual analysis of high doses.
— Radiation risk assessment in radiotherapy: This risk analysis is important to avoid incidents and accidents. Increasing complexity involves increasing opportunity for major errors.
— Requirement for sufficient trained staff (medical, and paramedical including medical physicists, radiographers and nurses) for the proper management of radiological protection in medical installations and the need for cooperation between these professional groups.

4. CONCLUSIONS

The ICRP is ready to cooperate with other international organizations and with medical societies involved in the use of ionizing radiation to address the topics in which radiological protection advice is needed in the next decade. The ICRP is determined to improve the standards and the system of radiological protection in medicine using scientifically based evidence and to encourage the use of good science underlying radiation protection in medicine.

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Board of Governors General Conference, 31 July 2012, International Action Plan for the Radiological Protection of Patients, http://www.iaea.org/About/Policy/GC/GC46/Documents/gc46-12.pdf

[2] Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy (Proc. Int. Conf. Malaga, 2001), IAEA, Vienna (2001).

[3] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Paediatric Diagnostic and Interventional Radiology, Publication 121, Elsevier (2013).

[4] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Cardiology, Publication 120, Elsevier (2013).

[5] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Fluoroscopically Guided Procedures Performed outside the Imaging Department, Publication 117, Elsevier (2010).

[6] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Education and Training in Radiological Protection for Diagnostic and Interventional Procedures, Publication 113, Elsevier (2009).

[7] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, Publication 112, Elsevier (2009).

[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Dose to Patients from Radiopharmaceuticals: Addendum 3 to ICRP Publication 53, Publication 106, Elsevier (2008).

[9] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Medicine, Publication 105, Elsevier (2007).

[10] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Managing Patient Dose in Multi-detector Computed Tomography, Publication 102, Elsevier (2007).

[11] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Safety Aspects of Brachytherapy for Prostate Cancer Using Permanently Implanted Sources, Publication 98, Elsevier (2005).
[12] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of High-dose-rate Brachytherapy Accidents, Publication 97, Elsevier (2005).
[13] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Release of Patients after Therapy with Unsealed Radionuclides, Publication 94, Elsevier (2004).
[14] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Managing Patient Dose in Digital Radiology, Publication 93, Elsevier (2004).
[15] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Supporting Guidance 1: Radiation and Your Patient: A Guide for Medical Practitioners, Pergamon Press, Oxford and New York (2001).
[16] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Supporting Guidance 2: Reference Levels in Medical Imaging: Review and Additional Advice, Pergamon Press, Oxford and New York (2001).
[17] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Managing Patient Dose in Computed Tomography, Publication 87, Pergamon Press, Oxford and New York (2000).
[18] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of Accidents to Patients Undergoing Radiation Therapy, Publication 86, Pergamon Press, Oxford and New York (2000).
[19] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Avoidance of Radiation Injuries from Medical Interventional Procedures, Publication 85, Pergamon Press, Oxford and New York (2000).
[20] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Pregnancy and Medical Radiation, Publication 84, Pergamon Press, Oxford and New York (2000).

RADIOLOGICAL PROTECTION IN MEDICINE

Veni, vidi, vici

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1. AIM

The purpose of this paper is to recapitulate some lessons learned from past experiences in radiological protection in medicine, in the expectation that they are considered when mobilizing for future effective work in this area.

Since X rays and radium started to be used in medicine, there has been a gigantic development in diagnosis and therapy practices making use of ionizing radiation. There have also been growing international efforts to improve radiological protection in medicine. This successful history has been exhaustively recorded in B. Lindell's opus magnum on the subject [1]. At present, the epilogue of this thriving saga is the International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade [2], which was held in Bonn, Germany, 3–7 December 2012, organized by the 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 (hereinafter referred to as the 'Bonn conference'). Thus, the Bonn conference completed a cycle of unprecedented international cooperation for protecting patients and medical staff against the detrimental effects of radiation exposure. The time seems to be ripe for this paper summing up the achievements and the remaining challenges of radiological protection in medicine, the main purpose being to pursue a future strategy for dealing with these issues.

The paper is organized under the old Roman motto *veni, vidi, vici* in three parts, namely: *veni* — coming from a successful history; *vidi* — examining new challenges; and *vici* — successfully moving towards an international regime for radiation safety in medicine.

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2. VENI: COMING FROM A SUCCESSFUL HISTORY

Long ago, in 1928, in Stockholm, the Second International Congress of Radiology founded the International X-Ray and Radium Protection Commission, the precursor of what is now the International Commission on Radiological Protection (ICRP), triggering the genesis of international radiation protection. An international radiological protection regime would eventually evolve under the aegis of several prestigious international organizations, becoming a network of science, paradigm and regulatory standards. In 1955, the United Nations General Assembly created the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), with the scientific mandate of estimating global levels and effects of radiation. One year thereafter, the IAEA was born with the statutory mandate of establishing standards of safety for protection of health (including such standards for labour conditions), and also providing for the application of these standards. Since the 1960s, the IAEA has been exercising this important function in co-sponsorship with, inter alia, the WHO, the Pan American Health Organization (PAHO) and the International Labour Organization (ILO). Thus, while the ICRP mantra provided a globally accepted protection paradigm as a foundation for an international regime, UNSCEAR offered a scientific umbrella and the IAEA, co-sponsored by the relevant specialized agencies within the United Nations family, was endowed with the creation of an intergovernmental regulatory system.

What follows is a summary account of this successful history, with a focus on protection in medicine, particularly of patients.

2.1. ICRP recommendations

2.1.1. The early stages

At the beginning of the twentieth century, the knowledge of radiation and its effects was limited and the main concern was protecting the staff practising the medical use of the sole radiations being employed at that early time, namely X rays and radium emissions. Unsurprisingly, the objective of the first recommendations of the proto-ICRP [3] was rather self-interested, to protect the radiologists themselves! Those early recommendations state that:

> "the dangers of over-exposure to X rays and radium can be avoided by the provision of adequate protection and suitable working conditions. It is the duty of those in charge of X ray and radium departments to ensure such conditions for their personnel" (para. 1 of Ref. [3]).

The only reference to patients shows concern with the sufferers becoming a radiation source, exposing the staff, rather than with their protection. That early recommendation states that "screening stands and couches should provide adequate arrangements for protecting the operator against scattered radiation from the patient" (para. 18 of Ref. [3]) and that "nurses and attendants should not remain in the same room as patients undergoing radium treatment" (para. 36 of Ref. [3]). The early advice included some curious counsel on ergonomics, such as that X ray departments should not be situated below groundfloor level and that all rooms (including dark rooms) should be provided with windows affording good natural lighting and ready facilities for admitting sunshine and fresh air whenever possible, and with adequate exhaust ventilation capable of renewing the air of the room not less than 10 times an hour, and with air inlets and outlets arranged to afford cross-wise ventilation of the room, and, surprisingly, they should preferably be decorated in light colours (paras 3–6 of Ref. [3]).

It would take some years for the ICRP to consider the protection of patients — who for many years would de facto be excluded from international radiation safety standards. It would take even more years for the ICRP to address the complicated interrelation between the protection of patients and the protection of medical staff. Over the years, the ICRP recommendations continued to focus on occupationally exposed personnel first and, by the middle of last century, on members of the public, being somehow ambivalent with regard to the protection of patients.

2.1.2. Excluding patients

In its first recommendations of the current series, ICRP Publication 1 [4], there is only one reference to the protection of patients. The Commission recognizes "that in medical procedures, exposure of the patient to primary radiation is generally limited to parts of the body, but the whole body is exposed to some extent to stray radiation." It furthermore recognizes that the contributions to the doses in various organs and the part played in the overall effects on the individual were practically impossible to evaluate at that time (para. 35 of Ref. [4]). The ICRP, however, especially recognized "the importance of the gonad doses resulting from medical exposure and the attendant genetic hazard to the population". Accordingly, it recommended that "the medical profession exercise great care in the use of ionizing radiation in order that the gonad dose received by individuals before the end of their reproductive periods be kept at the minimum value consistent with medical requirements". Notwithstanding these concerns, the ICRP underlined that individual doses resulting from medical exposure were excluded from the recommended protection system!

In its 1965 recommendations, in ICRP Publication 9 [5], the ICRP made clear again that they were concerned "entirely with exposures other than those received by the patient in the course of medical procedures", namely other than "all types of medical exposure of patients administered by radiologists, general practitioners, dentists, obstetricians, osteopaths, chiropractors, etc." (para. 32 of Ref. [5]). Moreover, concerning the exposure of patients for medical reasons, the Commission believed that "it would not be possible to make specific recommendations on dose limitation that would be appropriate for all examinations on individual patients". The Commission also emphasized that the term 'medical exposure' referred "to the exposure of patients in the course of medical procedures and not to the exposure of the personnel conducting or incidentally associated with such procedures" (para. 53 of Ref. [5]). On the other hand, already at that time, the Commission started to show growing concern for the exposure of patients. It emphasized "the need for limiting the doses from radiological procedures to the minimum amount consistent with the medical benefit to the patient" (para. 33 of Ref. [5]), and also recommended that "all radiological examinations of the lower abdomen and pelvis of women of reproductive capacity that are not of importance in connection with the immediate illness of the patient, be limited in time" to the period when pregnancy is improbable (para. 76 of Ref. [5]). The Commission noted that medical exposures constituted already at that time and for the foreseeable future "the main source of population exposure". Since it was considered likely that in most countries the number of persons medically exposed would increase, owing to the development of new procedures as well as to improved conditions for medical care, the Commission judged "increasingly important that these technological improvements should be matched by appropriate consideration of the radiation protection of the patient" (para. 78 of Ref. [5]). The Commission also re-emphasized that "careful attention to techniques would, in many cases, result in a considerable reduction of the dose due to medical procedures, without impairment of their value". To achieve this reduction, the Commission pointed out "the value of adequate training in radiological protection for all persons who administer radiation exposures to patients" (para. 79 of Ref. [5]).

2.1.3. Optimization of protection

ICRP Publication 9, however, also planted the seed for a major shift in the radiological protection objectives. In a single paragraph, the ICRP recommended that "as any exposure may involve some degree of risk, the Commission recommends that any unnecessary exposure be avoided, and that all doses be kept as low as is readily achievable, economic and social considerations being taken into account" (para. 52 of Ref. [5]). This was the genesis

of the fundamental concept of optimization of protection. This would follow with recommendations on the implications of its recommendations that doses be kept as low as readily achievable, in ICRP Publication 22 [6] published in 1973, and would be materialized by recommendations on the practical applications of this fundamental principle in ICRP Publication 37 [7], published in 1983.

2.1.4. Protection of patients

ICRP Publication 15 [8], published in 1970, contained the earliest recommendations from the ICRP Committee dealing with protection in medicine — ICRP Committee 3. These recommendations provide primary general recommendations on medical uses of radiation. For diagnostics, the recommendations covered X ray diagnostic installations, fluoroscopy, radiography, photofluorography, dental radiography and diagnostic uses of radioactive substances. For therapy, it covered beam therapy, conventional X ray therapy, superficial X ray therapy, 'megavolt' X ray and particle beam therapy, sealed source beam therapy, non-collimated sealed source therapy, and therapy with unsealed sources. It also generally addressed, perhaps for the first time, the issue of protection of patients.

