Innovative technologies for optimizing radiation dose to patients

COCIR's support of the ESR's Eurosafe Imaging Campaign

COCIR welcomes the European Society of Radiology's EuroSafe Imaging campaign to promote awareness and build collaboration around the optimised use of radiological imaging, as industry and healthcare professionals share a long history of pioneering technologies to reduce and optimise exposure to radiation.

The safety of patients and healthcare workers is of paramount importance and the use of ionising radiation will continue to be an essential tool in the diagnosis and treatment of disease. New technologies can enable dramatic reductions in the dose to patient s in both unique and repeat procedures and optimize their dose over time.

COCIR's four Es: Endorse, Explain, Enhance, Educate

Innovative technologies are crucial elements in improving clinical outcome. Amongst other technologies, X-ray, CT, radiation therapy, interventional procedures are used at all stages of patient care: screening, early diagnosis, treatment planning, monitoring and therapeutic procedures.

The industry continuously develops technologies to minimise radiation dose to patients and healthcare professionals. For example:

- Moving conventional radiology to digital radiology
- Introducing major technology breakthroughs to achieve low-dose CT
- Measuring and monitoring dose through management software

COCIR encourages healthcare providers to prioritise dose reduction and dose optimisation when replacing ageing equipment or planning new investment.

COCIR also supports the European Society of Radiology in the promotion of training and education for healthcare professionals.

COCIR welcomes the newly published European Union legislation that promotes dose reduction to improve patient safety and support the EuroSafe campaign.

We appreciate initiatives to improve safety and encourage the European Union to promote the faster introduction of dose optimisation – both through guidance to Member States and the use of its own funding mechanisms.

COCIR technologies - supporting clinicians, benefiting patients

Ionizing radiation has been used for over a century in medical imaging and has proven absolutely critical in improving clinical outcomes, driving efficiencies and expanding the breadth and capabilities of healthcare systems to the benefit of millions of patients in Europe and throughout the world. Though rising radiation dose from increasing medical procedures is of concern, it is important to recognize the benefit of a 'quality imaging

examination' that addresses pertinent clinical issues affecting patient care. Examinations should only be conducted when necessary and at the lowest radiation dose consistent with acquisition of the desired clinical information or outcome, and in adherence to the principle of ALARA - as low as reasonably achievable – widely used in radiological protection.

Manufacturers and healthcare professionals share a long history of pioneering technologies to reduce and optimize exposure to radiation. Technological advances are continually providing new tools that can advance the principle of ALARA, and as Rehani commented when reviewing the challenges involved in radiation protection of patients, "*most of the challenges facing different stakeholders are actually based on the contribution required from industry; thus, manufacturers play the greatest role in making patients safer in this century*."[1] COCIR's Members accept this and will continue to work with clinicians to design and develop technologies to improve patient safety.

1. Low Dose CT systems – Delivering quality images using lower radiation

CT has made a dramatic contribution to the accurate and earlier detection of disease and is used extensively in cardiovascular and cancer diagnosis, pelvic examinations and complex fractures. By combining multiple X-ray 'slices' and complex computer software, detailed 3 dimensional images are constructed, providing clinicians with unprecedented visual and functional information on their patients. Until recently, these images required using levels of radiation several times greater than conventional X –Ray. However, the industry has worked with healthcare professionals to design and develop software and engineering solutions in breakthrough new 'low-dose' CT systems that reduce the amount of radiation exposure required that is now comparable to conventional X-Ray, without losing clinical functionality.

As well as the benefit of lower dose, these systems scan patients faster, enabling improved image collection and quality, increasing patient comfort and allowing for increased patient throughput in radiology departments, helping to improve efficiency. COCIR expects this new technology will become the equipment of choice in Europe as hospitals replace existing equipment. The principle of ALARA also suggests that hospitals and healthcare systems should use low dose CT for patients where relatively high cumulative dose from repeat scans is an issue, or where the scan is conducted on children.

