Preventing Unintended and Accidental Exposures in Nuclear Medicine

Report from the IAEA Technical Meeting held 16-18 May 2018 in Vienna, Austria

A Technical Meeting on "Preventing Unintended and Accidental Exposures in Nuclear Medicine" was held at IAEA Headquarters, Vienna on 16-18 May 2018. It was attended by 45 delegates from 33 Member States including nuclear medicine physicians, medical physicists, technologists, radiopharmacists, regulators and equipment manufacturers. There were also representatives of the World Health Organization (WHO), International Commission on Radiological Protection (ICRP), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), International Society of Radiographers and Radiological Technologist (ISRRT), Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA), Heads of the European Radiological Protection Competent Authorities (HERCA), European Association of Nuclear Medicine (EANM), European Federation of Organisations For Medical Physics (EFOMP), The American Association of Physicists in Medicine (AAPM), European Society of Radiology (ESR), Conference of Radiation Control Program Directors (CRCPD), as well as a range of national regulatory agencies.

The need for improving prevention of medical radiation incidents and accidents was highlighted in the Bonn Call for Action by the IAEA and 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 and improve prevention.

The Technical meeting aimed to review the causes of, and the contributing factors to, unintended and accidental exposure during the different steps of the nuclear medicine process, and define actions for preventing such incidents. Since nuclear medicine involves use of radioactive materials, there is potential for a wide variety of types of incident to occur, so the meeting addressed ones relating to exposure of patient, staff and public, different routes for exposure, and factors relating to the management of radioactive material.

The meeting contained presentations on key aspects on which action is required and a summary of outcomes of the discussions is given here.

Presentations were given on therapeutic and diagnostic patient exposures. Incidents involving the wrong patient, the wrong radiopharmaceutical, or the wrong activity can occur due to errors in procedures within the Nuclear Medicine department, or failures during preparation in the radiopharmacy, but may also result from incorrect referrals or error in the IT support system. The meeting discussed good practices which should be in place to reduce the risk of such incidents occurring, which include regular analysis and review of procedures to look for vulnerabilities, as part of the development of a safety culture within Nuclear Medicine departments, with action taken to modify and improve arrangements to reduce risks of system failure. Policies should define responsibilities for every aspect of the nuclear medicine process within the department, and procedures include arrangements for the investigation of incidents and near-misses. Hospitals should encourage the reporting of incidents and investigate those that occur promptly looking for the root causes. A "no blame" environment should be created while balancing safety and accountability. It must always be remembered that there may be latent factors within a department that may contribute, and efforts should be made to identify these. The Quality Management system should include periodic reviews of reports and actions for improvement.

One example of a factor that had contributed to incidents was failure to clearly demarcate storage areas for different radiopharmaceutical kits or vials for administration, and as well as improving storage arrangements, the clarity of labelling using methods such as colour coding or pictorial identifiers may be useful in improving correct identification. There have over the years been numerous examples of a radiopharmaceutical being administered in error to a patient with the same name. The need to seek positive information from the patient to confirm their identity, was re-emphasised, and the value of developing computer systems that could avoid booking patients of the same name on the same day was proposed to address this issue.

Once factors that have contributed to an incident are highlighted, there is a need to implement changes to address deficiencies and a manager should be given responsibility for this within departmental procedures. Typically, actions might be giving additional training to staff members, modifying procedures, or changing processes to try to prevent recurrence of a similar incident in the future. It is important that experiences are shared among other staff through safety meetings and reviews, so that the whole department is aware of any changes.

In order to ensure that correct activities are administered, it is of the utmost importance that activity levels are measured shortly before administration. However, inaccuracies in radionuclide calibrators that can occur if the device itself is not calibrated and checked periodically can also lead to errors in administration that may affect many patients. In therapeutic procedures the calibration for new radionuclides, and the proper radiation protection skills to handle and accurately measure the administered activity are important

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Failure of the imaging equipment or loss of image data can lead to an unnecessary radiation dose to a patient. Steps that can reduce risks of failures in equipment include comprehensive acceptance testing when equipment is installed and effective QA programmes to ensure performance is maintained, coupled with adequate maintenance as recommended by the manufacturer and an equipment replacement programme.

Mistakes can be made during the injection in which the radiopharmaceutical collects in local tissues, and several examples of significant tissue damage were reported from therapeutic administrations, some requiring excision and grafting of new tissue. Staff should receive extensive training in injection technique, but if there is extravasation of a radiopharmaceutical, it is important to stop the process immediately and try to reduce the patient's exposure by removing or dispersing the extravasated radiopharmaceutical. Procedures should be agreed in advance so that action can be taken immediately the problem is recognised.

Pregnancy is not a contraindication for a well justified diagnostic nuclear medicine procedure, but pregnancy status should be known in order to minimize risk to the unborn child and mother. Incidents that occur from time to time are inadvertent exposure of an embryo or foetus, resulting because the mother failed to realise that she was pregnant. Systems such as notices in patient waiting areas asking female patients to inform staff if they could be pregnant in appropriate languages help to reduce this risk, but there should also be agreed procedures for screening female patients and confirming the date of their last menstrual period prior to examination. Several presenters showed flow charts which are a useful aid to decision making. Identification of any patient who may be pregnant is crucial for therapy patients, especially when ^{131}I is to be administered, as this is taken up avidly by the foetal thyroid from 8-10 weeks gestation. In this case it is necessary to verify with a pregnancy test, to confirm that the patient is not pregnant. Precautions are also necessary for female patients who are breast feeding. For most diagnostic radiopharmaceuticals, a temporary cessation in breast feeding coupled with storage of milk expressed prior to the examination and discarding of expressed milk for a few hours or days afterwards is sufficient precaution in most cases. But for ^{131}I and ^{123}I administrations, cessation of breast feeding will be required both for protection of the infant and of the mother's breast tissue.