The first ICRP recommendations specifically addressing the protection of patients were ICRP Publication 16 [9], published in 1970. The report collated information necessary "for an adequate understanding of the principles and practice of protection of the patient in the widest sense". The ICRP recognized then that, taking into account all of the available evidence, "the great and growing service to the individual and the community from X ray diagnostic methods should not be in any way impaired because of possible radiation hazards". At the same time, the ICRP cautioned that there was a need to ensure "that the advantages of diagnostic radiology are obtained with the minimum of risk to the individual and to future generations". It was recognized that the achievement of this purpose "was not within the scope of a single discipline, but requires a multidisciplinary effort by all who instigate X ray investigations, by those in any way concerned with the use of X ray diagnostic equipment and techniques, and by those responsible for the relevant educational programmes". The ICRP also acknowledged that "the many groups of people whose work is in some way associated with diagnostic radiology require appropriate education and training to varying depth and extent in the underlying physical and biological concepts of importance in patient protection". The ICRP concluded that the principles of patient protection were "an essential basis for the diagnostic applications of radiation, and their adoption should be an integral part of medical, technical and administrative practice".

2.1.5. A major shift

Unsurprisingly, after these developments, the following general ICRP recommendations, issued as ICRP Publication 26 [10] in 1977, produced a major shift in radiological protection in medicine. They re-emphasized protection against medical exposures, which were redefined as "the intentional exposure of patients for diagnostic and therapeutic purposes, and to the exposures resulting from the artificial replacement of body organs or functions (e.g. by heart pumps and cardiac pace-makers)", further indicating that it applied "to exposures administered by medical and paramedical personnel" but it did not refer "to the irradiation of the staff involved in the administration of medical exposures to patients, nor to the irradiation of one patient by another" (para. 91 of Ref. [10]). Unprecedentedly, the ICRP declared that medical exposures were generally subjected to the radiological protection system namely:

> "unnecessary exposures should be avoided; necessary exposures should be justifiable in terms of benefits that would not otherwise have been received; and the doses actually administered should be limited to the minimum amount consistent with the medical benefit to the individual patient."

However, the ICRP then considered that because "the individual receiving the exposure is himself the direct recipient of the benefit resulting from the procedure", it was not appropriate to apply dose limits to medical exposures, and that with certain medical exposures a very much higher level of risk may in fact be justified by the benefit derived than by the dose limits judged by the ICRP to be appropriate for occupational exposure or for exposure of members of the public (para. 92 of Ref. [10]). Furthermore, the ICRP considered that in the case of high medical exposures (e.g. in radiotherapy), it would be the doses from these exposures that would dominate, and the consideration of possible risks of non-stochastic effects (e.g. to the lens of the eye) would be part of the medical considerations in the treatment of the patient, rather than the task of those responsible for radiation protection in general (para. 96 of Ref. [10]). Moreover, ICRP Publication 26 dedicates a full section to examinations or treatments directly associated with illness, recommending that:

— The decision as to whether an examination involving a certain radiation dose to a patient is justified is sometimes the responsibility of the referring physician, and sometimes of the practitioner who carries out the procedure. In either case, however, it is imperative that the decision be based on a correct assessment of the indications for the examination, the

expected yield from the examination and the way in which the results are likely to influence the diagnosis and subsequent medical care of the patient. It is equally important that this assessment be made against a background of adequate knowledge of the physical properties and the biological effects of ionizing radiation.

— In therapeutic exposures, the absorbed doses to organs are, in general, very much higher and both the dangers of the exposure and the benefits of the treatment can be assessed more quantitatively. The decision can then be based on a balance between these aspects. It is also necessary to consider alternative therapeutic procedures and to compare their effectiveness and their dangers with those associated with radiological treatment.

— While it is important that the decision to proceed with examinations or treatment involving exposure to radiations should take into account the dangers of such exposures, it is equally important that these dangers should not be overestimated, since this might lead to the rejection of justified examinations or treatments.

In 1982, the ICRP issued new ad hoc recommendations for the protection of the patient in diagnostic radiology. ICRP Publication 34 [11], which superseded ICRP Publication 16, was the earliest very comprehensive publication on the subject. It intended to guide radiologists and others concerned with diagnostic radiology with regard to the factors that influence radiation doses and, hence, radiation risks from different types of X ray examination. Moreover, a few years later, the ICRP issued recommendations on the protection of the patient in radiation therapy as ICRP Publication 44 [12]. Recognizing that the protection of the patient in radiotherapy requires, uniquely, not the avoidance of radiation exposure or even the avoidance of risk of severe damage to some tissues, but rather achieving the optimal balance between the efficacy of sterilizing the malignant growth and minimizing treatment related complications by keeping radiation doses as low as reasonably achievable, the recommendations presented a broad overview useful to all involved in the proper therapeutic application of radiation.

The ICRP general recommendations, which were issued as Publication 60 [13] in 1991, reconfirmed and deepened the trends in radiological protection in medicine, namely protecting the patient and not only the staff. The new recommendations were very detailed and comprehensive and are still widely used today. The recommendations defined medical exposure as being:

> "confined to exposures incurred by individuals as part of their own medical diagnosis or treatment and to exposures (other than occupational) incurred knowingly and willingly by individuals

> helping in the support and comfort of patients undergoing diagnosis or treatment. Exposure of an individual to other sources, such as stray radiation from the diagnosis or treatment of other persons, is not included in medical exposure. Nor is any occupational exposure of staff. Exposures incurred by volunteers as part of a programme of biomedical research are also dealt with in this document on the same basis as medical exposure" (para. 139 of Ref. [13]).

They address the issue of dose limits in medical exposure indicating that:

> "they are usually intended to provide a direct benefit to the exposed individual. If the practice is justified and the protection optimised, the dose in the patient will be as low as is compatible with the medical purposes. Any further application of limits might be to the patient's detriment"

and, therefore, recommending that "dose limits should not be applied to medical exposures", but introducing the concept of dose constraints (para. 182 of Ref. [13]). The ICRP also indicates that:

> "it is not appropriate to include the doses incurred by patients in the course of diagnostic examinations or therapy when considering compliance with dose limits applied to occupational or public exposures. Furthermore, each increment of dose resulting from occupational or public exposure results in an increment of detriment that is, to a large extent, unaffected by the medical doses" (para. 183 of Ref. [13]).

The recommendations also assessed, perhaps for the first time, the issue of medical exposure of pregnant women. The ICRP considered then that "exposure of the embryo in the first three weeks following conception is not likely to result in deterministic or stochastic effects in the live-born child". It further considered that:

> "a pregnant patient is likely to know, or at least suspect, that she is pregnant after one missed menstruation, so the necessary information on possible pregnancy can, and should, be obtained from the patient herself. If the most recent expected menstruation has been missed, and there is no other relevant information, the woman should be assumed to be pregnant. Diagnostic and therapeutic procedures causing exposures of the abdomen of women likely to be pregnant

> should be avoided unless there are strong clinical indications" (para. 184 of Ref. [13]).

The question of dosimetry in medical exposure is also addressed indicating that:

> "the assessment of doses in medical exposure, i.e. doses to patients, is of critical importance in radiotherapy and frequent measurements on equipment should form an important part of the quality control programme. In diagnostic radiology, there is rarely a need for routine assessment of doses, but periodic measurements should be made to check the performance of equipment and to encourage the optimisation of protection. In nuclear medicine, the administered activity should always be recorded and the doses, based on standard models, will then be readily available" (para. 272 of Ref. [13]).

In sum, the ICRP's 1990 recommendations addressed comprehensively the control of medical exposure indicating that:

> "in the justification of a practice leading to medical exposures, the practice should be defined in broad terms. However, each procedure, either diagnostic or therapeutic, is subject to a separate decision, so that there is an opportunity to apply a further, case-by-case, justification for each procedure. This will not be necessary for simple diagnostic procedures based on common indications, but may be important for complex investigations and for therapy" (para. S33 of Ref. [13]).

They also recognize that:

> "there is considerable scope for dose reductions in diagnostic radiology using the techniques of optimisation of protection. Consideration should be given to the use of dose constraints, or investigation levels, selected by the appropriate professional or regulatory agency, for application in some common diagnostic procedures. They should be applied with flexibility to allow higher doses where indicated by sound clinical judgement" (para. S34 of Ref. [13]).

They also indicated that:

> "constraints should also be considered in the optimisation of protection for medical exposures when the procedures are not intended to be

> of direct value to the exposed individual, as in scientific and clinical studies involving the exposure of volunteers" (para. S35 of Ref. [13]).

They recalled again that "medical exposures are usually intended to provide a direct benefit to the exposed individual. If the practice is justified and the protection optimised, the dose in the patient will be as low as is compatible with the medical purposes" (para. S36 of Ref. [13]). The ICRP's 1990 recommendations, therefore, recommended that:

> "dose limits should not be applied to medical exposures. Further, it is not appropriate to include the doses incurred by patients in the course of diagnostic examinations or therapy when considering compliance with dose limits applied to occupational or public exposures" (para. S36 of Ref. [13]),

emphasizing that:

> "diagnostic and therapeutic procedures causing exposures of the abdomen of women likely to be pregnant should be avoided unless there are strong clinical indications. Information on possible pregnancy should be obtained from the patient herself. If the most recent expected menstruation has been missed, and there is no other relevant information, the woman should be assumed to be pregnant" (para. S37 of Ref. [13]).

A few years after issuing ICRP Publication 60, the ICRP, in 1996, issued recommendations for radiological protection and safety in medicine, as ICRP Publication 73 [14]. The purpose of ICRP Publication 73 was to clarify how the recommended system of radiological protection described in the 1990 recommendations should be applied in medicine. It principally addressed physicians and physicists directly engaged in medical radiology, including diagnosis in medicine and dentistry, nuclear medicine and radiotherapy; those responsible for the management of institutions operating in these fields; and international regulatory and advisory bodies.

2.1.6. The current approach

The latest general recommendations of the ICRP were issued in 2007 as ICRP Publication 103 [15]. These recommendations comprehensively address the issue of medical exposure. A full chapter is dedicated to medical exposure of patients, comforters and carers, and volunteers in biomedical research, covering

justification for medical procedures, optimization of protection in medical exposures, effective dose in medical exposure, exposure of patients who are pregnant, accident prevention in external beam therapy and brachytherapy, protection of carers and comforters of patients treated with radionuclides, and volunteers for biomedical research. ICRP Publication 103 was supplemented with ICRP Publication 105 on radiological protection in medicine [16], which would definitively underpin the ICRP recommendations with regard to the medical exposure of patients, including their comforters and carers, and volunteers in biomedical research. It addresses the proper application of the fundamental principles of justification, optimization of protection, and application of dose limits to these individuals. The basic ICRP paradigm was reconfirmed, namely that with regard to medical exposure of patients, it is not appropriate to apply dose limits or dose constraints, because such limits would often do more harm than good, recognizing that, often, there are concurrent chronic, severe or even life threatening medical conditions that are more critical than the radiation exposure. The emphasis should then be on justification of the medical procedures and on the optimization of radiological protection. In diagnostic and interventional procedures, justification of procedures (for a defined purpose and for an individual patient), and management of the patient dose commensurate with the medical task, are the appropriate mechanisms to avoid unnecessary or unproductive radiation exposure. Equipment features that facilitate patient dose management, and diagnostic reference levels derived at the appropriate national, regional or local level, are likely to be the most effective approaches. In radiation therapy, the avoidance of accidents is a predominant issue. With regard to comforters and carers, and volunteers in biomedical research, dose constraints are appropriate.