2. Dose Management – New solutions for accurate measurement and patient tracking

COCIR Members have recently introduced new, powerful software tools for CT and other procedures that enable hospitals and healthcare providers to monitor and track dose during diagnostic and therapy procedures. Dose management strategies directed toward optimization, rather than dose reduction, per se, recognise the need to balance the risks of exposure with the clinical benefits to the patient. These software advances allow healthcare professionals to predict and monitor dose to the individual patient from unique and multiple exposures. Analysis can identify where dose can be optimized and reduced

[1] *Rehani M, Madan, 'Challenges in Radiation Protection of Patients for the 21st Century', AJR,* ***200*** *(2013): 762-764, 762*

and the systems can link into hospital and wider health system electronic patient records and collate data from different centres and procedures. The software can also help to estimate additional dose from a planned procedure and alert clinicians to a risk of elevated dose.

COCIR urges healthcare providers to work towards their routine use in procedures where the tracking and optimisation of dose is desirable for improved patient safety and as tool that can aid compliance with European legislation and guidance.

3. Healthcare ICT and data management

Investment in Health ICT enabling integration across all care settings will be essential for data sharing between disparate parts of the healthcare system. Health ICT is essential to help build and manage 'dose repositories' that will facilitate the collection and analysis of individual cumulative dose data, enable clinical audit and monitor improvements. Collective data held on national and international data bases will also be invaluable for healthcare researchers and epidemiologists wishing to track health data and exposure to radiation.

COCIR – partnering for radiation protection in Europe

Since 2010, COCIR has worked with HERCA (Heads of European Radiological Protection Competent Authorities) to address increasing exposure from the use of CT. In May 2011, COCIR's CT manufacturers issued a voluntary commitment to pursue initiatives on improving dose reporting, promote transparency in dose efficacy and drive technological reduction of medical exposure and training on the use of CT and dose management techniques.

COCIR's Radiation Task Force monitors regulations affecting radiation use in imaging and radiotherapy. The group contributed to the development of the new EURATOM basic safety provisions found in Council Directive 2013/59/EURATOM (the 'Basic Safety Standards Directive') which consolidates and updates previous Directives protecting workers and the public from exposure to ionising radiation. Adopted on 5 December 2013, this Directive addresses the use of radiation for medical purposes including "*the recording and reporting of doses from medical procedures, the use of diagnostic reference levels and the availability of dose-indicating devices*."

It also includes, in Article 56.1, mention that Member States must take measures to "*…ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable …*"

All reasonable steps to minimise dose to patients, including mechanisms that can estimate, measure and track radiation, should also be taken. Article 60.3 states: "*Member States will ensure that equipment used for interventional radiology and CT and any new equipment used for planning, guiding and verification purposes has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing the patient dose,"* and *"can transfer the information to the record of the examination."*

The need for many of these objectives are also reflected in the recently launched **EuroSafe Imaging Campaign** which aims to promote awareness and build collaborations around the importance of appropriate and optimised use of radiological imaging while taking measures to protect patients from unnecessary exposure to radiation. COCIR supports the EuroSafe Campaign, for which new technology will be a critical element in progressing optimisation of radiation dose, and will be pleased to work with the ESR and other key stakeholders to contribute to the **Campaign's** objectives.

Action from the EU and Member States

Some European hospitals are using new technologies, benefiting patients, clinicians and increasing efficiencies, but others are still to replace ageing equipment or introduce 'low-dose' systems for sensitive populations such as children or patients requiring multiple examinations. With the principle of ALARA reinforced in new EU legislation COCIR expects these technologies to become more prevalent in Europe and urges the European Commission to look beyond its regulatory remit and develop policies and actions to increase patient safety through improving access to these new technologies.

Guidance should be given to Member States on ways to accelerate the uptake of innovative solutions and procedures that optimise radiation dose. COCIR encourages the EU to use funding mechanisms, such as Structural Funds to assist eligible countries to replace aging medical equipment. Dose tracking and management software could also be funded through funds allocated for Health ICT, and EU employment budgets could be used to fund programmes to train healthcare professionals and providers on dose optimization as a component of sustainable, safe and efficient healthcare systems.

Member States must also work with their local healthcare professionals and technology sector to examine ways how procurement and reimbursement policies in their healthcare system can be used to secure improved access to technologies like low dose CT. Patients needing accurate, fast and repeated diagnostic imaging using CT should not have to worry as to whether part of their treatment may be causing them harm. Access to low dose CT would be a major step forward for these patients.