Radiopharamaceutical preparation is a complex process, particularly in PET centres, and close co-operation between radiopharmacists and medical physicists/ radiation protection experts is necessary to ensure safety is optimal. Poor planning of patient workflow and work procedures that do not make sufficient use of the protection systems can increase

staff doses considerably. Devices such as automatic systems for dispensing of activity directly into syringes are an important component that can reduce staff dose. In the case of semi-automatic or manual separation-injection working systems, the syringes with Luer lock are preferable. However, these devices can fail, so agreed actions are required for proper mitigation if this occurs.

Simple precautionary procedures, such as not sending patients injected with ^{99m}Tc for an ultrasound scan, while they are waiting to be imaged, can ensure that other staff within the hospital are not exposed unnecessarily. Extensive training of staff concerned with patients undergoing radionuclide therapy is particularly important to enable staff members to minimise their doses. All personnel should be given training in the procedures to be followed in situations where there is an equipment failure that could lead to further exposure.

A potential problem with radiopharmaceuticals is spread of contamination, with potential intake by staff. Precautions such as only handling radionuclides in facilities built for the purpose, with benches and floors that have sealed surfaces for easy decontamination, using fume hoods or isolators, and wearing disposable gloves and other appropriate protective clothing will minimise risks if a spill occurs. All manipulations of radiopharmaceuticals should be carried out over a tray with absorbent material to contain any spills and on a bench where the risk of dropping and breaking vials is lower. Laboratory materials should not be stored on floors or benches where they would impede decontamination, and syringes and vials should be transported in shielded containers that will contain any spillage. When giving an injection, close attention should be paid to ensuring that the connection between the syringe and needle are secure, excessive pressure should not be applied, and the whole syringe and needle assembly should be disposed of in a sharps container immediately after use in accordance with the established procedure for the disposal of radioactive waste. If measurement of residual activity in the syringe is required, safe recap devices should be used.

Since patients' body fluids will contain radioactivity, these also pose risks of contamination. If a patient were to vomit after administration of ^{131}I therapy, the level of contamination could be significant if this occurred in a public area within the hospital. It is therefore advisable to arrange for outpatients to remain in the department for 15-20 minutes in a designated area where a wash-basin/sink and toilet are available. Incontinent patients also present a risk and an assessment should be carried out when considering how a therapy is to be undertaken. Catheterisation may be considered, but potential problems of leakage from around a catheter, a split urine bag, or an open tap should be considered. Care is needed in protecting urinary bags when patients are moved. A frequent bag voiding and basic biologic protection measures normally provide adequate safety, but both staff and carers need to be aware of the precautions to be taken and potential risks.

Strict procedures should be in place for lung ventilation studies. If procedures are not followed properly there is a risk of air contamination leading to personnel contamination as well as unreliable ventilation study results. Checks should be made to ensure that the mask fits the patient and they are able to tolerate wearing it for the duration of the procedure, before commencing.

Management of radioactive material in general requires planning with systems to receive and document when radioactivity is delivered to a department, and ensure that it is transferred to secure, dedicated storage. Radioactive waste should be labelled and staff trained in procedures for dealing with it. Routing of pipework through which liquid waste is drained should be planned at installation, and tests monitoring removal of short half-life liquid should be carried out to check that waste does not collect at particular positions. Easy access should be provided in case of failure.

Public exposures may need to be limited. The criteria for hospitalization and release of therapy patients should be aimed at ensuring an effective dose less than 1 mSv to persons who come in contact with the patient. Solid or liquid wastes released from therapy patients, either during hospitalization or later at home, have the potential to induce the occurrence of "innocent accidents/incidents" at waste management facilities. There is a need for specific guidelines for the authorized release of hospital radioactive waste (radionuclides with very short half-lives, used in nuclear medicine therapy), based on realistic exposure pathways and envisaging the harmonization of legislation between neighbouring countries.

In addition to the internal reporting and incident management in the Nuclear Medicine department, a large scale gathering of events is beneficial in looking for trends that extend beyond a 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. The Meeting recommended upgrade of the IAEA voluntary reporting and learning system SAFRON (Safety in Radiation Oncology) to include also radionuclide therapy.

The meeting participants agreed that the improved continuous dialog between the national Regulatory bodies and the nuclear medicine professionals can be beneficial for incident prevention and improving radiation safety. Patients' representatives also need to be involved.

It was apparent that the range of radiation incidents that could and have occurred was wide, and some, particularly those involving therapy patients could have significant consequences. The need for guidance in setting out actions and recommendations was therefore apparent. The IAEA should prepare such guidance for preventing incidents and accidents in nuclear medicine, and disseminate through a publication, training material and training events.

Countries represented at the meeting

Austria	Italy	Qatar
Australia	Kyrgyzstan	Saudi Arabia
Belgium	Latvia	Serbia
Brazil	Lithuania	Switzerland
Canada	Luxembourg	Thailand
Chile	Montenegro	Ukraine
Denmark	Mozambique	United Arab Emirates
Estonia	Netherlands	United Kingdom
Ethiopia	Oman	United States of America
France	Poland	Uruguay
Indonesia	Portugal	Uzbekistan

Organizations represented at the meeting

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