These latest general ICRP recommendations for the protection in medicine provide the basic elements for mobilizing for future effective work in this area, as follows: justification of a radiological practice in medicine, a defined radiological procedure, and a procedure for an individual patient; optimization of the protection of patients; use of dose constraints; management of medical exposures; diagnostic reference levels; individual dose limits; preventing accidents in radiation therapy; managing incidents and accidents involving radioactive materials; education and training; institutional arrangements; practical methods of protection other than for patients; occupational exposure in medicine; public exposure in medicine; exposure of volunteers in biomedical research; and exposure of comforters and carers of patients.

Before and after ICRP Publication 103, the ICRP issued many practice focused recommendations (which will be discussed hereinafter), presenting new challenges and covering, inter alia, prevention of high dose rate brachytherapy accidents, radiation safety aspects of brachytherapy for prostate cancer using

permanently implanted sources, managing patient dose in multidetector computed tomography (MDCT), preventing accidental exposures from new external beam radiation therapy technologies, education and training in radiological protection for diagnostic and interventional procedures, and radiological protection in fluoroscopically guided procedures outside the imaging department.

2.2. UNSCEAR estimates

2.2.1. From nuclear testing to medicine

On 3 December 1955, the United Nations General Assembly adopted Resolution 913 (X), the founding resolution of UNSCEAR. The Assembly requested UNSCEAR, inter alia, to receive and assemble in an appropriate and useful form the following radiological information furnished by Member States of the United Nations or members of the specialized agencies: (i) reports on observed levels of ionizing radiation and radioactivity in the environment; and (ii) reports on scientific observations and experiments relevant to the effects of ionizing radiation upon humans and their environment already under way or later undertaken by national scientific bodies or by authorities of national governments. As can be seen, the Assembly's intentions were far from medical exposures; its objective was to estimate the environmental levels and effects of radiation, which at that time were due to nuclear weapons testing.

However, over the years that followed, UNSCEAR evolved into a scientific body dealing with all types of radiation exposure, including those from medical practice. It became the official international authority on the levels and effects of ionizing radiation, used for peaceful as well as military purposes and derived from natural as well as human-made sources. UNSCEAR promptly recognized that medical diagnostic and therapeutic exposures were a major component of artificial radiation exposure globally, a fact that remains true today. Since then, UNSCEAR has systematically reviewed and evaluated global and regional levels and trends of medical exposure, together with its estimates of exposure of the public and workers. These reviews have prompted significant worldwide reductions in unnecessary radiation exposure, and continue to influence the programmes of international bodies such as the ICRP, the IAEA and the WHO. UNSCEAR has also regularly evaluated the evidence for radiation induced health effects from studies of the survivors of the atomic bombings in Japan in 1945 and other exposed groups. It has also reviewed advances in scientific understanding of the mechanisms by which radiation induced health effects can occur. These assessments have provided the scientific foundation used by the ICRP in developing its recommendations on radiation protection and

by the relevant agencies in the United Nations system in formulating international protection standards.

2.2.2. Medical exposures

Following its nuclear testing related beginnings, the UNSCEAR reports [17–23] put special interest in medical exposures, estimating the annual frequency of medical examinations and procedures involving the use of radiation, as well as their associated doses. Reviews were performed in diagnostic radiology, in the use of nuclear medicine and in radiation therapy. Data were analysed to deduce temporal trends, to evaluate the collective population dose due to medical exposure and to identify procedures for which the doses are major contributors to the total collective dose.

In earlier UNSCEAR reports on doses from medical irradiation [22, 23], the annual frequency of medical exposures was estimated on the basis of a very limited series of surveys, mainly but not exclusively performed in developed countries. Initially, information was obtained under broad headings such as diagnostic radiography or diagnostic fluoroscopy [23].

2.2.3. Current levels

In one of its latest reports to the United Nations General Assembly [24], UNSCEAR addressed the exposure of patients in diagnostic radiology, nuclear medicine and radiotherapy, conducting a survey of medical exposures for the period 1997–2007, but cautioning that there are some limitations on the survey data, with the majority of the responses being received from relatively more developed countries. Thus, UNSCEAR estimated that the total number of diagnostic medical examinations (both medical and dental) have risen from 2.4 billion in the period 1991–1996 to 3.6 billion — an increase of approximately 50%. As in previous reports, the data were grouped according to a country's health care level (I, II, III or IV — I being the highest, IV the lowest — based on the number of physicians per population). The annual frequency of medical X ray examinations by health care level were over 65 times more frequent in level I countries (which account for 24% of the global population) than in level III and IV countries (which account for 27% of the global population). The wide imbalance in health care provision was also reflected in the availability of X ray equipment and physicians. As part of that trend, new, high dose X ray technology (particularly CT scanning) was causing extremely rapid growth in the annual number of procedures performed in many countries and, by extension, a marked increase in collective doses. For several countries, this has resulted, for the first time in history, in a situation in which the annual collective and per

caput doses of ionizing radiation due to diagnostic radiology have exceeded those from the previously largest source (natural background radiation). Thus, since the last survey analysed by UNSCEAR, the total collective effective dose from medical diagnostic examinations was estimated to have increased by 1.7 million man Sv, rising from about 2.3 million to about 4 million man Sv, an increase of approximately 70%.

UNSCEAR also estimated that 32.7 million diagnostic nuclear medicine examinations were performed at that time annually worldwide, which represents an increase of 0.2 million examinations per year or under 1% since the 1991–1996 survey. Over that same period, the collective effective dose due to nuclear medicine examinations rose from 150 000 to 202 000 man Sv, representing an increase of 52 000 man Sv or about 35%. People living in health care level I countries account for about 90% of all nuclear medicine examinations.

UNSCEAR also evaluated annual data on the most common types of radiotherapy treatment during the period 1997–2007. The level I countries accounted for about 70% of all radiotherapy treatments. An estimated 5.1 million courses of radiotherapy treatment were administered annually in that period, up from an estimated 4.3 million in 1988. About 4.7 million of those treatments involved teletherapy and 0.4 million brachytherapy.

In sum, UNSCEAR concluded that medical exposure of patients remains by far the largest artificial source of exposure to ionizing radiation and continues to grow at a remarkable rate. Medical exposures account for 98% of the contribution from all artificial sources and were at that time already the second largest contributor to the population dose worldwide, representing approximately 20% of the total. About 3.6 billion medical radiation procedures were performed annually during the survey period, compared with 2.5 billion in the previous survey period; that is an increase of 1.1 billion procedures, or over 40%, in the last decade of the century. The total annual collective effective dose due to medical exposures (excluding radiotherapy) stood at approximately 4.2 million man Sv, an increase of 1.7 million man Sv (or just over 65%) over the previous period. Almost 75% of the worldwide collective effective dose due to medical exposures is accounted for by health care level I countries.

UNSCEAR also addressed the annual collective dose to workers involved in the medical use of radiation, which was estimated to be about 3540 man Sv, with the average annual effective dose being about 0.5 mSv. The average annual dose to monitored workers involved in medical uses of radiation increased by a factor of 1.7 from 1994 to 2002. However, UNSCEAR warned that workers involved in interventional procedures have high effective doses; and extremity doses can reach the regulatory limits. As the number of interventional procedures has increased significantly, the number of workers involved in the medical use

of radiation increased by a factor of seven in the period from 1975 to 2002, and the estimated number was about 7.4 million for 2002.

Explicit comparison of doses resulting from medical exposures with those from other sources is inappropriate, inter alia because patients receive a direct benefit from their exposure and they may be sick or older than the general population. Moreover, increasing medical exposure is likely associated with increased health benefits to the population. Notwithstanding these caveats, it is clear from the UNSCEAR data that one of the most striking changes over the past decades has been the sharp increase in medical exposures, owing to the rapid expansion in the use of CT scanning and other modern medical techniques. In several countries, this has meant that medical exposure has displaced exposure due to natural sources of radiation as the largest overall component.

2.3. International intergovernmental standards

2.3.1. The IAEA mandate

In 1955, the international community of countries established the IAEA upon the terms and conditions set forth in the IAEA Statute. The IAEA is statutorily authorized to establish or adopt (in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned) standards of safety for protection of health and minimization of danger to life and property (including such standards for labour conditions), and to provide for the application of these standards, at the request of a State. Thus, the regulation of radiological protection became internationalized through intergovernmental organizations.

2.3.2. The early standards

The Board of Governors of the IAEA first approved radiation protection and safety measures in March 1960 [25], when it was stated that "The Agency's basic safety standards...will be based, to the extent possible, on the recommendations of the International Commission on Radiological Protection (ICRP)". The Board first approved Basic Safety Standards (BSS) in June 1962; they were published by the IAEA as Safety Series No. 9 [26]. A revised version was published in 1967 [27]. A third revision was published by the IAEA as the 1982 Edition of Safety Series No. 9 [28]. In all these standards, radiological protection in medicine was confined to the occupational protection of the medical staff; the protection of patients was excluded from the standards.

2.3.3. Harmonizing intergovernmental international agencies

In 1990, an important step towards international harmonization of radiation protection took place: the creation of the Inter-Agency Committee on Radiation Safety (IACRS) [29]. Within this framework, a Joint Secretariat for the preparation of the BSS was established and an era of extraordinary international collaboration on radiation protection in medicine was initiated. The IACRS initially comprised the Commission of the European Communities (CEC), the Council for Mutual Economic Assistance (CMEA) (now defunct), the Food and Agriculture Organization of the United Nations (FAO), the IAEA, the ILO, the OECD Nuclear Energy Agency (OECD/NEA), UNSCEAR, which estimates the levels and effects of radiation exposure, and the WHO (PAHO joined subsequently). The ICRP, which makes available the basic recommendations providing the basis for radiation protection standards, the International Commission on Radiation Units and Measurements (ICRU), the International Electrotechnical Commission (IEC), the International Radiation Protection Association (IRPA) and the International Organization for Standardization (ISO) have observer status at the IACRS.

2.3.4. The first international standards including medical exposure

The IACRS sponsored the creation of an inter-agency Secretariat charged with developing new International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS). On 12 September 1994, the IAEA Board of Governors approved the BSS at its 847th meeting [30]. Similar actions of the governing bodies of intergovernmental organizations co-sponsoring the BSS, namely the FAO, ILO, OECD/NEA, PAHO and the WHO. Thus, for the first time, an international intergovernmental instrument set-up safety standards for medical exposure, including requirements on responsibilities, justification of medical exposures, optimization of protection for medical exposures, guidance levels, dose constraints, maximum activity for patients in therapy on discharge from hospital, investigation of accidental medical exposures and records. This was an unprecedented move that would change the history of radiation protection in medicine.

The introduction of international regulation for the protection of patients was really revolutionary at that time and, as all revolutions, it was criticized and questioned. Many important regulatory authorities were very vocal in their disagreement. Such controversy triggered many projects to deal with the new challenge. A forum was needed to provide an opportunity for venting dissent. That forum would be the International Conference on Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and

Radiotherapy [31], which was held in Malaga, Spain, 26–30 March 2001 (the Malaga conference).

