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Organización Mundial de la Salud

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ICRP
INTERNATIONAL COMMISSION ON RADIOLIGICAL PROTECTION

FORO
Foro Iberoamericano de Organismos Reguladores Radiológicos y Nucleares

IAEA
International Atomic Energy Agency

IRPA
International Radiation Protection Association

“Nuclear medicine” session

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Abstract

In the session dedicated to Nuclear Medicine (NM) the five aspects considered the most problematic in radiation safety in NM were identified. These refer to:

1) Ensure the correct dose is delivered to the patient;
2) Avoid contamination and irradiation of the upper extremities, lens of the eyes and rest of the body;
3) Ensure the optimization of doses in diagnosis and treatment;
4 Promote the justification of the examinations in NM; and
5) Prevent incidents and accidents.

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The solutions provided to these problems were:

1) To implement quality management systems and quality control protocols as well as to educate and to train adequately the workers;
2) To improve the training and formation of workers, systematic use of personal protection equipment (PPE) and standard operation procedures (SOP's) and adaptation of working procedures;
3) To use standardized doses in diagnosis and planning each treatment by patient-specific dosimetry;
4) To train referring physicians and nuclear medicine physicians and to use referral guidelines for appropriate MN examinations; and
5) To incorporate effectively an incident reporting system for later analysis and learning through the use of event analysis techniques.

The proposed indicators for an adequate evaluation of the obtained progress in each one of the assessed aspects were:

1) Number of centres with an implemented quality management system and its degree of compliance in each centre;
2) Continuous trend analysis of dosimetric reports values;
3 Number of studies with dose optimisation protocols and/or patient-specific dosimetry;
4) Number of undergraduate medical programs that include subjects related to radiation safety and number of written standard operation procedures with indications of each study and percentage of studies that comply with these guidelines;
5) Degree of implementation of security incident reporting systems, degree of use of predictive analysis tools and number of incident evaluation meetings;

Some of the proposed solutions can be easily incorporated into daily practice. However, others require more time and, additionally, actions by international groups working together to provide concrete solutions.

KEY WORDS: radiological protection, nuclear medicine, justification, optimization.

Introduction

Technological development has opened up new perspectives for the use of radiation in medicine, notably improving its safety and efficiency. Nevertheless, as with all human activity, its incorrect or improper use can create health risks.

Given these potential risks, numerous intergovernmental institutions have contributed to the creation of basic radiological safety standards that harmonise the radiological protection requirements of patients, workers and the general public.

As an example, the European Union adopted Directive 2013/59 / EURATOM which establishes the basic safety standards and which has to be transposed into the legislation of

each of the member states before February 2018 [1]. At the global level, eight international organisations have co-sponsored the new basic international standards for radiation safety (BSS) [2].

An international conference on radiation protection organized by the International Atomic Energy Agency (IAEA) and the World Health Organisation (WHO) was held in Bonn in December 2012, culminating in the so-called **"Bonn Call for Action"**, which identified ten priority actions to improve radiological protection in medicine.

The Ibero-American Conference on Radiological Protection in Medicine (CIPRaM) was held in Madrid in October 2016 in order to verify the progress made in implementing the actions proposed in the "Bonn Call for Action", to identify problems and their possible solutions, to promote good practices and to define indicators to confirm that progress is being made. Specifically, the session devoted to Nuclear Medicine sought to formulate these aspects in the field of radiation protection in nuclear medicine (NM).

Development

No activity that uses ionising radiation is without risk, and therefore it must be adequately justified and optimised and, in the case of workers and members of the public, also subject to the established dose limits.

In MN practice - both its diagnostic and therapeutic aspects - the risks are of irradiation of the patient as well as of the worker and public, and of contamination, mainly for the worker.

There are many aspects associated with human resources, technology and the processes involved in radiation protection in MN. These are reflected in the actions identified in the so-called **BONN CALL FOR ACTION**.

During the dedicated MN session, the guest speaker José Luís Rodríguez Pérez (Chile), presented the five aspects that, in his opinion, he considered to be the most problematic for NM radiological protection in the Ibero-American area.

