Session 7

Learning from unintended and accidental exposures in medicine

RISK ANALYSIS BASED ON OCCURRENCE AND SEVERITY OF INCIDENTS FROM AN INSTITUTIONAL INCIDENT LEARNING SYSTEM

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Abstract

The study aims are to develop an institutional Incident Learning System (ILS) and estimate the occurrence and severity of radiotherapy incidents that were reported over a period of 6 years, and then rank the major radiotherapy processes based on their vulnerability for errors at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). Data was collected from the Departmental Incident Report files, and the radiotherapy errors were classified into five levels (where levels 1 and 2 were considered clinically significant, reportable errors and Levels 3 to 5 as errors without clinical significance). In addition to this, the AAPM TG-100 severity scoring table (1 to 10) was used to quantify the risk. Due to the severity and occurrence of incidents, pre-treatment processes (mainly, treatment planning and data transfer processes) were found to have the highest risk for treatment errors. By strengthening the pre-treatment quality control measures in the department, a significant number of treatment errors could be prevented.

1. INTRODUCTION

Incident Learning System (ILS) is one of the many approaches to improve patient safety and treatment quality [1]**.** Unlike in many developed countries, there is a lack of published data on the nature and occurrence of radiotherapy incidents from developing countries [2, 3]. The only available information is through the International Atomic Energy Agency (IAEA) and World Health Organization's (WHO) regular basis TLD postal dose audits of hospitals in developing countries [2].

In the comparisons of radiotherapy settings between developed countries and developing countries, there are differences in the treatment techniques, human resources, treatment machines and other infrastructures [4]. However, implementing sophisticated technologies and treatment techniques in some of the developing countries are ever increasing. Therefore it is equally important to move to learn safety culture and underline the need to have the incident learning system in place [3].

Therefore, this study aimed to develop an institutional Incident Learning System (ILS) and measure the occurrence and severity of radiotherapy incidents that were reported over a period of 6 years. Moreover, then rank the major radiotherapy processes based on their vulnerability for errors at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) Johannesburg, South Africa.

2. MATERIAL AND METHODS

A total of 129 radiotherapy incidents were reported from January 2010 to December 2015 at CMJAH. Data was collected from the Departmental Incident Report files and the radiotherapy errors were classified into five levels, where levels 1 as the highest level and reportable incident, level 2 considered as clinically significant incidents, levels 3 minor radiation incidents and level 4 and 5 are near misses and non-conformance, respectively [5]. In addition to this, the American Association of Physicists in Medicine (AAPM) TG-100 [6] severity scoring table (1 to 10) was used to quantify the risk.

The department has a structured Quality Assurance (QA) program with documented policies, periodic and routine medical physics Quality Control (QC) procedures, and a paper-based incident reporting system.

Regarding the incident reporting and learning system, a Root Cause Analysis (RCA) committee has been formed and conducts a regular monthly meeting to analyze the underlying causes of incidents.

3. RESULTS

97% of incidents were related to External Beam Radiotherapy (EBRT). About 93% of incidents were process-related (only nine incidents were due to hardware failures).The majority of incidents were reported under incident level 3 (minor radiation incident) as shown in Figure 1.

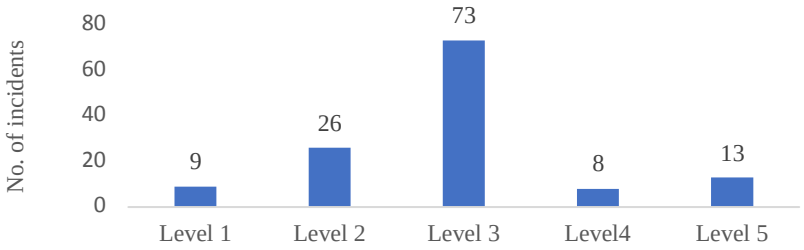

Figure 1. Level of incidents

33% (42 reports) of incidents arose at the treatment planning (including Monitor Unit calculations) stage, and incidents during the treatment delivery and patient treatment data transfer processes were 27% (35 incidents) and 21% (27 incidents), respectively. The rest 19% incidents occurred at different stages (patient evaluation, prescription, simulation and imaging, positioning and immobilization, and block preparation). Among these incidents, about 27% (35 out of 129) were clinically significant (Level 1 and 2) with high severity values ($\geq$7).

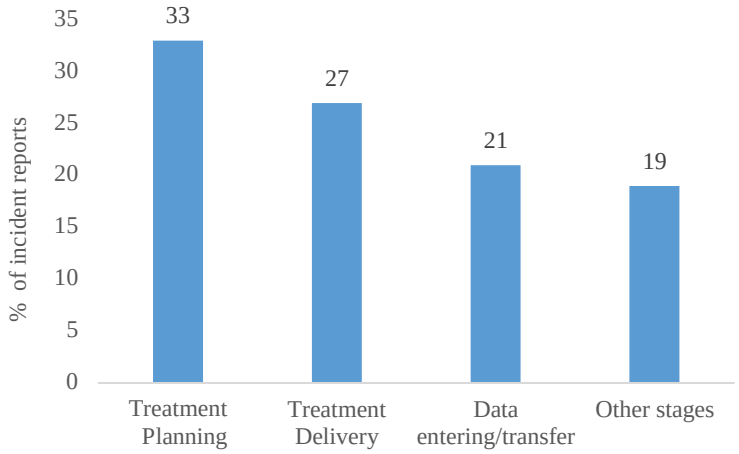

Figure 2: Occurance of Incidents at different treatment stages

4. DISCUSSIONS

There was an average of 21 incidents reported per year which is small compared with other similar studies, for example, Mutic *et al.* have observed an incident report rate of 1 per 1.6 patients treated [7] and Clark *et al.* have also reported 11.6 incident report per week [8]. The majority of incidents arose at different stages of the pre-treatment processes (mainly treatment planning and data transfer) but were not detected until the treatment delivery stage. Most errors were detected at the time of patient treatment (87 out of 129) as shown in Figure 3.

