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Confronting Risk

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That the use of ionising radiation for medical purposes holds both tremendous potential and entails serious risks is not a new insight. The first resolution aiming to protect individuals from excessive exposure through x-rays was adopted a full one hundred years ago by the British Roentgen Society. However, various developments have lent new urgency to, and sparked renewed interest in, the issue, and both regulatory bodies and professional societies are seizing the opportunity to push for greater vigilance.

A Growing Problem

Today's practitioners rely on a dizzying array of imaging modalities for both diagnostic and treatment purposes, several of which – including projection radiography, computed tomography (CT), fluoroscopy and positron emission tomography (PET) scans – use ionising radiation to generate images. As a result, medical procedures have become by far the main artificial source of radiation exposure to the general population.

Such exposure can trigger both stochastic and non-stochastic, or deterministic, effects. Stochastic effects are more likely to result from increased exposure, but are not necessarily more severe as a result of higher exposure. These include a higher risk of cancer. While the doses emitted in diagnostic and interventional radiology may increase that risk, sound estimates of radiationinduced cancers remain elusive. By contrast, non-stochastic or deterministic effects, which generally result from short-term exposures to high radiation levels, do become more severe with increased exposure, and often appear quickly. Examples include burns and radiation poisoning.

Technological advances have both alleviated and exacerbated these risks. While innovative devices now include features that facilitate intelligent dose customising, for example, technological progress has also resulted in the introduction of new medical procedures that rely on the use of ionising radiation. In addition, sophisticated health services are increasingly widely and readily available across the globe, meaning that both cumulative radiation doses are increasing, and that more patients, practitioners and medical staff are at risk of suffering negative side effects.

The growing use of CT is particularly striking. The modality entails notably high radiation doses compared to traditional radiography, accounting for only a fraction of total exams performed (under 15%), but for a large percentage (around 65-70%) of imaging radiation (Voress 2007). Nonetheless, thanks to its ability to provide cross-sectional views of organs, it is an immensely popular tool, and its use has multiplied significantly since the early 1990s. In English hospitals, for example, the number of CT scans performed per year rose from around 1 million in 1997 to almost 5 million in 2013 (Elliott 2014). In germany the number increased by 130% between 1996 and 2010, with around 4.88 million patients receiving at least one CT scan in 2009 (Federal Office for Radiation Protection 2014). The trend is even more dramatic in the United States, where the threat of litigation may be pushing practitioners to err on the side of ordering more exams: fewer than 19 million CT scans were performed there in 1993, while 85 million were carried out in 2012 (IMV 2012).

Fluoroscopy is another modality that has triggered considerable debate on balancing risks and benefits. Its ability to provide real-time imaging of internal organs has revolutionised medical treatment, particularly by making possible a variety of interventional radiological (IR) procedures that permit patients to forgo invasive surgery. But its use is also associated with significant radiation doses. Complex IR procedures that involve long exposure times are of particular concern, with embolisation (especially in the brain), the creation of transjugular intrahepatic portosystemic shunts (TIPS), and percutaneous transluminal coronary angioplasty often singled out for entailing high doses. Dose reduction is especially vital for practitioners and other staff members who are chronically exposed. Interventional radiologists, for example, have been found to face an elevated risk of developing radiation-induced cataracts.

Concerns about exposure have already spurred some improvements. Publicity about the increase in CT use did impel manufacturers to lower the dose emitted per scan, resulting in significant reductions. But with reliance on imaging for both diagnostic and therapeutic purposes continuing to expand, heightened awareness is crucial. A recent flurry of initiatives, both at the regulatory and professional society levels, is aiming to achieve that result.

Directing Change through Regulation

The European Union has long immersed itself in radiation protection, both by way of regulatory efforts and by issuing non-binding guidelines. Its latest measure on the issue is Council Directive 2013/59/Euratom of 5 December 2013, laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. Also referred to as the Basic Safety Standards Directive, it came into force in February 2014. It consolidates and updates a group of previously applicable rules, and member states have until February of 2018 to comply with its requirements.

The Directive reiterates the EU's commitment to two main principles often invoked in radiation protection efforts in the medical context: the "justification principle", which requires that decisions that introduce changes in radiation exposure result in more good than harm, viewed either from an individual or a societal perspective; and the "optimisation principle", which mandates that exposures are to be kept as low as reasonably achievable. Also referred to as the ALARA principle, this concept acknowledges that worse can actually be better, with practitioners encouraged to aim for images that are adequate for diagnosis or intervention, and not necessarily for maximum precision, which generally entails higher exposure levels.

The instrument is comprehensive in scope. Emphasising communication with patients, it obligates physicians to inform patients about the benefits and risks associated with examinations before these take place, and requires resulting reports to include information on patient exposure. Recording and communicating dose information is also a central element of the sections targeting medical equipment. Amongst other things, these require equipment used for IR procedures to provide information about the radiation quantity produced during the procedure. In addition select equipment, including CT, must be able to produce parameter information, based on which practitioners can assess patient dose at the end of a procedure, and transfer this information to examination records. (Equipment installed before the Directive enters into force may be exempt from parts of these requirements.)

CIRSE’s radiation protection campaign highlights the risk of eye disease for interventional health professionals.