2.4. The Malaga conference

In October 1999 — in Resolution GC(43)/RES/12 — the General Conference of the IAEA requested the Secretariat to organize an international meeting "on the radiological protection of patients for the purpose of an exchange of information and the development of recommendations, as appropriate, regarding the radiological protection of patients". Thus, the Malaga conference was organized by the IAEA and co-sponsored by the European Commission, PAHO and the WHO. The other two main organizations underpinning the international radiation protection regime, namely UNSCEAR and the ICRP, also collaborated with the conference. Perhaps the major example of international cooperation triggered at the Malaga conference was the deep involvement and collaboration from the professional international organizations representing the relevant medical practices: namely the International Organization for Medical Physics (IOMP), the International Society for Radiation Oncology (ISRO), the International Society of Radiographers and Radiological Technologists (ISRRT), the International Society of Radiology (ISR) and the World Federation of Nuclear Medicine and Biology (WFNMB), as well as by the International Radiation Protection Association (IRPA).

The main issues to be covered by the Malaga conference were:

— The radiological protection of patients in diagnostic radiology, including such specific procedures as mammography and CT, in interventional radiology, including fluoroscopy not carried out by radiologists, and in nuclear medicine;
— The use of guidance or reference levels in radiology and nuclear medicine examinations;
— The radiological protection of the embryo and foetus in pregnant patients;
— The radiological protection of paediatric patients, including those undergoing radiotherapy;
— The radiological protection of patients in biomedical research;
— The influence that standardizing medical radiological equipment has on radiological protection;
— Education and training, research and development, and the implementation of regulations.

The Malaga conference was the epilogue of an era of continuous but somehow modest evolution of radiological protection in medicine. The issuing

of new intergovernmental international standards that covered this area and the rich discussions at the conference would give rise to an international action plan, which identified new challenges, many of which still need to be addressed; this will be the subject of the next section.

3. VIDI: EXAMINING NEW CHALLENGES

3.1. The International Action Plan for the Radiological Protection of Patients

As a follow-up of the Malaga conference, in September 2001, the IAEA Board of Governors requested the Secretariat to convene a group of experts to formulate, on the basis of the Malaga conference's findings, conclusions and recommendations, an "action plan for future international work relating to the radiological protection of patients" — a request subsequently endorsed by the IAEA General Conference in Resolution GC(45)/RES/10.A. In September 2002, an International Action Plan for the Radiological Protection of Patients was approved by the IAEA Board of Governors and endorsed by the IAEA General Conference, by Resolution GC(46)/RES/9. The plan contained actions common to diagnostic and interventional radiology, nuclear medicine and radiotherapy, such as actions on education and training, information exchange, assistance and guidance, as well as specific actions for diagnostic and interventional radiology, nuclear medicine and radiotherapy. The Action Plan is being successfully implemented by the IAEA, which created a dedicated web page[2] that has become the most successful international initiative for fostering the exchange of information in this area.

3.2. Lessons and challenges

At the time of the Bonn conference, the first apparent lesson learned from the successful account presented heretofore is that the protection of patients is a constitutive whole of radiological protection and should be part of relevant national and international radiation safety standards. The reader might correctly conclude that it was not necessary to mobilize thousands of scientists to two big international gatherings in order to arrive at such an obvious conclusion, but the situation was very different in Malaga in March 2001.

[2] http://rpop.iaea.org

Thus, the situation of radiological protection in medicine is much better today than it was a decade ago. Currently, the protection of patients is taken very seriously by most countries and their regulatory authorities. It is part of the new international standards and of regional and national regulations, mainly in Europe. However, there are still legal loopholes in most countries. The universal regulation of radiation protection of patients has not yet been fully achieved and this should be a major challenge for the years to come. There are many scientific and policy challenges and also protection challenges, both generic and practice specific.

Many scientific challenges have recently been solved. These include, notably, the epistemological limitations of radiopathology and radioepidemiology that have been studied by UNSCEAR, and that, inter alia, concluded that for a relatively low radiation dose a huge difference exists between inferring risks from, and attributing effects to, radiation exposures. However, there are other challenges that still need to be addressed, including:

— Addressing the different radiosensitivity of people;
— Better estimating paediatric radiation risk;
— Dealing with concerns about the risk of internal exposure.

A number of policy challenges also need further assessment. These comprise:

— The justification of medical practices involving radiation exposure (including the practice of fee splitting);
— The techniques of optimization of radiological protection, particularly at the manufacturers' level;
— The globalization of diagnostic reference levels and dose constraints;
— The specific problems of occupational protection in medicine;
— The protection of comforters and carers;
— Emergency planning, preparedness and response;
— Institutional arrangements for regulating radiological protection in medicine.

However, there are also many practical challenges that need to be addressed. In the following, they will be discussed, grouped in arbitrary order and under the following subjective titles: quantification for radiological protection purposes, management of doses, pregnancy and paediatrics, public protection, 'accidentology' and the fundamental issue of education and training, and fostering information exchange.

The ICRP has, over the past decade, published a number of publications that provided detailed advice related to some of these challenges. Each of the

publications addresses a specific topic defined by the type of radiation source and the medical discipline in which the source is applied, and was written with the intent of communicating directly with the relevant medical practitioners and supporting medical staff. They will be referenced hereinafter.

3.3. Quantification for radiological protection purposes

3.3.1. Shortcomings in quantities

The basic quantities for radiological protection purposes were summarized by the ICRP in its compilation of the major concepts and quantities in use, which was issued as ICRP Publication 42 [32]. While ICRP Publication 103 [15] has superseded that compilation, the main structure has not changed. The quantities used in the ICRP system of radiological protection and their selected names are as follows:

— The fundamental quantity is the mean absorbed dose in specified organs and tissues in the human body, i.e. the mean energy deposited in an organ or tissue divided by its mass, with the unit joule per kilogram (J/kg) and the special name gray (Gy) for this unit.
— The absorbed dose is a basic quantity for radiotherapy but it is not appropriate for radiological protection. In order to relate this quantity better to radiation risk, in the ICRP system, the organ and tissue absorbed doses are weighted by dimensionless radiation weighting factors to take approximate account of relative differences in biological effectiveness of different types of radiation from external and internal sources. The values of radiation weighting factors are chosen by the ICRP on the basis of values of the relative biological effectiveness (RBE) of various radiation types, as determined in radiobiological experiments.
— The radiation weighted organ and tissue absorbed doses are termed equivalent (organ or tissue) doses. The equivalent dose is the mean absorbed dose from radiation in a tissue or organ weighted by the radiation weighting factors. As radiation weighting factors are dimensionless, the unit of equivalent organ or tissue dose is identical to absorbed dose, i.e. J/kg. However, for better distinction, the special name sievert (Sv) is used for the unit.
— In order to obtain a risk related dose quantity for the whole body, the quantity effective dose has been defined. The effective dose is the sum of the equivalent doses in all specified tissues and organs of the body, each weighted by tissue weighting factors representing the relative contribution of that tissue or organ to the total health detriment (on the

detriment weighted averaging, it is noted that doses to different organs cannot be added by their nature; in that sense, the use of the word 'sum' is a simplification). The calculation uses age and sex independent tissue weighting factors, based on updated risk data that are applied as rounded values to a population of both sexes and all ages and the sex averaged organ equivalent doses to the reference individuals rather than a specific individual. It is the sum of all (specified) organ and tissue equivalent doses, each weighted by a dimensionless tissue weighting factor, the values of which are chosen to represent the relative contribution of that tissue or organ to the total health detriment. (It is noted that the radiation weighting factors are for simple weights to escalate the doses due to high linear energy transfer (LET) radiation but the tissue weighting factors are for risk weighted averaging of the organ/tissue equivalent doses over the whole body.) The definition uses age and sex independent tissue weighting factors which are based on updated risk data. For a population of both sexes and all ages, these tissue weighting factors are applied as rounded values to the sex averaged organ equivalent doses of the reference person rather than to a specific individual (para. (i) of Ref. [15]). The values of each tissue weighting factor are less than one and the sum of all tissue weighting factors is one. The values are chosen by the ICRP on the basis of results of epidemiological studies of organ specific detriment factors, in particular of Japanese A-bomb survivors. As the tissue weighting factors are also dimensionless, the unit for effective dose is also J/kg. As effective dose is the (weighted) sum of equivalent organ and tissue doses, the special name sievert is also used for effective dose.

The quantities 'equivalent dose' and 'effective dose' are only defined for the low dose range. Thus, the ICRP quantification system works properly for the protection of medical staff, comforters and the public, and also for most cases of patients undergoing diagnostic examinations, all of whom are subjected to relatively low radiation doses. However, it may be inappropriate for higher doses, as they may be incurred in medicine, because a radiation weighted dose quantity applicable to the high dose range is not available. This presents a real challenge to the reporting of doses from medical practice. Should the doses from the medical procedures be high, this deficiency could cause problems of dose specification. The problem created by the lack of a formal quantity for a radiation weighted dose for high doses is not limited to medicine but is also a real challenge in accidents involving radiation, and remains unsolved.

The ICRP has created an ad hoc working group on the use of effective dose as a risk related radiation protection quantity, which should bring clarity to the issue. It will address the purpose of the ICRP protection quantities,

equivalent and effective dose, and the central role of effective dose in the control of stochastic radiation risks, the relationship between dose and risk, why effective dose, calculated using sex averaged phantoms and age and sex averaged tissue weighting factors, should be used with caution when considering dose and risk to individuals, and the differences between risk management and risk assessment.

It is noted that the ICRP dose limits for tissue effects, i.e. for exposures at higher doses, are given in the unit of effective and equivalent dose, i.e. sievert, without explicit specification of the quantity to be used. In situations after accidental high dose exposures, health consequences have to be assessed and, potentially, decisions have to be made on treatments. The fundamental quantities to be used for quantifying exposure in such situations are organ and tissue absorbed doses (given in grays). However, if not only low LET radiation is involved in high dose exposures, absorbed dose weighted with an appropriate RBE is required. Such RBE weighted absorbed doses are not defined quantities although in (clinical) practice they are being used (para. B25 of Ref. [15]). The ICRU is studying this issue of iso-effective or equi-effective dose in the context of radiation therapy.

3.3.2. Radiation dose to patients from radiopharmaceuticals

Another dosimetric issue of concern is the radiation dose to patients from internal emitters, mainly radiopharmaceuticals. ICRP Publication 53 [33] and its addenda, ICRP Publications 80 [34] and 106 [35], address this relevant issue. Initially, biokinetic models and best estimates of biokinetic data for some 120 individual radiopharmaceuticals were presented, giving estimated absorbed doses, including the range of variation to be expected in pathological states, for adults, children and the foetus. Absorbed dose estimates are needed in clinical diagnostic work for judging the risk associated with the use of specific radiopharmaceuticals, both for comparison with the possible benefit of the investigation and to help in giving adequate information to the patient. These estimates provide guidance to ethics committees having to decide upon research projects involving the use of radioactive substances in volunteers who receive no individual benefit from the study.

ICRP Publication 80 provided biokinetic models, absorbed doses and effective doses, using ICRP Publication 60 dosimetry, for ten new radiopharmaceuticals. It also provides recalculated dose data for the 19 most frequently used radiopharmaceuticals from ICRP Publication 53, using ICRP Publication 60 dosimetry, and correcting various printing errors in ICRP Publication 53. It included an integrated index to all radiopharmaceuticals treated in ICRP publications listing effective doses per unit activity administered

to adults and an addendum to ICRP Publication 72 concerning age dependent doses to members of the public from intakes of radionuclides.