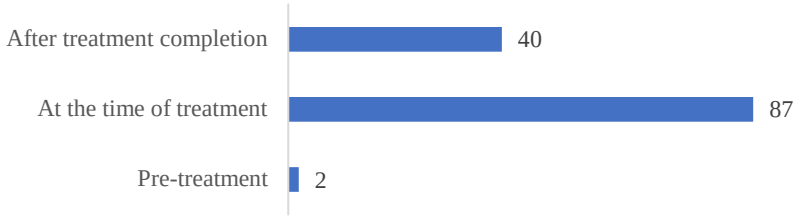

Figure 3: The number of incident detected at pre, during and after treatment course

The data show that a total of 340 treatment fractions were incorrectly delivered. Out of these, 128 fractions were clinically significant (level 1 and 2 incidents), mainly due to the errors in the treatment planning and data transfer stages. Out of 35 clinically significant incidents, 11 incidents arose at the treatment delivery stage and most of these incidents were due to errors in patient identification (9 patients were treated with another patient's data for one treatment fraction). Incidents that arose at the treatment planning and data transfer processes were usually detected after the patients had received two or more fractions. As shown in Figure 3, only two incidents were reported at pre-treatment stage while most of the errors were originated in the treatment planning and data transfer processes. The data indicates that 128 incorrect treatment fractions may not have been delivered if additional pre-treatment quality control measures had been instituted.

Since the majority of incidents were poorly reported and near misses were not well documented, it was difficult to identify the primary causes and contributing factors of incidents as well as how the incidents were detected (incident detection mechanism).

In an attempt to improve the incident reporting and develop departmental ILS, a universal incident reporting database has been developed and tested, figure 4. The content and structure of this electronic database were developed based on the document presented by Ford and his colleagues [1]. The treatment processes were mapped for the corresponding treatment techniques (2D, 3D, and IMRT) used in the department. The treatment stages where the incident initiated, the severity values of the dosimetric effect of the incident, contributing factors, stages where/how the incident detected and the number of patient treatment fractions affected by the incident is included in drop-down option list in the database.

Patient ID	Date	Tx Technique	Tx Stage	Factors	Effect	Siverity	Level	Detected on	No.#s	Incident description	Reported by
ID 001	######	Two_D	MU-calculation	[illegible]	limited_toxicity	5	Level-3	During_tx	3	.....	RTT
ID 002	######	Conformal_3D	Treatment-information-transfe	Technical	Tumor_underdose	6	Level-2	Tx_completed	23	.....	MP
ID 003	16-Sep-12	Three_D	Patient-set-up	[illegible]	Inconvienience	2	Level-5	Pre_tx		.....	QA-RTT
ID 004	12-Dec-15	IMRT	Planning	Other	[illegible]	6	Level-3	Pre_tx		.....	RO

Figure 4: Departmental incident reporting database

5. CONCLUSIONS

Due to the severity and occurrence of incidents, pre-treatment processes (mainly, treatment planning and data transfer processes) were found to have the highest risk for treatment errors. By strengthening the pre-treatment quality control measures in the department, a significant number of treatment errors could be prevented.

Further research is ongoing on **Risk analysis of EBRT by measuring the occurrence and detectability of errors using the Failure Mode and Effect Analysis (FMEA) in a low and a middle-income country**.

ACKNOWLEDGEMENTS

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REFERENCES

[1] Ford, E.C., Fong de Los Santos, L., Pawlicki, T., Sutlief, S. and Dunscombe, P., 2012. Consensus recommendations for incident learning database structures in radiation oncology. *Medical physics*, *39*(12), pp.7272-7290.
[2] Shafiq, J., Barton, M., Noble, D., Lemer, C. and Donaldson, L.J., 2009. An international review of patient safety measures in radiotherapy practice. *Radiotherapy and Oncology*, *92*(1), pp.15-21.
[3] Ganesh, T., 2014. Incident reporting and learning in radiation oncology: Need of the hour. *Journal of Medical Physics/Association of Medical Physicists of India*, *39*(4), p.203.
[4] Cunningham, J., Coffey, M., Knöös, T. and Holmberg, O., 2010. Radiation Oncology Safety Information System (ROSIS)–profiles of participants and the first 1074 incident reports. *Radiotherapy and Oncology*, *97*(3), pp.601-607.
[5] RCR, S., CoR, I.P.E.M. and NPSA, B., 2008. Towards safer radiotherapy. *London, UK: The Royal College of Radiologists*.
[6] Thomadsen BR, Dunscombe P, Ford E, Huq MS, Pawlicki T, Sutlief S. Quality and safety in radiotherapy: Learning the new approaches in task group 100 and beyond. AAPM Monograph. 2013 Jun 16(36):273-349.
[7] Mutic, S., Brame, R.S., Oddiraju, S., Parikh, P., Westfall, M.A., Hopkins, M.L., Medina, A.D., Danieley, J.C., Michalski, J.M., El Naqa, I.M. and Low, D.A., 2010. Event (error and near-miss) reporting and learning system for process improvement in radiation oncology. *Medical physics*, *37*(9), pp.5027-5036.
[8] Clark, B.G., Brown, R.J., Ploquin, J.L., Kind, A.L. and Grimard, L., 2010. The management of radiation treatment error through incident learning. *Radiotherapy and Oncology*, *95*(3), pp.344-349.

LEARNING OUTCOMES FROM RADIATION INCIDENTS IN HOSPITAL AND DENTAL SETTINGS (4 CASE STUDIES)

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Abstract

The Department of Medical Physics and Bioengineering, St. James's Hospital, Dublin provides Radiation Protection Advisory and Physics Support services to a large number of hospitals and dental practices across Ireland. Radiation incidents of varying severity occur occasionally and are recorded and reported upon as required by national legislation. Four radiation incidents are reviewed in the paper and follow up actions and learning outcomes are identified.

1. INTRODUCTION

The Department of Medical Physics and Bioengineering, St. James's Hospital, has been providing Radiation Protection Advisory and Physics support services to a large number of external Hospitals and Dental Practices throughout the country for over 30 years. Radiation incidents of varying severity occasionally occur in the external hospitals and dental practices and are recorded, reviewed and reported upon as required by national legislation [1-4]. Following the assessment of each radiation incident, learning opportunities are identified and measures are put in place to avoid a re-occurrence as per local policies and national guidelines [1-2].