The first, and perhaps the most important, because it can be understood as encompassing all the other aspects, is **GUARANTEEING THAT THE DOSE ADMINISTERED TO THE PATIENT IS CORRECT**: The treatment administered to the patient, both in terms of diagnosis and therapy, is that which gives the patient the absorbed dose and, for it to be adequate, the first dose must be correct, as well as being the correct radiopharmaceutical, and the prescription must be administered to the right patient and must be properly justified, planned, optimised and executed. In the words of Elisa Vázquez (Spain), "whatever you have to do, do it right". At the same time, the equipment (activimeter, gamma camera, PET tomograph, etc.) must be properly calibrated (within correct usage parameters) for adequate radiation detection.

To ensure this, the guest speaker indicated that it would be appropriate to implement comprehensive quality systems (e.g. QUANUM [3,4]) and quality-control protocols, and to ensure that workers are properly trained. Eduardo Savio (Uruguay) went a step further in his

intervention, suggesting that the implementation of comprehensive quality systems and the training of users should be prerequisites for the authorisation of departments by regulators.

The second aspect considered was **CONTAMINATION AND IRRADIATION OF THE UPPER EXTREMITIES**: The manipulation of radiopharmaceuticals during MN practices involves the irradiation and possible contamination of the hands, as the work is done with open sources (it should be pointed out that this problem is exclusive to MN and does not affect radiodiagnosis). Due to low perception of risk by workers (because of overconfidence, malpractice, lack of knowledge, etc.), and according to the ORAMED study [5], the safe limits for skin doses can be exceeded, even more so at present due to the use of higher-energy beta, alpha and positron emitters. Renan Ramírez (Peru) proposed that the scope of this problem be studied, while Erick Mora (Costa Rica) and Elisa Vázquez (Spain) suggested the merits of taking lens irradiation and bodily incorporation into account as well.

The solution proposed by the guest speaker involves better training of workers, systematic use of protective measures and protocols, and the tailoring of working procedures to take these aspects into account. Juliano Cerci (Brazil) placed special emphasis on aspects of proper training and use of guidelines.

The third aspect was the **OPTIMISATION OF DOSES IN DIAGNOSIS AND TREATMENT**: The treatment administered to the patient is not always linked to optimal values or suited to new technologies; the same doses are maintained although the characteristics of the current, more sensitive equipment do not match those of old equipment. This also occurs in therapeutic practices in which the treatments administered are the result of the custom of using fixed doses without taking into account the individual characteristics of the patient. Eduardo O. Savio (Uruguay) added a problematic aspect regarding the traceability of radiopharmaceuticals, indicating that, sometimes, “even the meat of Uruguayan cattle that comes to our tables has better traceability than radiopharmaceuticals.”

The proposed solutions were the use of standardised diagnostic doses, such as those proposed by the Society of Nuclear Medicine and Molecular Imaging of the United States of America (SNMMI) or the European Association of Nuclear Medicine (EANM), and planning treatments with a specific internal dosimetry for each patient. According to Javier de Haro (Spain), to facilitate the latter would require a deeper knowledge of the pharmacokinetics of the radiopharmaceuticals used, and the information provided by the radiopharmaceutical datasheets should be more explicit with regard to these aspects - something which should be required by regulators.

The fourth aspect that was raised was the **JUSTIFICATION OF NM EXAMINATIONS**: This aspect is essential since referring physicians sometimes request MN examinations without knowing how their outcome will impact subsequent clinical decisions, and the nuclear doctor has no say in the proper prescription for the same.

The proposed solution is to improve the training of medical prescribers and nuclear physicians and to provide, and periodically review, appropriate guidelines for MN examinations. Renán Ramírez (Peru) pointed out that few health authorities have established criteria to prescribe ionising radiation tests that allow prescribers to be informed and trained to make suitable prescriptions.

Finally, the last aspect dealt with in the session was **PREVENTION OF INCIDENTS AND ACCIDENTS:** The speaker stated that very little analysis tends to be made of the causes of incidents or accidents, which might otherwise help us to learn from mistakes to avoid them in the future. Renán Ramírez (Peru) indicated that no serious accidents have been known[8] to take place in NM, and Fernando Godinho (Portugal) pointed out that the existence of incidents and accidents should be seen as an opportunity for improvement. Although their consequences may be limited, their occurrence indicates poorly-organised work.