Finally, ICRP Publication 106 provides biokinetic models, absorbed doses and effective doses for the following radiopharmaceuticals: ^{11}C-acetate; ^{11}C-amino acids; ^{11}C-brain receptor substances; ^{11}C-methionine; ^{18}F-amino acids; ^{18}F-FET; ^{18}F-FDG; ^{111}In-monoclonal antibodies/fragments; ^{123}I-fatty acids (BMIPP, IPPA); ^{123}I-monoclonal antibodies/fragments; ^{131}I-monoclonal antibodies/fragments; and the ^{201}Tl-ion. It also provides realistic maximum models for ^{11}C and ^{18}F substances, for which no specific models are available.

3.4. Management of doses

3.4.1. Managing patient dose in digital radiology

Digital techniques have the potential to improve the practice of radiology but they also risk the overuse of radiation. The main advantages of digital imaging, i.e. wide dynamic range, post-processing, multiple viewing options, and electronic transfer and archiving possibilities, are clear but overexposures can occur without an adverse impact on image quality. In conventional radiography, excessive exposure produces a black film. In digital systems, good images are obtained for a large range of doses. It is very easy to obtain (and delete) images with digital fluoroscopy systems, and there may be a tendency to obtain more images than necessary. In digital radiology, higher patient dose usually means improved image quality, so a tendency to use higher patient doses than necessary could occur.

The challenges of managing patient dose in digital radiology are many and have been dealt with in ICRP Publication 93 [36]. Different medical imaging tasks require different levels of image quality, and doses that have no additional benefit for the clinical purpose should be avoided. Image quality can be compromised by inappropriate levels of data compression and/or post-processing techniques. All of these new challenges should be part of the optimization process and should be included in clinical and technical protocols. Local diagnostic reference levels should be re-evaluated for digital imaging, and patient dose parameters should be displayed at the operator console. Frequent patient dose audits should occur when digital techniques are introduced. Training in the management of image quality and patient dose in digital radiology is necessary. Digital radiology will involve new regulations and invoke new challenges for practitioners. As digital images are easier to obtain and transmit, the justification criteria should be reinforced. Commissioning of digital systems should involve clinical specialists, medical physicists and radiographers to ensure that imaging capability and radiation dose management are integrated. Quality control

requires new procedures and protocols (visualization, transmission and archiving of the images).

3.4.2. Managing patient dose in CT

CT examinations can involve relatively high doses to patients. The doses can often approach or exceed levels known with certainty to increase the probability of cancer. As UNSCEAR has shown, the frequency of CT examinations is increasing worldwide and the variety of examinations is also increasing. However, in contrast to the common trend in diagnostic radiology, the rapid developments in CT have not, in general, led to a reduction of patient dose per examination. Thus, management of patient dose is crucial.

ICRP Publication 87 [37] addresses the challenging issue of managing patient dose in CT. Proper justification of examinations, use of the appropriate technical parameters during examinations, proper quality control and application of diagnostic reference levels of dose, as appropriate, would all contribute to this end. There is also scope for further technical development of the equipment used. All of these issues should be addressed for providing assistance in the successful management of patient dose.

3.4.3. Managing patient dose in multidetector CT

CT technology has changed considerably in recent years with the introduction of increasing numbers of multiple detector arrays. There are several parameters specific to MDCT scanners that increase or decrease patient dose systematically compared to older single detector computed tomography (SDCT) scanners. There are a number of distinct issues with MDCT, namely the complicated technology, the MDCT radiation doses, which are different to doses from SDCT, and factors that affect dose, radiation risks, and the responsibilities for patient dose management.

In Publication 102 [38], the ICRP deals with the difficult issue of managing patient dose in MDCT and provides elements for addressing future challenges. Users need to understand the relationship between patient dose and image quality and be aware that image quality in CT is often higher than that necessary for diagnostic confidence. Automatic exposure control (AEC) does not totally free the operator from selection of scan parameters, and awareness of individual systems is important. Scanning protocols cannot simply be transferred between scanners from different manufacturers and should be determined for each MDCT. If the image quality is appropriately specified by the user, and suited to the clinical task, there will be a reduction in patient dose for most patients. Understanding some parameters is not intuitive and the selection of image quality parameter values

in AEC systems is not straightforward. CT is increasingly being used to replace conventional X ray studies and it is important that patient dose be given careful consideration, particularly with repeated or multiple examinations. It is essential to practise dose management, in particular in CT examinations, including those of the chest, the heart for coronary calcium quantification and non-invasive coronary angiography, colonography, the urinary tract, children, pregnant patients, trauma cases and CT guided interventions.

3.5. Obstetrics and paediatrics

3.5.1. Pregnancy and medical radiation

Thousands of pregnant patients are exposed to radiation each year as a result of obstetrics procedures. Pregnant medical radiation workers may be exposed as well. Lack of knowledge is responsible for great anxiety and probably unnecessary termination of many pregnancies. Dealing with these problems continues to be a challenge primarily for physicians, but also for medical and health physicists, nurses, technologists and administrators.

ICRP Publication 84 [39] addresses challenges in the management of pregnant patients as well as pregnant workers in medical establishments where ionizing radiation is used. It is worthwhile summarizing the challenging issues found by the ICRP in relation to pregnancy and radiation. Medical professionals using radiation should be familiar with the effects of radiation on the embryo and foetus, including the risk of childhood cancer, at most diagnostic levels. Doses in excess of 100 ± 200 mGy risk nervous system abnormalities, malformations, growth retardation and fetal death. Justification of medical exposure of pregnant women poses a different benefit/risk situation to most other medical exposures, because in in utero medical exposures there are two different entities (the mother and the foetus) that must be considered. Prior to radiation exposure, female patients of childbearing age should be evaluated and an attempt made to determine who is or could be pregnant. For pregnant patients, the medical procedures should be tailored to reduce fetal dose. After medical procedures involving high doses of radiation have been performed on pregnant patients, fetal dose and potential fetal risk should be estimated. Pregnant medical radiation workers may work in a radiation environment as long as there is reasonable assurance that the fetal dose can be kept below 1 mGy during the course of pregnancy. Radiation research involving pregnant patients should be discouraged. Termination of pregnancy at fetal doses of less than 100 mGy is deemed to be unjustifiable, but at higher fetal doses, informed decisions should be made based upon individual circumstances.

3.5.2. Radiological protection in paediatric diagnostic and interventional radiology

Diagnostic radiological examinations carry a higher risk per unit of radiation dose for the development of cancer in infants and children compared to adults. The higher risk is due to the longer life expectancy of children, in which radiation effects could manifest, and the fact that developing organs and tissues are more sensitive to radiation. Risk is particularly high in infants and young children compared to older children.

With the increasing use of X ray technology, in particular CT, which has resulted in a situation in which the annual collective and per capita doses of ionizing radiation due to diagnostic radiology has exceeded that from the previously largest source (natural background radiation) in several developed countries [17], it is imperative that all radiological examinations be justified and optimized with regard to radiological protection in every patient, and especially in paediatric patients. Paediatric CT examinations, which may involve a relatively high radiation dose, are estimated by the ICRP to account for 10% of all CT examinations [40]. The absorbed doses to organs and tissues from paediatric CT (typically more than 10 mGy) can sometimes approach or exceed the epistemological limit in epidemiological studies to detect increases in the probability of tumour development.

The ICRP has just published recommendations providing guiding principles to protect paediatric patients from radiation for referring clinicians and clinical staff performing diagnostic imaging and interventional procedures involving ionizing radiation, and highlighting the specific issues which may be unique to imaging children [40]. The ICRP report provides advice on how to deal with the challenges presented by paediatric diagnostic and interventional radiology. Justification of every examination involving ionizing radiation, followed by optimization of radiological protection is particularly important in every paediatric patient, in view of the higher risk of adverse effects per unit of radiation dose compared to adults. According to the justification principle, if a diagnostic imaging examination is indicated and justified, this implies that the risk to the patient of not performing the examination is greater than the risk of potential radiation induced harm to the patient. The implementation of quality criteria and regular audits should be instituted as part of the radiological protection culture in the institution. Imaging techniques that do not employ the use of ionizing radiation should always be considered as a possible alternative. For the purpose of minimizing radiation exposure, the criteria for the image quality necessary to achieve the diagnostic task in paediatric radiology may differ from adults, and noisier images, if sufficient for radiological diagnosis, should be accepted. As most imaging equipment and vendor specified protocols

are often structured for adults, modifications of equipment and exposure parameters may be necessary. The advice of medical physicists should be sought, if possible, to assist with installation, setting imaging protocols and optimization. Exposure parameters that control radiation dose should be carefully tailored for children and every examination should be optimized with regard to radiological protection. For CT, dose reduction should be optimized by adjustment of scan parameters (mA, kVp and slice thickness) according to patient weight or age, and weight adapted CT protocols have been suggested and published. Apart from image quality, attention should also be paid to optimizing study quality. For CT, study quality may be improved by image post-processing to facilitate radiological diagnoses and interpretation. Acceptable quality also depends on the structure and organ being examined and the clinical indication for the study. Additional training in radiation protection is recommended for paediatric interventional procedures, which should be performed by experienced paediatric interventional staff due to the potential for high patient radiation dose exposure.

3.6. Public protection: Release of patients after therapy with unsealed radionuclides

A major concern for public protection related to medicine is the release of patients after therapy with unsealed radionuclides. After some therapeutic nuclear medicine procedures with unsealed radionuclides, precautions may be needed to limit doses to other people. ICRP Publication 94 [41] deals with the challenges presented by this practice.

Iodine-131 results in the largest dose to medical staff, the public, caregivers and relatives. Other radionuclides used in therapy are usually simple beta emitters (e.g. ^{32}P, ^{89}Sr and ^{90}Y) that pose much less risk. Dose limits apply to exposure of the public and medical staff from patients. The ICRP has recommended that a source related dose constraint for optimization of a few millisieverts per episode apply to relatives, visitors and caregivers at home, rather than a dose limit. Young children and infants, as well as visitors not engaged in direct care or comforting, should be treated as members of the public (i.e. be subject to the public dose limit).

The modes of exposure to other people are external exposure, internal exposure due to contamination, and environmental pathways. Dose to adults from patients is mainly due to external exposure. Contamination of infants and children with saliva from a patient could result in significant doses to the child's thyroid. It is important to avoid contamination of children and pregnant women. After radioiodine therapy, mothers must cease breast-feeding immediately. Many types of therapy with unsealed radionuclides are contraindicated in pregnant females. Women should not become pregnant for some time after radioisotope therapy.

Technetium-99m dominates discharges to the environment from excreta of nuclear medicine patients, but its short half-life limits its importance. The second largest discharges, ^{131}I, can be detected in the environment after medical uses.

Radionuclides released into modern sewage systems are likely to result in doses to sewer workers and the public that are well below public dose limits. The decision to hospitalize or release a patient should be determined on an individual basis. In addition to residual activity in the patient, the decision should take many other factors into account. Hospitalization will reduce exposure to the public and relatives, but will increase exposure to hospital staff. Hospitalization often involves a significant psychological burden as well as monetary and other costs that should be analysed and justified. Patients travelling after radioiodine therapy rarely present a hazard to other passengers if travel times are limited to a few hours.

Environmental or other radiation detection devices are able to detect patients who have had radioiodine therapy for several weeks after treatment. Personnel operating such detectors may need specific training to identify and deal with nuclear medicine patients. Records of the specifics of therapy with unsealed radionuclides should be maintained at the hospital and given to the patient along with written precautionary instructions. In the case of death of a patient who has had radiotherapy with unsealed radionuclides in the last few months, special precautions may be required.