The paper reviews 4 radiation incidents with a focus on the learning outcome from each case. While some of the incidents occurred some time ago, the learning outcomes remain relevant, particularly with the planned implementation of the new Basic Safety Standards Directive into European Legislation in February 2018 [5-6]. One case study has been taken in each of the following categories: (1) Equipment safety, (2) Patient safety, (3) Staff and public safety and (4) Safety of the foetus.

2. CASE STUDY 1 – EQUIPMENT SAFETY:

2.1. Description of the incident and Dosimetry:

A new intra-oral dental X-Ray unit was installed in a newly equipped dental surgery [7]. The suppliers of the equipment installed the X-Ray unit following instruction from the Health Board. The dentist and dental assistant attended the surgery in preparation for it's opening the following week and plugged in the X-Ray machine. After about an hour and a half the dentist became aware of a humming sound and noted that the head of the X-Ray unit was hot. He identified that the X-Ray unit had been exposing in error, with the use of an X-Ray film. The dentist had been sitting close to the tube head during the period and the assistant was some distance away. The machine was unplugged and arrangements were made to have the fault corrected. The dentist returned to the clinic the following week, tested the unit with a film and found there to be no blackening so assumed the fault had been corrected. As he went to undertake the first X-Ray, the machine exploded spraying cooling oil around the surgery. The patient was uninjured. Between 3 and 5 weeks later the dentist and dental assistant experience a variety of symptoms including severe abdominal pain, nausea vomiting, and localised symptoms in the shoulder, hand, mouth and eyes. An account of the incident appeared in a 1996 BIR publication [7]. The technical cause of the incident was that on installation the exposure-timer switch was bypassed. As a result, the electrical supply was directly connected to the X-Ray tube once the equipment was

plugged in and the socket turned on. The colour coding of the internal wires in the unit was such that a mistake of this type was not excluded and constituted a serious design fault. No acceptance testing or commissioning of the equipment had been performed on behalf of the purchasers by an agency or expert independent of the suppliers. At the time, local arrangements for reporting incidents of this type were not satisfactory - There was a lapse of time before the incident was raised by the dentist and assistant with the medical advisers and the Health Board did not pursue a report on the incident.

Following investigation, the dose to the dentist was estimated to be of the order of 0.24+/-0.17Sv. The dose to the assistant was estimated to be of the order of 0.2mSv. A significant range of medical findings arose for the dentist and the dental assistant. For the dentist these included: skin lesions, ocular problems, lesions in mouth, GI symptoms and persistent IBS, anxiety and phobia re radiography. The added risk of fatal cancer for the dentist was estimated to be of the order of 1%.

2.2. Follow up and Learning outcomes:

The design fault was reported to and taken up by Electrical Standards Organisations. Strong recommendations were made to national authorities for X-Ray equipment to be commissioned by an expert independent of the suppliers and for Quality Assurance and maintenance programmes to be implemented. These recommendations were taken up in national Code of Practice published by the National Regulatory Authority in Ireland [8]. A requirement for prompt notification of incidents was included in the National Regulatory Authority licence conditions. A requirement for more rigorous training of engineers was also recommended. Dental radiation protection committees were established in the public sector and fostered a substantial equipment replacement programme and training staff/patient radiation protection that was both successful and sustained to the present day.

3. CASE STUDY 2 – PATIENT SAFETY:

3.3. Description of the incident and Dosimetry:

In 2015, a patient presented for a CT neck and thorax scan at a busy University Hospital. The Hospital is part of a group of 6 within a region. The CT referral had been vetted by a radiologist prior to the appointment having been made and previous records had been sought using the patient's hospital identification number as part of the justification process. There were no records of such a scan haven been undertaken previously in the hospital and the scan was performed. Following the examination, the patient informed the radiographer that a similar examination was already performed on him in another hospital in the region.

The cause of the incident was that two requests were issued for the same CT examination by the same clinical team. The first request was issued to the University hospital, which had a waiting list. A second request was issued to a different hospital in the region with a shorter waiting list. This scan was initially performed in the hospital with the shorter waiting list. The other request was not cancelled and the patent had the same scan, in the initial hospital. It transpired during the course of the investigation that issuing multiple requests by clinical staff, to bypass waiting lists, was not a unique occurrence. Furthermore, the patient had three different patient identification numbers in three different hospitals in the region. A National Integrated Medical Imaging system is in place, but it does not support a unique patient identification number across hospital sites. The presence of such a unique identification number would have facilitated a more comprehensive review of the patient's diagnostic imaging history as part of the justification process. The patient dose for the incident was approx. 8 mSv.

3.4. Follow up and Learning outcomes:

The practice of requesting multiple examinations across the hospital group (and indeed between the public and private health sector) in an attempt to obtain the earliest possible appointment was raised with the clinical staff and has ceased. An additional CT scanner was recently installed in the University Hospital which should address some of the problems relating to long waiting lists. A request was made to the National Integrated Medical Imaging management team to escalate the establishment of a unique patient identifier at an aid to more comprehensively assess previous diagnostic records as part of the justification process.

4. CASE STUDY 3 – STAFF AND PUBLIC SAFETY:

4.5. Description of the incident and Dosimetry:

In 2001, a radiographer working in the Operating Department of a large Hospital noticed a number of lead aprons outside an operating theatre that was not designated for X-Ray use. Upon investigation, it transpired that a UK company was conducting X-Ray screening procedures for lithotripsy, in a non-designated operating theatre, on behalf of the Urology Consultants unknown to the Radiation Protection Adviser (RPA) or the Radiology Department. The procedures were being undertaken using a mobile C-Arm which had been brought on site from the UK. The UK company was not in compliance with Irish legislation for the use of radiation in Hospitals. Further analysis demonstrated that the practice had been systematically performed for a period of 4 years by two separate UK companies. In all, 293 X-Ray screening procedures took place. Furthermore, the mobile C-Arm equipment was routinely left unattended in the hospital the night before the procedures.

