IAEA Technical Meeting on Preventing Unintended and Accidental Medical Exposures in Radiology

The Meeting held at the International Atomic Energy Agency (IAEA)’s Headquarters in Vienna, Austria, from 6 to 8 March 2017 gave Member States, international organizations and professional societies an opportunity to exchange information on methods for investigation, reporting and prevention of unintended and accidental exposure in diagnostic radiology and interventional procedures. The meeting was attended by 52 participants from 25 countries including radiologists, medical physicists, radiation technologists, and regulators as well as equipment manufacturers. It was attended by representatives from WHO, UNSCEAR, ISR, ISRRRT, IOMP, Image Gently Alliance, DITTA, HERCA, CRCPD, ESR, EFOMP, EFRS, as well as a range of national organisations and regulatory authorities.

The need for improving primary prevention of medical radiation incidents and accidents was highlighted in the Bonn Call for Action by the IAEA and World Health Organisation (WHO). This is linked with the action for strengthening the radiation safety culture in health care. The International Basic Safety Standard (IAEA Safety Standards Series No. GSR Part 3) sets out requirements for minimizing the likelihood of unintended and accidental medical exposures and investigating when such exposures occur in order to learn from such events. The meeting contained presentations on key aspects on which action is required and a summary of outcomes of the discussions is given here.

Managing skin doses in interventional procedures and CT

A growing number of deterministic injuries (tissue reactions) resulting from interventional procedures are being reported. Some of these may result from poor technique, but others while not intended could be difficult to avoid because of procedure complexity. Hospitals should identify procedures that have a high potential to cause injury and ensure equipment settings are satisfactory, but also review protocols periodically, especially those for the more common procedures. There are many factors that can contribute to incidents involving skin injury, including incorrect image acquisition rates, fluoroscopy modes, patient position and use of too oblique projections. Training in techniques and radiation protection for cardiologists, surgeons and other clinicians, as well as radiologists helps to avoid these practices.

Approaches to reducing risks in different parts of the world will need to take into consideration the technology and human resources available. The threshold and severity of tissue reaction is linked to peak skin dose. A measure is not available on current interventional fluoroscopy equipment, but there are dose indicators such as cumulative air kerma at the interventional reference point, kerma area product, fluoroscopy time and number of cine runs/frames. The accuracy of the dosimetry data should be validated by a medical physicist. Protocols should be available which take account of patient size and contain alert and trigger levels set in terms of the displayed quantities. The first alert would occur during the procedure to warn the interventional clinician that the dose level was high. Even if the level is reached, the clinical
outcome must be the priority, so clear recommendations should be made about action to be taken at alert levels. These may include modifying the procedure and consulting a colleague for advice. Older equipment may not provide dosimetry information and here fluoroscopy time should be used as a guide. Higher trigger levels would be set above which the patient would be informed and followed-up, and for external reporting of the exposure. The levels should be based on recommendations of professional societies, and the values included in operator training (cardiologist, radiologist, and radiation technologist). If the dosimetry parameter exceeds the patient trigger level, then the patient should be informed, and their condition followed up on return to the hospital or they should be contacted after about 3 weeks to check whether they have had any reaction. The patient’s general practitioner, referring doctor, and other professionals involved in the service should all be informed.

Events that lead to deterministic effects in CT are rare, but several examples have been reported for CT perfusion cases in the USA, and if they occur these can affect multiple patients. Lessons that have been learned from these accidental overexposures are to act immediately; assess the radiation incident; communicate the findings with everyone involved; and establish procedures to avoid future incidents. The CTDI$_{\text{vol}}$ displayed on the scanner console provides useful information about skin dose. For head CT scans, the CTDI$_{\text{vol}}$ is similar to the skin dose, while for body CT perfusion, the CTDI$_{\text{vol}}$ underestimates surface skin dose by over 20%. The US FDA proposed a CT alert value for CTDI$_{\text{vol}}$ of 1 Gy checked prior to performing the procedures to avoid this type of injury.

The IAEA has established an international web-based database SAFRAD (Safety in Radiological Procedures) to collect radiation exposure data for procedures reaching defined trigger levels in interventional radiology and cardiology. The purpose is to identify patients at high risk of developing deterministic effects from interventional procedures, encourage follow-up examinations for adverse side effects and educate health care personnel.