3.7. ‘Radioaccidentology’

‘Radioaccidentology’, namely the study of radiation accidents for preventing misadministration of radiation doses and other mishaps in medical practices, is a requirement for addressing one of the major challenges of radiological protection in medicine: the avoidance of this type of misfortune for patients who wish to be cured rather than injured. Primum non nocere, the old Latin motto meaning ‘first, do no harm’ should be prevalent in the medical uses of radiation. Deriving from the maxim, one of the principal precepts of radio-diagnostic and radio-therapeutic practitioners should be non-maleficence or mischief, namely that given a medical problem, it may be better not to do something, or even to do nothing, than to risk causing more harm than good. It reminds the practitioner that other diagnostic or therapeutic procedures may be available and that they must be taken into consideration when debating the use of any procedure that carries an obvious risk of harm but a less certain chance of benefit. The challenges for preventing medical accidents are many and the ICRP has tackled some as described hereinafter.

3.7.1. Prevention of accidents to patients undergoing radiation therapy

Many accidents and mis-administrations have occurred involving patients undergoing treatment from external beam or solid brachytherapy sources. Therapy involving unsealed sources is also a cause of mishaps, but affects a different kind of professional and should be treated separately. An effective approach for preventing such situations is to study illustrative severe accidents, discuss the causes of these events and contributory factors, summarize the sometimes devastating consequences of these events, and provide recommendations on their prevention. Challenges include institutional arrangements, staff training, quality assurance programmes, adequate supervision, a clear definition of responsibilities and prompt reporting.

ICRP Publication 86 [42] contains recommendations on the prevention of this type of accidental exposure. It addresses a diverse audience of professionals directly involved in radiotherapy procedures, hospital administrators, and health and regulatory authorities. It is worthwhile summarizing the challenging issues found by the ICRP. In many of the accidental exposures that have occurred, a single cause cannot be identified. Usually, there was a combination of factors contributing to the accident, for example, deficient staff training, lack of independent checks, lack of quality control procedures and absence of overall supervision. Such combinations often point to an overall deficiency in management, allowing patient treatment in the absence of a comprehensive quality assurance programme. The use of radiation therapy in the treatment of cancer patients has grown considerably and is likely to continue to increase. Major accidents are rare, but are likely to continue to happen unless awareness is increased. Explicit requirements on measures to prevent radiotherapy accidents are needed with respect to regulations, education and quality assurance.

3.7.2. Preventing accidental exposures from new external beam radiation therapy technologies

New external beam radiation therapy technologies are becoming increasingly used. These new technologies are meant to bring substantial improvement to radiation therapy. However, this is often achieved with a considerable increase in complexity, which, in turn, brings with it opportunities for new types of human error and problems with equipment. The ICRP has prepared a report on protection under these new techniques, which has been issued as ICRP Publication 112 [43]. It is based on lessons learned from accidental exposures, which are an invaluable resource for revealing vulnerable aspects of the practice of radiotherapy, and for providing guidance for the prevention of future occurrences. These lessons

have successfully been applied to avoid catastrophic events with conventional technologies and techniques.

Dissemination of information on errors or mistakes as soon as they become available is crucial in radiation therapy with new technologies. In addition, information on circumstances that almost resulted in serious consequences (near misses) is also important, as the same type of event may occur elsewhere. Sharing information about near misses is, thus, a complementary and important aspect of prevention. Disseminating the knowledge and lessons learned from accidental exposures is crucial in preventing recurrence. This is particularly important in radiation therapy; the only application of radiation in which very high radiation doses are deliberately given to patients to achieve cure or palliation of disease.

Notwithstanding the above, disseminating lessons learned from serious incidents is necessary but not sufficient when dealing with new technologies. It is of the utmost importance to be proactive and continually strive to answer questions such as: 'What else can go wrong?', 'How likely is it?' and 'What kind of cost-effective choices do I have for prevention?' The report is a valuable resource for radiation oncologists, hospital administrators, medical physicists, technologists, dosimetrists, maintenance engineers, radiation safety specialists and regulators. While the recommendations specifically apply to new external beam therapies, the general principles for prevention are applicable to the broad range of radiotherapy practices in which mistakes could result in serious consequences for the patient and practitioner. The recommendations provide elements for mobilizing for future effective work as outlined below.

The ICRP recommendations provide advice on how to deal with the challenges presented by these new techniques. Independent verification should be performed of beam calibration in beam radiation therapy. Independent calculation should be performed of the treatment times and monitor units for external beam radiotherapy. Prospective safety assessments should be undertaken for preventing accidental exposures from new external beam radiation therapy technologies, including failure modes and effects analysis, probabilistic safety assessment, and risk matrix, in order to develop risk informed and cost effective quality assurance programmes. Moderated electronic networks and panels of experts supported by professional bodies should be established in order to expedite the sharing of knowledge in the early phase of introducing new external beam radiation therapy technologies.

3.7.3. Prevention of high dose rate brachytherapy accidents

High dose rate (HDR) brachytherapy is a rapidly growing technique that has been replacing low dose rate (LDR) procedures over the past few years in both industrialized and developing countries. The ICRP has estimated

that about 500 000 procedures (administrations of treatment) are performed by HDR units annually [44]. LDR equipment has been discontinued by many manufacturers over the past few years, leaving HDR brachytherapy as the major alternative. HDR brachytherapy techniques deliver a very high dose, of the order of 1.6–5.0 Gy/min, so mistakes can lead to under- or overdosage with the potential for clinical adverse effects. More than 500 HDR accidents (including one death) have been reported along the entire chain of procedures from source packing to delivery of dose. Human error has been the prime cause of radiation events. The ICRP concluded that many accidents could have been prevented if staff had had functional monitoring equipment and paid attention to the results. Since iridium has a relatively short half-life, the HDR sources need to be replaced approximately every four months. Over 10 000 HDR sources are transported annually, with the resultant potential for accidents; therefore, appropriate procedures and regulations must be observed.

ICRP Publication 97 [44] addresses the challenges presented by this practice and provides elements for mobilizing for future effective work. In practices of HDR brachytherapy, there is a need for regulating the prevention of loss or theft of sources and the emergency plans, and practising emergency procedures. A collaborating team of specifically trained personnel following quality assurance procedures is necessary to prevent accidents. Maintenance is an indispensable component of quality assurance; external audits of procedures reinforce good and safe practice, and identify potential causes of accidents. Quality assurance should include peer review of cases. Accidents and incidents should be reported and the lessons learned should be shared with other users to prevent similar mistakes.

3.7.4 Brachytherapy for prostate cancer using permanently implanted sources

The use of permanent radioactive implants (^{125}I or ^{103}Pd seeds) to treat selected localized prostate cancer patients has been increasing rapidly all over the world. The ICRP [45] estimated that more than 50 000 patients are treated this way every year in the world, and this number was anticipated to increase.

Although no accidents or adverse effects involving medical staff and/or members of the patient's family have been reported to date, this brachytherapy technique continues to raise a number of issues and challenges, which have been addressed in ICRP Publication 98 [45].

The available data on doses received by people approaching patients after implantation show that, in the vast majority of cases, the dose to comforters and carers remains well below 1 mSv/a. Moreover, due to the low activity of an isolated seed and its low photon energy, no incident/accident linked to seed loss has ever been recorded. However, this is a safety issue that may be of concern. When performed in the first few months after implantation, cremation of bodies

(frequent in some countries) may raise several safety issues. A review of available data shows that cremation can be allowed if 12 months have elapsed since implantation with ^{125}I (3 months for ^{103}Pd). If the patient dies before this time has elapsed, specific measures must be undertaken.

In most cases, brachytherapy does make the patient infertile. However, although the therapy related modifications of the semen reduce fertility, patients must be aware of the possibility of fathering children after such a permanent implantation, with a limited risk of genetic effects for the child. Patients with permanent implants must be aware of the possibility of triggering certain types of security radiation monitor. Considering the available experience after brachytherapy and external irradiation of prostate cancer, the risk of radio-induced secondary tumours appears to be extremely low, but further investigation might be helpful.

Only the (rare) case where the patient's partner is pregnant at the time of implantation may need specific precautions. Expulsion of sources through urine, semen or the gastrointestinal tract is rare. Specific recommendations should be given to patients to allow them to deal adequately with this event. As far as cremation of bodies is concerned, consideration should be given to the activity that remains in the patient's ashes and the airborne dose, potentially inhaled by crematorium staff or members of the public. Specific recommendations have to be given to the patient to warn the surgeon in case of subsequent pelvic or abdominal surgery. A 'wallet card' with all relevant information about the implant is useful. The wallet card including the main information about the implant (see above) may prove to be helpful in such a case of triggering certain types of security radiation monitor. The risk of radio-induced secondary tumours following brachytherapy should be further investigated.

3.7.5. Avoidance of radiation injuries from medical interventional procedures

Interventional radiology (fluoroscopically guided) techniques are being used by an increasing number of clinicians not adequately trained in radiation safety or radiobiology. Many of these interventionists are not aware of the potential for injury from these procedures or the simple methods for decreasing their incidence. Many patients are not being counselled on the radiation risks, nor followed up when radiation doses from difficult procedures may lead to injury. Some patients are suffering radiation induced skin injuries and younger patients may face an increased risk of future cancer. Interventionists are having their practice limited or suffering injury, and are exposing their staff to high doses. In some interventional procedures, skin doses to patients approach those experienced in some cancer radiotherapy fractions. Radiation induced skin injuries are occurring in patients due to the use of inappropriate

equipment and, more often, poor operational technique. Injuries to physicians and staff performing interventional procedures have also been observed. Acute radiation doses (to patients) may cause erythema, cataract, permanent epilation and delayed skin necrosis. Protracted (occupational) exposures to the eye may cause opacities in the crystalline lens.

ICRP Publication 85 [46] addresses the challenge of avoiding radiation injuries from medical interventional procedures. The absorbed dose to the patient in the area of skin that receives the maximum dose is of priority concern. Each local clinical protocol should include, for each type of interventional procedure, a statement on the cumulative skin doses and skin sites associated with the various parts of the procedure. Interventionists should be trained to use information on skin dose and on practical techniques to control dose. Maximum cumulative absorbed doses should be recorded in the patient record, and there should be a patient follow-up procedure for such cases. Patients should be counselled if there is a significant risk of radiation induced injury, and the patient's personal physician should be informed of the possibility of radiation effects. Training in radiological protection for patients and staff should be an integral part of the education of those using interventional techniques. All interventionists should audit and review the outcomes of their procedures for radiation injury. Risks and benefits, including radiation risks, should be taken into account when new interventional techniques are introduced.

3.7.6. Interrelation between patient and staff radiological protection in cardiology

Cardiac nuclear medicine, cardiac CT, interventional cardiology procedures and electrophysiology procedures are increasing in number and account for an important share of the radiation exposure of patients and medical staff. Complex percutaneous coronary interventions and cardiac electrophysiology procedures are associated with high radiation doses. These procedures can result in patient skin doses high enough to cause radiation injury and an increased risk of cancer. Treatment of congenital heart disease in children is of particular concern. Additionally, staff in cardiac catheterization laboratories may receive high radiation doses if radiological protection tools are not used properly.