The direct cause of the incident was poor awareness of the Irish Legal framework relating to the safe use of radiation in hospitals among the professionals involved and the service provider. The company was operating under UK legislation (obviously not applicable in Ireland), and was in breach of its Irish licence as it had failed to consult with the Hospitals RPA. The previous company was unlicensed to operate in Ireland which is an offence. The Consultant Urologists, hospital management or the purchasing department had not communicated with the RPA or any member of the Radiology Department prior to engaging the services of the companies and commencing a new practice. As the RPA had not been consulted, the Hospital was in breach of its licence conditions and consequently all of the requirements tasks involving RPA input had not been carried out. Doses of the order of 0.012 – 0.074 mSv may have been received by staff working in adjoining areas over the 4 year period. It was fortunate that the operating theatre in question had been partially shielded and staff doses were substantially lower than they might have been and a more significant incident was avoided.

4.6. Follow up and Learning outcomes:

A report was made to the National Regulatory Authority and the licence requirements for external companies using mobile X-Ray equipment in Irish Hospitals were strengthened. Education sessions on the Irish Legal framework were provided by the Hospital's RPA to the UK company. Awareness was raised at hospital management and purchasing level regarding the requirement to consult with the RPA prior to the commencement of new practices involving ionising radiation. Measures were put in place for the future lithotripsy procedures in the hospital including licensing, shielding, radiology cover and security arrangements. A reporting structure between the UK company and the Hospitals Radiation Protection Committee/RPA was established.

5. CASE STUDY 4 – SAFETY OF THE FOETUS:

5.7. Description of the incident and Dosimetry:

A patient attended the Nuclear Medicine Department in a hospital for a bone scan of her pelvis and SI-Joints in 2015. In compliance with the local policy on the irradiation of female patients of childbearing age, the patient was asked if there was any possibility that she might be pregnant. The risks of radiation exposure during pregnancy were explained and the patient replied that there was no possibility of pregnancy. In addition to questioning regarding possible pregnancy, the '10 day rule' is routinely used in the hospital for all Nuclear Medicine examinations as a further measure to outrule exposure of the foetus. The '10 day rule' dictates that Nuclear Medicine examinations only be conducted on female patients of childbearing age within the first 10 days of the Last Menstrual Period (LMP), unless it is overruled on clinical grounds. The first day of the patients LMP was not within the previous 10 days. Following further questioning the patient assured the radiographer that she was not pregnant and signed the hospital form indicating that this was the case. The form was countersigned by the radiographer. The examination was carried out although the'10 day rule' requirement was not overruled by a practitioner. The patient contacted the department two weeks later to advise of her newly discovered pregnancy status and to indicate that she was pregnant at the time of the scan. Although proper questioning regarding pregnancy status took place, the local policy on the use of the '10 day rule' was not

adhered to. The Nuclear Medicine Department is open only one week per month and less often during Summer months due to resource issues and limited service demands. Given the restricted opening hours, adherence with the policy on the use of the '10 day rule' is difficult. The dose to the foetus was estimated to be in the order of 3mGy with an estimated small increase in stochastic risk of 1 in 4,300 compare to the baseline risk of childhood cancer of 1 in 500.

5.8. Follow up and Learning outcomes:

The department had implemented a policy to which adherence was difficult given the opening times. As a result, overruling the policy had become commonplace. The use of the '10 day rule' was reviewed by the hospital staff in conjunction with the RPA and measures were put in place to facilitate it's continued use. These included reviewing the opening times of the Department and staggering the days each month to facilitate improved flexibility in scheduling appointments. Higher activity generators also allow more flexibility during the week the Department is open.

6. DISCUSSION:

The 4 case studies have relevance today with the scheduled enactment of the new Basic Safety Standards Directive (BSS) into European Legislation by February 2018 [5]. Case 1 relates to dental radiology which is in general considered to be a low dose practice. The new BSS requires a graded approach to regulatory control commensurate with the magnitude and likelihood of exposures resulting from the practice. While a different approach to regulatory control in dental radiology may be taken in future, case 1 is worth revisiting giving the fact that one of the most significant radiation incidents to have occurred in Ireland relates to a simple intra-oral dental X-Ray unit. As recently as 2017, the authors have identified technical problems with intra oral-dental equipment with radiation outputs in excess of 60% higher than the norm. Case 2 relates to patient safety and is relevant in the current climate with a high demand for services resulting in long waiting lists. It is essential that proper justification is made for each examination, as required by the new BSS and that modern systems facilitate relatively easy access to previous diagnostic records.

Case 3 relating to staff safety highlights the need for a robust radiation safety culture and good communication in an organisation. There is a need for individuals involved with the use of ionising radiation to have knowledge of their responsibilities and the appropriate education and training as required in the BSS. Case 4 relates to the protection of the foetus, some of the difficulties encountered in this regard and the need for enquiry about pregnancy status, a requirement of the BSS.

7. CONCLUSIONS:

Four radiation incidents are reviewed and the learning outcomes are presented in the light of the new BSS Directive. The cases highlight the importance of reporting and critically reviewing occurrences (incidents and near misses) in order to improve radiation safety culture and practices.

REFERENCES

[1] Guidelines for reporting radiological incidents to the Radiological Protection Institute of Ireland, RPII, 13/03, 2013.

[2] Template for developing a Patient Radiation Protection Manual for facilities using medical ionising radiation, Medical Exposures Radiation Unit, Ireland, August 2013.

[3] S.I. no 478/2002 - European Communities (Medical Ionising Radiation Protection) regulations, 2002.

[4] Radiological Protection Act, 1991 (Ionising Radiation Order), SI 125, 2000.

[5] Radiation Protection and safety of radiation sources: International Basic Safety Standards, GSR Part 3, IAEA, 2014

[6] Council Directive 2013/50/EURATOM laying down the basic safety standards for protection against the dangers arising from exposure to ionising radiation, 2013.

[7] Faulkner K, Harrison R,M, Radiation Incidents, papers from the meetings Radiation Incidents in Hospitals, 5th December 1994 & Uncertainties, Errors and Accidents in Radiotherapy, 24th April 1995, BIR, 1996.

[8] Code of Practice for Radiological Protection in Dentistry, Radiological Protection Institute of Ireland, RPII 96/2, 1996.

LATIN AMERICA IN THE PREVENTION OF ACCIDENTS IN RADIOTHERAPY. USE OF THE RISK MATRICES METHODOLOGY.