**Managing unintended and accidental medical exposures in the healthcare facility**

Unintended and accidental medical exposures may occur with all types of imaging procedure and although health consequences are minimal in the majority of cases, proper investigation, and implementation of changes can avoid similar errors being made in the future. Grouping incidents into categories can help in deciding on the appropriate investigation route. Categories based on UK experiences, are errors in referral; in patient identification or examination type, or in radiology procedures. Other categories are unintended exposures of pregnant patients and overexposures due to equipment faults. Categories depend on the systems in place, the types of incident that can be recognised and followed up effectively, and the personnel groups that are employed by the facility, and would need to be adapted for individual countries. Factors responsible for the incidents can be classified as: latent (in system) such as deficient procedures, inadequate staff training, poor staffing levels, and ill-defined responsibilities, and active factors that can involve human error linked to poor staff alertness and awareness. Follow-up should look at remedial actions, to see what improvement could be made. All staff groups should
collaborate in the process. Incident data should be kept at hospital level and should be available to the general manager, and disseminated through safety committees. Systems should be in place for follow-up and implementation of changes to avoid recurrence of similar incidents. Professional organisations, such as Image Gentle alliance promote the use of tools to help in this process, such as checklists, audits, improved communication and briefing/debriefing to assist in the improvement process.

Reporting of radiation doses following unintended and accidental exposures may be based on organ, skin or effective doses. Organ doses should be used for significant exposures, but the effective dose for a reference person provides an assessment that can be used when several organs are irradiated. Methods of calculation should be fairly simple. If the dose is less than a few mSv, then generic values from published data can be used. At low radiation levels the dose can be derived from exposure data (e.g. DLP coefficients to derive effective dose in CT). When the effective dose is tens mSv or greater a full evaluation using doses for individual radiosensitive tissues may be required. Local/regional agreement will be required on the level at which determination of organ doses is necessary. General terminology can be used to describe risks of cancer incidence, linked to the dose level. Recommended risk terms when effective doses lie within different ranges are <0.1 mSv – negligible, 0.1–1 mSv – minimal, 1–10 mSv – very low, 10–100 mSv – low, and >100 mSv – moderate. This is appropriate for providers, patients, public, and administrators. For professionals with knowledge of radiation effects, quantitative risks derived using coefficients provided by international organizations such as BEIR VII and ICRP might be used.

Radiological examinations involving the abdomen or pelvis are capable of delivering radiation doses of tens mGy to the unborn child, but doses of 100 mGy, above which fetal abnormalities may occur, are extremely rare in diagnostic radiology. Therefore, termination of pregnancy due to a diagnostic X ray examination would almost never be justified. However, if a pregnant patient is exposed unintentionally, an internal investigation should be undertaken. An estimation of conceptus dose is needed, because there is a small increased risk of childhood cancer. Relevant publications are available describing methods for dose assessment and above 10 mGy, a detailed dose assessment will be required.

Managing national reporting and collation of data

A large scale gathering of events is beneficial in looking for trends that extend beyond a particular facility and so helping to improve safety culture. This is a process for reacting to gross incidents and should incorporate a mechanism to disseminate lessons learnt nationally and internationally. This could be done through professional bodies, a regulatory body, or for high skin doses through SAFRAD, the web-based IAEA reporting system. Reporting should be based on the event and not on the dose, however, the analysis should include evaluation of the dose delivered. The basis for external reporting may be different for different bodies.

Regulators will wish to be informed of events that are indicative of demonstrable harm to the individual(s), events that involve vulnerable groups (e.g. pregnant individuals) and events that
are of lesser potential for harm, but are indicative of safety culture failings. Regulatory bodies need to establish their response policy. They should adopt a graded approach, using criteria that may be qualitative or quantitative when investigating. The resources and capacity of the regulatory body will influence the reporting criteria. The regulatory body should take all reports seriously, respond accordingly, not impose unnecessary burdens on institutions, and respect confidentiality. They should base activities on the assumption that internal investigation, recording of events and dissemination within the institution is taking place or has taken place. But the regulatory body has the responsibility to support the legal framework for patient safety in cases where significant harm is demonstrated. They should look at the internal quality management system of the organisation, query the frequency of occurrence of incidents, and query the local dose distribution and intended doses (local DRLs). There should be a single reporting portal of all bodies collating information, so that those who report these events can select which bodies they want to report to. If developed further, SAFRAD could play a useful overarching role for high skin doses. Promotion of SAFRAD among national professional bodies, and in radiation protection, radiology, cardiology meetings for collation of data on high skin dose events should be encouraged.

The meeting concluded with recommendations that the IAEA could usefully provide training material on managing unintended and accidental exposures in radiology. This could be in the form a set of Powerpoint slides and possibly e-learning material.