The ICRP has provided recommendations for radiological protection during fluoroscopically guided interventions in ICRP Publication 85, for radiological protection in CT in ICRP Publications 87 and 102, and for training in radiological protection in ICRP Publication 113 [37, 38, 46, 47]. Recently, the ICRP has published recommendations addressing both patient and staff radiological protection in cardiology [48], which identify a number of challenges. The new report is focused specifically on cardiology, and brings together information

relevant to cardiology from the ICRP's publications. There is emphasis on those imaging procedures and interventions specific to cardiology. The material and recommendations in this paper have been updated to reflect the most recent recommendations of the ICRP.

The new recommendations provide guidance to assist the cardiologist with justification and optimization of cardiac CT studies, cardiac nuclear medicine studies and fluoroscopically guided cardiac interventions. It includes discussions of the biological effects of radiation, principles of radiological protection, protection of staff during fluoroscopically guided interventions, radiological protection training and establishment of a quality assurance programme for cardiac imaging and intervention. They also provide advice on how to deal with the challenges presented by patient and staff radiological protection in cardiology. As tissue injury, principally skin injury, is a risk for fluoroscopically guided interventions, particular attention is devoted to clinical examples of radiation related skin injuries from cardiac interventions, methods to reduce patient radiation dose, training recommendations, and quality assurance programmes for interventional fluoroscopy. Individuals who request, perform or interpret cardiology imaging procedures should be aware of the radiation risks of the procedure. Appropriate use criteria and guidelines for justification should be used in clinical practice. As with all other medical exposures, nuclear cardiology examinations, cardiac CT examinations, interventional cardiology procedures and electrophysiology procedures should be optimized and dose reduction techniques should be used whenever applicable. The informed consent process should include information on radiation risk if the risk of radiation injury is thought to be significant. Radiation dose data should be recorded in the patient's medical record after the procedure; patient dose reports should be archived for quality assurance purposes. When the patient's radiation dose from an interventional procedure exceeds the institution's trigger level, clinical follow-up should be performed for early detection and management of skin injuries. Individuals who perform cardiology procedures where there is a risk of tissue reactions should be able to recognize these skin injuries, and those who perform interventional cardiology or electrophysiology procedures should be familiar with methods to reduce radiation dose to patients and staff. Nurses, radiographers/technologists and other health care professionals who assist during imaging procedures (fluoroscopy, CT and scintigraphy) should be familiar with radiation risks and radiological protection principles, in order to minimize their own exposure and that of others. When there is a risk of occupational radiation exposure, staff should use appropriate personal protective shielding. In addition to the training recommended for all physicians who use ionizing radiation, interventional cardiologists and electrophysiologists should receive a second, higher level of radiological protection training. Training programmes

in radiological protection should include both initial training for all incoming staff and regular updating and retraining. A cardiologist should have management responsibility for the quality assurance programme aspects of radiological protection for cardiology procedures, and should be assisted by a medical physicist. Quality assurance programmes in cardiology should include patient dose audits for fluoroscopy, CT and scintigraphy, and ensure the regular use of personal dosimeters and should include a review of all abnormal dose values.

3.7.7. Radiological protection in fluoroscopically guided procedures performed outside the imaging department

A serious problem of our times is that an increasing number of medical specialists are using fluoroscopy outside imaging departments. It should be noted that there has been general neglect of radiological protection coverage of this practice. Lack of radiological protection training of those working with fluoroscopy outside imaging departments can increase the radiation risk to workers and patients. Procedures such as endovascular aneurysm repair, renal angioplasty, iliac angioplasty, ureteric stent placement, therapeutic endoscopic retrograde cholangiopancreatography, and bile duct stenting and drainage have the potential to impart high skin doses, thus making fluoroscopy use outside imaging departments a potential source for serious tissue reactions and injuries.

ICRP Publication 117 [49] addresses radiological protection in fluoroscopically guided procedures outside the imaging department, providing advice on how to deal with the challenges presented by these ad hoc procedures. As patient dose monitoring is essential whenever fluoroscopy is used, particularly outside the imaging department, manufacturers should develop systems to indicate patient dose indices with the possibility of producing patient dose reports that can be transferred to the hospital network, and shielding screens that can be effectively used for the protection of workers using fluoroscopy machines in operating theatres without hindering the clinical task. Specific aspects are covered separately, including those for vascular surgery, urology, orthopaedic surgery, obstetrics and gynaecology, gastroenterology and the hepato-biliary system, anaesthetics and pain management. Although sentinel lymph node biopsy involves use of radioisotopic methods rather than fluoroscopy, this procedure performed in operation theatres is covered as well because the ICRP is unlikely to have another publication on this topic.

Information on the level of radiation doses to patients and staff, and dose management is presented against each specialty. Issues connected with pregnant patients and pregnant staff are also covered. Although the ICRP issued several recommendations on education and training, specific needs for the target groups in terms of orientation of training, competency of those who conduct

training and assess specialists, and guidelines on curriculum are provided. It is emphasized that patient dose monitoring is essential whenever fluoroscopy is used. Recommendations for manufacturers to develop systems to indicate patient dose indices with the possibility to produce patient dose reports that can be transferred to the hospital network are provided, as are shielding screens that can be effectively used for protection of staff using fluoroscopy machines in operating theatres without hindering the clinical task.

Training for health care professionals in radiation protection should be related to their specific jobs and roles. The physicians and other health professionals involved in procedures that irradiate patients should always be trained in the principles of radiation protection, including the basic principles of physics and biology. The final responsibility for radiation exposure lies with the physician providing the justification for the exposure being carried out, who should, therefore, be aware of the risks and benefits of the procedures involved. Education and training appropriate to the role of each category of physician should be given at medical schools during residency and in focused specific courses. There should be an evaluation of the training and appropriate recognition that the individual has successfully completed the training. In addition, there should be corresponding radiation protection training requirements for other clinical personnel that participate in the conduct of procedures utilizing ionizing radiation, or in the care of patients undergoing diagnosis or treatment with ionizing radiation. Scientific and professional societies should contribute to the development of the syllabuses, and to the promotion and support of the education and training. Scientific congresses should include refresher courses on radiation protection, attendance at which could be a requirement for continuing professional development for professionals using ionizing radiation. Professionals involved more directly in the use of ionizing radiation should receive education and training in radiation protection at the start of their career, and the education process should continue throughout their professional life as the collective knowledge of the subject develops. It should include specific training on related radiation protection aspects as new equipment or techniques are introduced into a centre.

3.8. Education and training

3.8.1. A major test

Adequate education and training of medical staff and practitioners is considered paramount and the major route to ensuring appropriate radiological protection in medicine. The ICRP has made basic recommendations for such education and training in ICRP Publications 103 105 and 113 [15, 16, 47].

These reports provide guidance regarding the necessary radiological protection education and training for use by: cognizant regulators, health authorities, medical institutions, and professional bodies with responsibility for radiological protection in medicine; the industry that produces and markets the equipment used in these procedures; and universities and other academic institutions responsible for the education of professionals involved in the use of ionizing radiation in health care. The ICRP provides advice on how to deal with the challenges presented by education and training. In pursuit of medical, dental, radiography and other health care degrees, education and training should be part of the curriculum and for specialists, such as radiologists, nuclear medicine specialists and medical physicists, as part of the curriculum of postgraduate degrees.

The term 'education' usually refers to imparting knowledge and understanding on the topics of radiation health effects, radiation quantities and units, principles of radiological protection, radiological protection legislation, and the factors in practice that affect patient and staff doses. The term 'training' refers to providing instruction with regard to radiological protection for the justified application of the specific ionizing radiation modalities (e.g. CT, fluoroscopy) that a medical practitioner or other health care or support professional will utilize in that individual's role during medical practice. Education and training are officially recognized with accreditation and certification.

3.8.2. Accreditation and certification

Organizations should be established to provide 'accreditation' that officially recognizes education and training on the radiological protection aspects of the use of diagnostic or interventional radiation procedures in medicine. Such organizations have to be approved by an authorizing or regulatory body, and required to meet standards that have been set by that body.

A system of 'certification' shall be established for officially stating that an individual medical or clinical professional has successfully completed the education or training provided by an accredited organization for the diagnostic or interventional procedures to be practised by the individual, demonstrating competence in the subject matter in a manner required by the accrediting body.

3.8.3. Specific education and training for diagnostic and interventional procedures

The more detailed recommendations issued in ICRP Publication 113 [47] expand considerably on the basic recommendations with regard to various categories of medical practitioners and other health care professionals who perform or provide support for diagnostic and interventional procedures and

nuclear medicine therapy. As the number of diagnostic and interventional medical procedures using ionizing radiations is rising steadily, and procedures resulting in higher patient and staff doses are being performed more frequently, the need for education and training of medical staff (including medical students) and other health care professionals in the principles of radiation protection will be a more compelling challenge for the future.

3.9. Fostering information exchange

Fostering information exchange is another key general challenge for improving radiological protection in medicine. Intergovernmental organizations, national regulatory bodies, medical professional associations, and medics and patients themselves should be part of a rich network of information exchange. The IAEA dedicated web page[3] is a good example and should be maintained and enriched.

The ICRP has also played its part. A good communicative summary of the questions presented by the new challenges is the ICRP didactic text called Radiation and Your Patient, which is organized in a questions and answers format [50]. This brochure underlines, on the one hand, the obvious benefits to health from medical uses of radiation, in X ray diagnostics, interventional radiology, nuclear medicine and radiotherapy, and, on the other hand, the well established risks from high doses of radiation (radiotherapy, interventional radiology), particularly if improperly applied, and the possible deleterious effects from small radiation doses (such as those used in diagnostics). This brochure describes the dilemma of protection of patients in uncomplicated prose: appropriate use of large doses in radiotherapy prevents serious harm, but even low doses carry a risk that cannot be eliminated entirely. Diagnostic use of radiation, therefore, requires methodology that would secure high diagnostic gains while minimizing the possible harm. The text provides ample information on opportunities to minimize doses and, therefore, the risk from diagnostic uses of radiation, indicating that this objective may be reached by avoiding unnecessary (unjustified) examinations, and by optimizing the procedures applied both from the standpoint of diagnostic quality and in terms of reduction of excessive doses to patients. Optimization of patient protection in radiotherapy must depend on maintaining sufficiently high doses to irradiated tumours, securing a high cure rate, while protecting the healthy tissues to the largest extent possible. Problems related to special protection of the embryo and foetus in the

[3] http://rpop.iaea.org

course of diagnostic and therapeutic uses of radiation are presented and practical solutions are recommended.

4. VICI: SUCCESSFULLY MOVING TOWARDS AN INTERNATIONAL REGIME FOR RADIATION SAFETY IN MEDICINE

4.1. Strategy

As described in the previous, *vidi*, chapter, the number of challenges still presented by radiological protection in medicine is enormous. In order to address these challenges and succeed in addressing them, a strategy is required. The purpose of this, *vici*, chapter is to suggest such a strategy. Relevant directions were provided by H.E. P. Altmaier, Federal Minister of Germany for the Environment, Nature Conservation and Nuclear Safety at the Bonn conference [2]. He stated that:

> "We need up-to-date and uniform standards for radiation protection in medicine, both for patients and for medical staff — worldwide and at the highest possible level…Setting these new, global standards for radiation protection for the decade ahead is the major challenge facing this IAEA conference."

The Bonn conference extended the remit of the Malaga conference. It did not only consider the protection of patients and their comforters but also the related and, many times, interrelated occupational protection of the medical staff attending the patients and the protection of members of the public who are usually casually exposed from medical sources. Notwithstanding this, the Bonn conference could well follow the pattern marked by the Malaga conference. Parliamentary State Secretary, U. Heinen-Esser, again comes to the rescue with a relevant suggestion by declaring: "I would be delighted if we were to adopt a new action programme by the end of this week and meet the shared objective of this conference: Setting the Scene for the Next Decade." [2].