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Abstract

This paper presents the advances and perspectives of the work developed, within the regional project RLA9075 of the IAEA, by Latin America countries, related to the prevention of accidents in Radiotherapy. RISK MATRICES methodology and the "SEVRRA" tool have been used to apply a prospective approach that allows estimating key risks in each Radiotherapy Department analyzed. In order to achieve this goal, many countries in the region have shown their interest in conducting workshops involving physicians, medical physicists and technologists of different radiotherapy services operating in each country. The workshop including: training in the risk matrix methodology, installation the SEVRRA tool, conducting a preliminary risk self-assessment exercise and the analysis of results of that self-assessment. The present work shows, as an example, the result of the evaluation carried out by a radiotherapy department in a country where the risk self-assessment process has been completed. Presents an Action Plan developed to reduce unacceptable risks. This plan should be use, to prioritize of those human and material resources necessary to improve the safety and quality of the radiotherapy process.

1. INTRODUCTION

Accident prevention in radiotherapy is a priority for regulators and users. Accidents occurring around the world show that it is a topical issue and that nobody can be satisfied with the actions carried out to date [1–3]. Such an assessment was confirmed during the Bonn Conference in December 2012. This conference decided to include, within the 10 "Bonn call for action" [4], a point that is specifically aimed at "Increasing the prevention of incidents and radiological accidents in medicine".Point # 7 of the “Bonn call for action” highlights the need for "Implementing prospective risk analysis methods concerning the safety of clinical practices" as these methods can be very important at identifying vulnerable aspects of safety, in the medical practices.

The Ibero-American Forum of Radiological and Nuclear Regulators (FORO) has been a pioneer in the application of risk analysis techniques for the prevention of accidents in radiotherapy [5–6]. Since 2006, FORO has developed and applied the methodology of "Risk Matrices" in different radiotherapy techniques. Already since 2012, the IAEA and the FORO jointly published IAEA-TECDOC-1685/S [6] with the results of these works and also announced the publication, free to use, of the SEVRRA tool (System of the Risk Assessment in Radiotherapy). After more than 3 years of SEVRRA pilot applications in nearly 150 radiotherapy services of the Spain and Latin America, the advantages of using the methodology had been evident. Therefore at the formulating moment of the IAEA Project RLA / 9/075, many of the Latin American countries showed their interest in this topic and proposed to develop actions to do specific self-assessments are run, using the methodology of risk matrices and the SEVRRA tool. The present paper shows the joint strategy developed by the IAEA, the FORO and the countries of Latin America to implement this aspect contained in the Bonn call for action. Taking advantage of the synergies of the joint work, it has been possible to train Radiotherapists,

Medical Physic and Technicians in the use of the Risk Matrix methodology and the SEVRRA tool and has contributed to raise the safety and quality of radiotherapy treatments performed in this region.

2. METHODS.

Safety assessments are the most important tool available for accident prevention, in this sense we traditionally recognize three approaches to safety assessments: the prescriptive approach, the retrospective approach and the prospective approach. The prescriptive approach consists in considering that safety is based on strict compliance with the rules, assuming that the requirements of the standards are met, the occurrence of an accident will be minimized. The retrospective approach is based on the lessons learned from accidents, assuming that one must be prepared to avoid recurring accidents. The prospective approach, in turn, is to evaluate the safety of the practice by postulating a sufficiently broad and detailed list of events that could trigger an accident, considering the defences that exist and evaluating the risk of occurrence of potential accidents.

The IAEA's RLA/9/075 project plans to disseminate in Latin American countries the application of the prospective approach in the practice of Radiotherapy by conducting Workshops for radiotherapist, medical physics and technicians working in that area. In these workshops, the participants are trained in the methodology of Risk Matrices, the SEVRRA computer tool is made available to them and risk self-assessment exercises are carried out in the Radiotherapy Services represented in these activities.

2.1. Prior preparation and organization of the Training workshop.

Under RLA / 9/075, countries request the IAEA to support this issue and undertake to assume the organizational aspects of the Workshop. The national counterpart of the project is responsible for disseminating the activity among all radiotherapy services in the country, highlighting the objectives of the workshop and selecting the potential participants in these activities. The emphasis of the counterpart is to ensure that at least one radiotherapist, a medical physicist, a technologist, and a radiation protection officer from each radiotherapy department participate in the workshop. This creates a team that can convey the full experience of this activity to the rest of the staff where they work.

2.2. Initial training on the theoretical aspects of the risk matrices methodology.

The initial training in the theoretical aspects of the risk matrices methodology is one of the fundamental objectives of the Workshop, since it is required that the participants can understand the methodology to carry out all the activities that will be addressed later. This training includes the following aspects:

- Background of the topic of risk matrices in radiotherapy.
- Approaches to safety assessments.
- General aspects of Risk Matrix methodology.
- Preparation of the list of initiating events.
- Estimation of the frequencies of occurrence of initiating events.
- Evaluation of the severity of the consequences of the initiating events.
- Defence in-depth analysis. Estimation of the probability of failure of barriers.
- Detailed analysis of the defences. Evaluation of the robustness of the defences.
- Risk estimation using the SEVRRA tool.

With all this content the participants can understand the methodology and acquire all the skills to be able to independent apply the methodology and use correctly the results of the analysis.

2.3. Installation of the SEVRRA tool and familiarization with the use of the tool.

Once the participants have all the theoretical knowledge of the methodology of risk matrices they are able to install the SEVRRA tool on their PC. Therefore, participants must download the tool from the FORO website (www.foroiberam.org) and select the technique of Radiotherapy (Teletherapy with LINAC, Teletherapy with Co-60, HDR brachytherapy and LDR brachytherapy) that they wish to evaluate. The IAEA expert explains the content and potential of SEVRRA, highlighting how this tool should be used to make a correct risk assessment.

2.4. Carry out a risk self-assessment exercise in the radiotherapy departments represented in the workshop, using the SEVRRA tool.