The solution proposed by the guest speaker consisted of the effective incorporation of incident reporting systems for later analysis and learning through the use of event analysis techniques (root cause analysis) or predictive tools such as the SEVRRA Risk Assessment System for Radiotherapy [6.7]

In the context of input from the panelists that fell outside the scope of the problems outlined by the speaker, Fernando Mut (Uruguay) made a plea in favour of the appropriate use of radiation and against "radiophobia", indicating that it should be accepted that we need it, but that it should be used intelligently. He added that optimisation of protection does not always imply a lower dose, but that the dose should be adequate for the intended purpose: in diagnosis, it is the dose sufficient to achieve adequate images and avoid repetition of tests, while in therapy it means subjecting the tumour to the maximum dose, whilst steering clear of healthy tissues. Mónica Penedo (Spain), as a representative of the industry, said that manufacturers have made a great effort to develop and implement tools as part of their equipment to help determine the dose received by the patient, as well as radiation protection and quality-control systems that require users to have a good knowledge of the optimal use of radiation, and in recent years they have also incorporated training as a key element of MN diagnostic and treatment equipment. Erick Mora (Costa Rica) indicated that isolation times must be tailored once the patient has received a therapeutic treatment in order to minimise exposure of family members and the general public.

The indicators proposed for the adequate assessment of the progress achieved in each of the aspects evaluated were:

1. The number of centres with a quality-assurance Programme implemented and compliance scoring for each centre.
2. Trend analysis of reported dosimetric data.
3. The number of examinations with dose optimisation protocols or patient-specific dose estimation.
4. The number of undergraduate medical curricula that include subjects related to Radiological Protection and the number of written clinical protocols with indications of each study and the percentage of examinations that comply with these guidelines.
5. The degree of implementation of security incident notification systems, the degree of use of predictive analysis tools and the number of event evaluation meetings.

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[8] See further comments on this point from the attendees

Once the problems were known and solutions proposed, the last aspect dealt with was the roadmap for their implementation. It is obvious that some of the proposed solutions can be easily incorporated into daily practice. However, others require more time and, most importantly, actions by international groups working together to provide concrete solutions.

Additional contributions from attendees

Following the presentation by the guest speaker and the panelists, those participating in the session made a number of highly interesting contributions:

Laura B. Castro (Argentina) brought up an important and specific aspect of MN (with radiopharmaceuticals being one). Since radiopharmaceuticals are the element responsible for irradiating the patient and the worker, the regulation and authorisation processes governing the same have an important role in radiological protection. Other attendees added additional aspects, such as the production of radiopharmaceuticals on-site in health centres, the importance of quality-control and protection in the manufacture of radiopharmaceuticals.

The implications of the proliferation of hybrid equipment such as SPECT-TC and PET-CT in radiological protection were also pointed out.

Josep Martí (Spain) pointed out the need to register the actual dose of radiopharmaceutical given to the patient as an element of the traceability of that radiopharmaceutical

Caridad Borrás (Spain) reported a case of a NM fatal accident as the result of administration of an inadequate therapeutic dose to the patient [8,9]. On the same subject, Erick Mora (Costa Rica) pointed out that, although radiation was not considered the cause of death, a patient death was reported a few years ago by the screening team [10].

Other participants referred to issues that had also been highlighted in other sessions of the conference, such as the ongoing training of MN workers and the need for more comprehensive training (in the case of Spain, university degrees), and others sought to underscore the existence and use of working protocols for MN explorations, the existence and use of quality-control protocols in MN, and that MN treatments should be effected according to personalised dosimetry, deprecating historical practices and standard or fixed doses.

Conclusions

The main problem encountered is the need to do our jobs well in order to protect the patient, ourselves as workers, and the population in general. To this end, we must work to ensure that the correct dosage is administered to the right patients and that appropriate and up-to-date training is required, that adequate working, quality-control and radiation protection protocols are used and updated according to the technology in service at any given time, carrying out the studies based on a correct prescription by the prescriber and supervised or validated by a qualified nuclear doctor and avoiding incidents or accidents but assuming these as an opportunity for improvement.

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