It seems that the general strategy should be the achievement of a renewed international Action Plan, this time covering all aspects of radiological protection in medicine.

4.2. New standards

It is to be noted that there is an important framework for such a strategy and for a new action plan. In September 2005, the IAEA General Conference, by way

of Resolution GC(49)/RES/9, requested the IAEA Secretariat to undertake a review of the BSS. The IAEA invited representatives of the United Nations and other intergovernmental organizations to participate in the review and revision of the BSS through the establishment of a BSS Secretariat made up of designated representatives of the potential sponsoring organizations: the European Commission (EC/Euratom), FAO, ILO, OECD/NEA, PAHO, UNEP and the WHO, supported by the IAEA Secretariat. On 12 September 2011, the IAEA Board of Governors established the revised BSS as a Safety Requirement in the IAEA Safety Standards Series [51]. The final version of the BSS were published in 2014 [52]. In addition to the classical general requirements, for example, on the application of the principles of radiation protection, responsibilities of the government and of the regulatory body, responsibilities for protection and safety and management requirements, the new BSS contain a chapter fully dedicated to protection in medicine as a planned exposure situation.

The new requirements comprehend ten specific mandatory 'commandments', namely:

(1) The government shall ensure that relevant parties are authorized to assume their roles and responsibilities and that diagnostic reference levels, dose constraints, and criteria and guidelines for the release of patients are established.
(2) The regulatory body shall require that health professionals with responsibilities for medical exposure are specialized in the appropriate area and that they meet the requirements for education, training and competence in the relevant specialty.
(3) Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.
(4) Relevant parties shall ensure that medical exposures are justified.
(5) Registrants and licensees, and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.
(6) Registrants and licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a woman is or might be pregnant or is breast-feeding.
(7) Registrants and licensees shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.
(8) Registrants and licensees shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures.

(9) Registrants and licensees shall promptly investigate any such exposure and, if appropriate, shall implement corrective actions.
(10) Registrants and licensees shall ensure that radiological reviews are performed periodically at medical radiation facilities and that records are maintained.

4.3. Epilogue

The epilogue of the long saga of radiological protection in medicine is clear: it is apparent that since the first ICRP recommendations (which de facto excluded the protection of patients) up to the recently approved international standards, a lot of water went under the bridge! The world now seems to be ready for a serious systematic and orderly intergovernmental process for internationalizing the protection of patients and medical staff.

4.4. Conclusions

In conclusion, this paper proposes that the IAEA formulate, formally approve and implement a renewed Action Plan on Radiation Protection in Medicine, which should be tailored to the successful Malaga Action Plan. The new Action Plan should be undertaken in co-sponsorship and cooperation with:

— Specialized agencies of the United Nations family;
— Relevant regional organizations;
— National regulators;
— Medical professional organizations;
— Senior specialists in the practices of radiodiagnosis and radiotherapy, and in radiological protection;
— The pertinent industry of manufacturers of medical equipment.

The strategic aim of such an Action Plan should be an intergovernmental international radiation safety regime for the practice of medicine.

REFERENCES

[1] LINDELL, B., Str*å*lningens, radioaktivitetens och str*å*lskyddets historia: Pandoras Ask, Damokles Sv*ärd, Her*kules Storverk, Sisyfos Möda (in Swedish), Atlantis, Stockholm. First volume translated into Castilian: Historia de la radiación, la radioactividad y la radioprotección — La Caja de Pandora; con prólogo de Abel J. González, Sociedad Argentina de Radioprotección, Buenos Aires (2012), http://radioproteccionsar.org.ar/noticias/la-caja-de-pandora

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA-CN-192, these Proceedings.

[3] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, International Recommendations for X-Ray and Radium Protection on the proposal of the Radio-Physics Section adopted by the Second International Congress of Radiology in Stockholm, July 27th, 1928, Pergamon Press, Oxford and New York (1928).

[4] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Recommendations of the International Commission on Radiological Protection, Publication 1, Pergamon Press, Oxford and New York (1959).

[5] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Recommendations of the International Commission on Radiological Protection (Adopted 17 September 1965), Publication 9, Pergamon Press, Oxford and New York (1966).

[6] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Implications of Commission Recommendations that Doses be Kept as Low as Readily Achievable, Publication 22, Pergamon Press, Oxford and New York (1973).

[7] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Cost-Benefit Analysis in the Optimization of Radiation Protection, Publication 37, Pergamon Press, Oxford and New York (1983).

[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Protection against Ionizing Radiation from External Sources, Publication 15, A Report by Committee 3 of the International Commission on Radiological Protection (Adopted by the Commission in November 1969), Pergamon Press, Oxford and New York (1970).

[9] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Protection of the Patient in X-ray Diagnosis, Publication 16, A Report prepared by a Task Group of Committee 3 of the International Commission on Radiological Protection (Adopted by the Commission in November 1969), Pergamon Press, Oxford and New York (1970).

[10] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Recommendations of the ICRP, Publication 26, Pergamon Press, Oxford and New York (1977).

[11] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Protection of the Patient in Diagnostic Radiology, Publication 34, Pergamon Press, Oxford and New York (1982).

[12] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Protection of the Patient in Radiation Therapy, Publication 44, Pergamon Press, Oxford and New York (1985).

[13] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, 1990 Recommendations of the International Commission on Radiological Protection, Publication 60, Pergamon Press, Oxford and New York (1991).
[14] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection and Safety in Medicine, Publication 73, Pergamon Press, Oxford and New York (1996).
[15] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, Publication 103, Pergamon Press, Oxford and New York (2007).
[16] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Medicine, Publication 105, Pergamon Press, Oxford and New York (2007).
[17] UNITED NATIONS, Effects of Ionizing Radiation, Volume I: UNSCEAR 2006 (Report to the General Assembly), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), Scientific Annexes A and B; Volume II: Scientific Annexes C, D and E, UN, New York (2008), and corrigendum (2009).
[18] UNITED NATIONS, Sources and Effects of Ionizing Radiation, Volume I: Sources, Volume II: Effects (Report to the General Assembly), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2000).
[19] UNITED NATIONS, Sources and Effects of Ionizing Radiation (Report to the General Assembly), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (1996).
[20] UNITED NATIONS, Sources and Effects of Ionizing Radiation (Report to the General Assembly), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (1993).
[21] UNITED NATIONS, Ionizing Radiation: Sources and Biological Effects (Report to the General Assembly), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (1982).
[22] UNITED NATIONS, Sources and Effects of Ionizing Radiation (Report to the General Assembly), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (1977).
[23] UNITED NATIONS, Ionizing Radiation: Levels and Effects, Volume I: Levels, Volume II: Effects (Report to the General Assembly), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (1972).
[24] UNITED NATIONS, Sources and Effects of Ionizing Radiation, Volume I (Report to the General Assembly), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), UN, New York (2010).
[25] The Agency's Health and Safety Measures, INFCIRC/18, IAEA, Vienna (1960); The Agency's Safety Standards and Measures, INFCIRC/18/Rev. 1, IAEA, Vienna (1976).
[26] INTERNATIONAL ATOMIC ENERGY AGENCY, Basic Safety Standards for Radiation Protection, Safety Series No. 9, IAEA, Vienna (1962).
[27] INTERNATIONAL ATOMIC ENERGY AGENCY VIENNA, Basic Safety Standards for Radiation Protection (1967 Edition), Safety Series No. 9, IAEA, Vienna (1967).

[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Basic Safety Standards for Radiation Protection (1982 Edition), Safety Series No. 9, IAEA, Vienna (1982).
[29] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Annual Report for 1990, IAEA/GC(XXXV)/953, IAEA, Vienna (1990) 86.
[30] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).
[31] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy (Proc. Int. Conf. Malaga, 2001), IAEA, Vienna (2001).
[32] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, A Compilation of the Major Concepts and Quantities in Use by ICRP, Publication 42, Pergamon Press, Oxford and New York (1985).
[33] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Dose to Patients from Radiopharmaceuticals, Publication 53, Pergamon Press, Oxford and New York (1988).
[34] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Dose to Patients from Radiopharmaceuticals (Addendum to ICRP Publication 53), Publication 80, Pergamon Press, Oxford and New York (1998).
[35] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Dose to Patients from Radiopharmaceuticals — Addendum 3 to ICRP Publication 53, Publication 106, Pergamon Press, Oxford and New York (2008).
[36] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Managing Patient Dose in Digital Radiology, Publication 93, Pergamon Press, Oxford and New York (2004).
[37] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Managing Patient Dose in Computed Tomography, Publication 87, Pergamon Press, Oxford and New York (2000).
[38] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Managing Patient Dose in Multi-Detector Computed Tomography (MDCT), Publication 102, Pergamon Press, Oxford and New York (2007).
[39] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Pregnancy and Medical Radiation, Publication 84, Pergamon Press, Oxford and New York (2000).
[40] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Paediatric Diagnostic and Interventional Radiology, Publication 121, Elsevier (2013).
[41] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Release of Patients after Therapy with Unsealed Radionuclides, Publication 94, Pergamon Press, Oxford and New York (2004).

[42] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of Accidents to Patients Undergoing Radiation Therapy, Publication 86, Pergamon Press, Oxford and New York (2000).
[43] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, Publication 112, Elsevier (2009).
[44] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Prevention of High-dose-rate Brachytherapy Accidents, Publication 97, Pergamon Press, Oxford and New York (2005).
[45] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiation Safety Aspects of Brachytherapy for Prostate Cancer using Permanently Implanted Sources, Publication 98, Pergamon Press, Oxford and New York (2005).
[46] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Avoidance of Radiation Injuries from Medical Interventional Procedures, Publication 85, Pergamon Press, Oxford and New York (2000).
[47] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Education and Training in Radiological Protection for Diagnostic and Interventional Procedures, Publication 113, Pergamon Press, Oxford and New York (2009).
[48] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Cardiology, Publication 120, Elsevier (2013).
[49] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Radiological Protection in Fluoroscopically Guided Procedures outside the Imaging Department, Publication 117, Elsevier (2010).
[50] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION Radiation and Your Patient — A Guide for Medical Practitioners, ICRP Supporting Guidance 2, Pergamon Press, Oxford and New York (2001).
[51] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards — Interim Edition, IAEA Safety Standards Series No. GSR Part 3 (Interim), IAEA, Vienna (2011).
[52] EUROPEAN COMMISSION, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANIZATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, UNITED NATIONS ENVIRONMENT PROGRAMME, WORLD HEALTH ORGANIZATION, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

Annex

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With the World Health Organization as co-sponsor, and the Government of Germany through the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety as host, the IAEA organized the International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade. The conference was held in Bonn, 3–7 December 2012, and aimed, in particular, to:

- Indicate gaps in current approaches to radiation protection in medicine;
- Identify tools for improving radiation protection in medicine;
- Review advances, challenges and opportunities in the field of radiation protection in medicine;
- Assess the impact of the International Action Plan for the Radiation Protection of Patients, in order to prepare new international recommendations, taking into account newer developments.

It resulted in the Bonn Call for Action, which will focus efforts in radiation protection in medicine in the next decade, and maximize the positive impact of such efforts.

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA
ISBN 978–92–0–103914–9
ISSN 0074–1884