The risk self-assessment exercise aims at the participants to use SEVRRA and to identify and correctly interpret the initiator events, barriers and reducers contained in this tool. The completion of the self-assessment exercise consumes most of the time scheduled for the Workshop (approximately 3 working days). Throughout this work, the IAEA expert monitors the progress of the exercise and controls the correct application of the methodology. At the end of the self-assessment exercise, each participant radiotherapy department can print the report, generated by SEVRRA, obtaining its corresponding risk profile. The results of each radiotherapy department are analysed in a plenary session with the aim of training participants to use these results in the development of an "Action Plan" to reduce risks to acceptable levels.

3. RESULTS

The following is an example of the results of the exercise performed by one of the radiotherapy departments participating in the workshops.

In making risks estimation in the actual specific working conditions of this radiotherapy department the following risk profile was obtained. As can be seen Fig.1, this radiotherapy department is working with 29% of High Risks (RA) considered unacceptable according to the acceptance criteria proposed in document IAEA-TECDOC 1685/S.

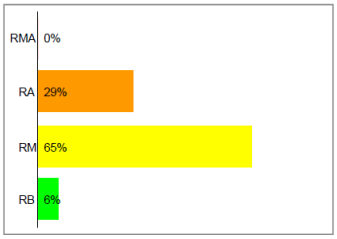

FIG. 1. Radiotherapy department risk profile.

Taking into account the need to reduce high risks, SEVRRA shows in its report, a list of those barriers and reducers that have not been implemented in the Department of Radiotherapy evaluated, highlighting those that could reduce the risk in several accidental sequences evaluated with Risk High (RA). In this case, this radiotherapy department has proposed implementing the following 5 safety measures (barriers and reducers) shown below.

- Portal image at the beginning of the treatment.
- Participation of the Radiotherapist, the Medical Physics and the Technician in the initial treatment session.
- Moderate work load.
- Planned maintenance schedule.
- Weekly medical check-up.

The application of only these 5 safety measures in this radiotherapy department, would reduce the High Risks (RA) from 29% to 5% as shown in Fig. 2.

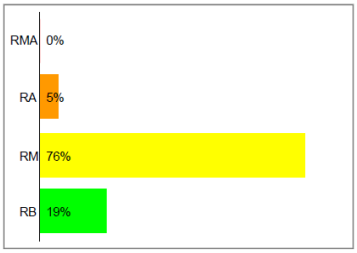

FIG. 2. Risk profile of the department after implementing the 5 prioritize safety measures.

From this result the "Plan of action" elaborated contemplates to implement these 5 defences as a priority. In addition, this action plan includes 7 other specific measures that would reduce the risk of the remaining 5% of events assessed with High Risk (RA).

4. DISCUSSIONS.

Until August 2016, these workshops were carried out in 11 countries of the Latin American region.

Table 1 provides detailed information on the number of radiotherapies departments that have been linked to these RLA / 9/075 project activities in each of the participating countries.

TABLE 1. Number of radiotherapies departments that have been linked to these RLA / 9/075 project activities in each of the participating countries.

Nr.	Country	Number of participating radiotherapy departments	Date of the Workshop
1.	El Salvador	6	October 12-16, 2015
2.	Venezuela	11	November 16-20, 2015
3.	Colombia	24	December 7-11, 2015
4.	Nicaragua	1	February 22-26, 2016
5.	Honduras	3	May 9-13, 2016
6.	Paraguay	2	April 18-22, 2016
7.	Costa Rica	4	June 20-24, 2016
8.	Guatemala	2	May 2-6, 2016
9.	Ecuador	9	May 23-27, 2016
10.	Perú	7	April 4-8, 2016
11.	Chile	13	August 22-27, 2016

As you can see it has made 82 radiotherapy departments train their staff and make their risk self-assessment exercises. In all these countries it was possible to achieve a broad representation of radiotherapists, medical physics and technicians, which demonstrates the need to work as a team aiming to improve the safety and quality of the treatments they perform.

The FORO continues to work to include in SEVRRA new models that allow the evaluation in other techniques of treatment and diagnosis (IMRT, Radiosurgery, IORT and Nuclear Medicine). These developments will expand the possibilities offered by the methodology of risk matrix and the SEVRRA tool to contribute to the prevention of accidents in medical practices.

5. CONCLUSIONS

Conducting safety assessments in the practice of radiotherapy should include the use of the prospective approach based on risk analysis techniques as suggested in the "Call for Action" at the Bonn Conference 2012. The methodology of risk matrices and the SEVRRA tool developed by the FORO have shown that they are a useful and easy to apply option.

The IAEA's RLA / 9/075 project has enabled physicians, medical physicists and technicians from various Latin American countries to receive training in risk analysis techniques, particularly in the use of the Risk Matrix methodology and the SEVRRA tool.

The workshops on "Prevention of accidents in radiotherapy with the use of the methodology of risk matrices and the SEVRRA tool" have allowed many departments of Radiotherapy in Latin America to detect their main weaknesses and implement action plans to reduce risks.

With the use of SEVRRA it has been possible to demonstrate that, in most cases, the application of a few measures (barriers and reducers) can have a high impact on risk reduction. These findings are very important to demonstrate to hospital management the priority that some improvement actions should have when human and material resources are limited.

ACKNOWLEDGEMENTS

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REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY. Lessons learned from accidents in radiotherapy, Safety Reports Series No. 17, IAEA, Vienna (2000).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY. Accidental overexposure of radiotherapy patients in San José, Costa Rica. IAEA, Vienna, (1998).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY. Investigation of an Accidental Exposure of Radiotherapy Patients in Panamá. IAEA, Vienna, (2001).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY. Bonn Call For Action, IAEA, Vienna, (2013).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY. Aplicación del Método de matriz de riesgo a la radioterapia, TECDOC-1685/S, IAEA, Viena, (2012).

[6] INTERNATIONAL ATOMIC ENERGY AGENCY. Análisis Probabilista de Seguridad de Tratamientos de Radioterapia con Acelerador Lineal, TECDOC-1670/S, IAEA, Viena, (2012).

[7] HOLMBERG, O., McCLEAN, B., Preventing treatment errors in radiotherapy by identifying and evaluating near-misses and actual incidents, Journal of Radiotherapy in Practice 3, (2002).