Incorporating new epidemiological insights about the effects of exposure on specific tissues, especially on the lens of the eye, an issue highlighted by the International Commission on Radiological Protection in 2011, the Directive also lowers applicable occupational dose limits. P reviously c apped a t 1 50mSv per year, the equivalent dose limit for the lens of the eye is now set at 20mSv per year, averaged over 5-year periods, during which the dose may not exceed 50mSv in any single year.

In addition the Directive seeks to harmonise and strengthen radiation protection education and training efforts across the EU. Having introduced requirements for such training in medical school curricula in the late 1990s, the new rules emphasise continuing education, obliging governments to ensure that post-qualification education and training is provided to all individuals involved in the practical aspects of medical radiological procedures. The Directive also specifically notes that where new techniques are introduced, targeted training that covers radiation protection aspects must be provided.

Enhancing Safety with Professional Society Initiatives

While legislative efforts can play important roles in prompting change, these will have little impact if a proper safety culture is missing in day-to-day practice. A genuine appreciation of the risks involved is vital for creating such a culture. Several professional societies have recently stepped up efforts to foster such awareness, and are leading a variety of initiatives that address several of the priorities emphasised in the new Basic Safety Standards Directive.

The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) is strongly committed to ensuring comprehensive and up-to-date radiation protection training. This is reflected in the European Board of Interventional Radiology, an exam offered to physicians seeking to cer tif y their IR expertise. The EBIR, which is based on *CIRSE’s European Curriculum and Syllabus for Interventional Radiology*, requires trainees to build on radiation protection education received during diagnostic radiology training and to achieve numerous specific learning outcomes, including being able to estimate effective doses from IR procedures and determining the best compromise between the risks and benefits of specific approaches.

The society was also one of the six professional organisations that contributed to the

Medical Radiation Protection Education and Training (MEDRAPET) project (www.eurosafeimaging.org/medrapet), an EU-funded initiative conducted between late 2010 and early 2013, which included a study exploring the status of radiation protection education and training of medical professionals within the EU.

The European Commission has incorporated insights obtained from that study into new guidelines issued in 2014, *Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union, Radiation Protection No. 175* (European Commission 2014), which outline a framework on which future curriculum development efforts for several different professional groups can be based.

In addition CIRSE is pushing practitioners to embrace the protective measures available for reducing the risk of developing lens opacities, associated with reduced contrast sensitivity as well as declined visual ability. Its first Radiation Protection Pavilion, launched at CIRSE 2014 in glasgow, featured eye exams, informational material outlining practical advice and tailored industry exhibits. CIRSE 2015 in Lisbon will feature a new, expanded edition of the pavilion.

The European Society of Radiology has also been an active advocate. In 2014 it launched its EuroSafe Imaging Campaign (**eurosafeimaging.org**), which aims to spread awareness both amongst the medical community and amongst patients. In addition, it is coordinating the European Diagnostic Reference Levels for Paediatric Imaging (PiDRL) project (**eurosafeimaging.org/pidrl**), which strives to better protect children from radiation exposure by developing and promoting the use of European diagnostic reference levels for paediatric imaging, focusing on CT, interventional procedures using fluoroscopy and digital radiographic imaging.

Paediatric radiation exposure is also getting more attention in the United States, where the Image gently ® campaign has urged caution since 2008 (**imagegently.org**). With children at heightened risk both because their developing organs and tissues are more vulnerable, and because of their longer life expectancy, such efforts are particularly vital.

Encouragingly, recent reports indicate that awareness is not just rising, but is also resulting in reduced exposure at individual hospitals. For example, Yale-New Haven Children's Hospital reports curtailing the number of CT scans performed on children by 50% since 2003, thanks to both advances in scanner technology that have facilitated adjusting doses for younger patients, and to increased mindfulness, with practitioners paying more attention to alternative options, such as MRI and ultrasound, or resorting to watchful waiting (Bessinger 2013). Cincinnati Children's Hospital Medical Center recently announced t h at it h as developed protocols that cut the radiation dose for paediatric digital subtraction angiography procedures by up to 95% without sacrificing image quality (Casey 2015).

Gaining Momentum

Such reports suggest that radiation protection efforts are gaining momentum. Administrators can help the medical community to capitalise on this renewed surge of interest in the issue in myriad ways. Tangible investments in relevant equipment, ranging from sophisticated imaging devices to surprisingly simple protective gadgets for both health workers and patients, are vital, but devices are only part of the equation. Administrators can also make crucial contributions by fostering a workplace culture that genuinely values and prioritises vigilance and diligence with respect to limiting exposure, as well as by facilitating access to accurate and up-to-date information amongst patients, practitioners and medical personnel alike.

Key Points

- Cumulative radiation doses are increasing, and patients, practitioners and medical staff are at risk. Complex IR procedures that involve long exposure times are of particular concern.
- A recent flurry of initiatives, both at the regulatory and professional society levels, is aiming to heighten awareness.
- Key EU documents are the Basic Safety Standards directive and the guidelines on Radiation Protection Education and training of Medical Professionals in the European Union.
- Several professional societies have initiatives underway to improve radiation protection education and awareness, including the Cardiovascular and Interventional Radiological Society of Europe, which included a Radiation Protection Pavilion at its 2014 congress for the first time.

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