EXPERIENCE FEEDBACK FROM EVENT, REPORTING AND LEARNING IN RADIOTHERAPY- HOW TO SHARE EXPERIENCE? THE FRENCH EXPERIENCE

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Abstract

Lessons must be drawn from each event related to radiation protection in order to reinforce the measures to prevent recurrence of the incident. In France, the notification of events in the medical field is a regulatory requirement since 2007. Each year, the French nuclear safety authority (ASN) receives about 200 notifications of events related to patients in radiation therapy. Since March 2011, ASN, together with a working group made of professionals including representatives from the French societies of radiation oncology, medical physics, radiographers and quality and risk managers in radiation therapy, publishes periodically a newsletter for sharing the lessons learned from these notifications. To date, 10 issues of this newsletter, entitled "Patient safety, Paving the way for progress", were published. These newsletters are also distributed to the professionals in the field of radiotherapy through a mailing list and 4 printed copies of each issue are sent to each radiation therapy department in France.
These newsletters can be used by the radiation therapy departments to improve the a priori risk analysis which must be conducted by all the radiation therapy departments in France.

1. INTRODUCTION

Lessons must be drawn from each event related to radiation protection (technical anomalies, deviations from procedures, etc.) in order to reinforce the measures to prevent recurrence of the incident.

In France, the notification of events in the medical field is a regulatory requirement since 2007.

Based on the notifications received in the field of radiation therapy and related to patients, the French nuclear safety authority (ASN), together with a working group made of professionals involved in radiation therapy, publishes periodically, for the whole radiotherapy community, documents for sharing the lessons learned from these notifications with all radiation therapy departments.

The objective of the paper is to present the requirements with regards to notification in France in radiation therapy, the tools which were developed and are now available to the radiation therapy departments for the notification of events and the experience feedback.

2. METHODS

In July 2007, ASN set up a system of notification of significant events of radiation protection (ESRs) for the nuclear activities in the medical field based on a set of criteria as well as a communication policy for events affecting a patient undergoing a radiotherapy procedure. This communication policy is based on a scale for rating events, known as the ASN-SFRO scale, which was developed jointly by ASN and the French Society of Radiation Oncology [1].

The events that can occur in the field of radiation protection do not necessarily justify being notified to the administrative authority. Consequently, ASN defined criteria for notifying the public authorities of events considered as "significant".

2.1. Notification criterion 2.1 regarding “Patients subjected to therapeutic exposure”

Six criteria of notification were defined by ASN. These six criteria take account of the consequences - whether real or potential - on the workers, the general public, patients or the environment, of the radiation protection events that can occur.

Among these criteria, the criterion 2.1 referrers specifically to the events affecting patients in the field of radiotherapy (external radiotherapy and brachytherapy).

This criterion 2.1 (Patients subjected to therapeutic exposure) is therefore worded as follows:

“The following are considered significant events:

- any adverse situation or any malfunction on an organizational, material or human level arising during the treatment of a patient in radiotherapy, having led to the realization of treatment that does not comply with the prescription in terms of the delivered dose(*);
- any adverse situation or any malfunction on an organizational, material or human level arising during the treatment of a patient, having led to deterministic effects which were unforeseeable in view of the therapeutic strategy agreed upon with the patient.

(*) Conforming to the delivered dose implies:

- in radiotherapy and brachytherapy: compliance with the total prescribed dose with a tolerance margin of +/-5%, and compliance with the planned overall treatment time and/or fractionation, taking into account the potential clinical or technical constraints involved in the treatment of a patient;
- in internal radiation therapy: compliance with the administered radiopharmaceutical activity with a tolerance margin of +10% of the prescribed activity;
- the absence of systematic dose errors for several patients, regardless of the value of this dose error.”

A guide (n°16) specific to this criterion n°2.1 was developed to help the professionals in identifying which events are to be reported to ASN [2]. This guide stems from the collaborative work undertaken with radiotherapy professionals from the French Society of Radiation Oncology, the French Society of Medical Physics and the French Association of Radiographers.

2.2. Tool for notification of events in radiation therapy

Since July 2011, radiotherapy departments can notify significant radiation protection events on line. The on-line notification portal is shared with the ANSM (French Health Products Safety Agency); it enables the professionals to notify ESRs and medical device vigilance events relating to radiotherapy.

This website has been extended in April 2017 so that professionals can notify any events related to the medical field (radiation therapy, nuclear medicine, radiology) [3].

Thanks to this website, when professionals notify an event, a pdf file is automatically sent to different institutions depending on the type of the notified event. The professionals can also send the report with the analysis of the event within the 2 months following the notification.

2.3. Tool for experience feedback

The lessons learned from these notifications are disseminated through periodic newsletters entitled "Patient safety, Paving the way for progress" which are elaborated in a dedicated working group led by ASN together with the French societies representing the radiation oncologists, medical physicists, radiographers and quality and risk managers in radiation therapy.

These newsletters are based on the lessons learned from the events notified to ASN and deal with a specific topic in each issue. These newsletters have several parts. A first part is about the key figures regarding the notifications considered in the issue, the description of the events, and the main causes identified. A second part is developed by the professionals of the working group and describes the steps for progress to avoid the kind of error presented in the issue. Then, a third part is about the experience of some centers, in which professionals are interviewed to describe their experience about this specific kind of error and the corrective actions they took.

3. RESULTS AND DISCUSSION

Since 2012, the number of ESRs in the medical field has totalled about 500 per year (including all the criteria). About 200 ESRs concerned patients in radiation therapy per year.

The large majority of these ESRs (95%) had no clinical consequences. 65% of these events were rated level 1 on the ASN-SFRO scale, which comprises 8 levels from 0 to 7. 2015 saw an increase in the number of ESRs rated level 2 on the ASN-SFRO scale. Eight ESRs of level 2 were notified (3 in 2014) and 1 ESR of level 2+ (2 patients concerned). They concerned errors in the target volume to treat (4 ESRs), the side to treat, dose fractionation, patient identity and lastly an error in activity level in a prostate brachytherapy treatment with permanent implants of iodine-131 seeds.

The analysis of these events show that the immediate causes are generally identified but that the underlying causes remain insufficiently understood. Methodological shortcomings and lack of time for the analysis limit the appropriate identification of corrective actions. As a result, the organization, the work environment or institutional context are not sufficiently questioned. The identification of failures and lines of defence that were or not efficient as well as the prioritization of causes are essential for defining the corrective actions.

Since March 2011, 10 issues of the newsletters entitled "Patient safety, Paving the way for progress" were released on the ASN website. These newsletters are also distributed to the professionals in the field of radiotherapy through a mailing list and 4 printed copies of each issue are sent to each radiation therapy department in France.

These newsletters are also available in English on the ASN website [4].

Since March 2011, several topics were covered as patient identification, in vivo dosimetry, laterality errors (Fig. 1), errors that came from the use of record and verify systems, errors in brachytherapy (PDR and HDR), high-precision hypofractionated irradiation (Fig. 2) and protraction / fractionation errors.

These newsletters can be used by the radiation therapy departments to improve the a priori risk analysis which must be conducted by all the radiation therapy departments in France when a new technique is implemented.

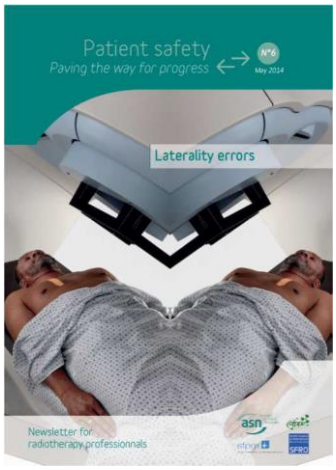

FIG. 1. Cover page of the newsletter n°6 on laterality errors

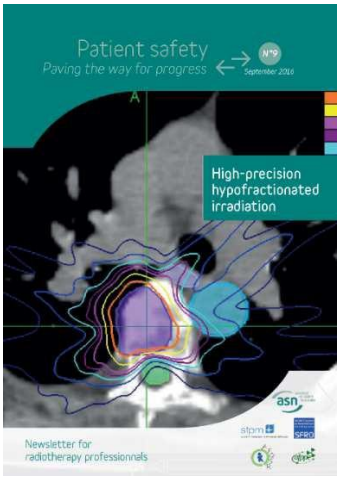

FIG. 2. Cover page of the newsletter n°9 on high-precision hypofractionated irradiation

4. CONCLUSION

Significant radiation protection events (ESR) have been notified to ASN since 2007. These notifications provide professionals with increasingly valuable experience feedback, helping to improve radiation protection in the medical field.

Thanks to the very active group of radiation therapy professionals lead by ASN, an efficient tool for experience feedback is periodically distributed to the radiation therapy departments to help the exchange of information and learning from errors.

5. REFERENCES

[1] ASN-SFRO scale (2008), http://www.french-nuclear-safety.fr/Media/Files/Fiche_SFRO2008-GB

[2] ASN Guide No. 16 - Significant radiation protection events affecting patients in radiotherapy (criterion 2.1): notification and ASN-SFRO scale rating (2010) http://www.french-nuclear-safety.fr/Media/Files/00-Guides-de-declarations/Anglais/Guide-no-16-Significant-radiation-protection-events-affecting-patients-in-radiotherapy-criterion-2.1-notification-and-ASN-SFRO-scale-rating

[3] On-line notification website for radiation protection events https://teleservices.asn.fr/

[4] Newsletters “Patient safety, Paving the way for progress” http://www.french-nuclear-safety.fr/Information/Publications/Publications-for-the-professionals

TEMPORAL DISTRIBUTION OF ABNORMAL EVENTS

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Abstract

A possibility of adverse incidents such as equipment faults, human errors and combinations thereof in use of radiation in healthcare is a necessary evil and should be minimized. In Finland STUK - Radiation and Nuclear Safety Authority shall be notified of all significant abnormal events. Here, reports of the abnormal events between years 2010-2017 in the national database were analyzed. The paper proposes a day-of-the-week-based approach to reduce human errors associated with abnormal events. In addition, an overview of classified abnormal events is provided.

1. INTRODUCTION

The day-of-the-week effect is a versatile concept and has been studied in several disciplines. It has been used to study length of stay in emergency department [1], failures in high-performance computing systems [2] and risks related to vehicle occupant fatalities [3]. This approach has provided several interesting findings. In early 80s it was reported that returns on common stocks and treasury bills are not constant across days of the week [4]. Recently existence of near-repeat patterns by weekday has been shown related to street robberies in the city of Vienna [5].

The abovementioned superficial literature review implies that the day-of-the-week effect may occur in temporal distributions of technical errors and that of human errors. Therefore, it could be beneficial to investigate temporal distributions of adverse incidents in use of radiation in healthcare.

In this study we hypothesized that 1) Temporal distributions of human errors is not uniform and 2) The other errors are uniformly distributed over time.

2. METHODS

In Finland STUK - Radiation and Nuclear Safety Authority shall be notified of all significant abnormal events. These reports are stored in a national database. In the present study we collected all reports of abnormal events in the years 2010-2017. Other than the abnormal events in X-ray examinations in health care were excluded. The remaining abnormal events formed the dataset for this paper. Table 1 shows how abnormal events are classified in the national database. Based on this classification each abnormal event was grouped in one of the four classes: abnormal events related to the referral, isolated case of equipment failure, human error and other. Finally, temporal distributions in each classes were determined.

Microsoft Excel software version 14.0.7188.5002 (Microsoft Corporation, Redmond, Washington, U.S.) and R programming language and software version 3.2.2 (The R foundation for Statistical Computing) were used for data analysis. Chi-squared test was used for determining associations. P value was set to be significant at 0.01.

TABLE 1. The grouping of abnormal events in X-ray examinations in health care.

Exposed party	Type of abnormal event	Cause or contributing factor
Abnormal events related to the referral		
Wrong Patient	Referral written for the wrong person	Human error
		Human error, the high likelihood of errors in the referral system*) a contributing factor
Patient	Incorrect examination or anatomical object in the referral	Human error
		Human error, the high likelihood of errors in the referral system*) a contributing factor
	Another type of error in the referral	
Abnormal events related to the performance of the examination		
Wrong patient	Wrong patient examined	The patient's identity was not verified before the examination
Patient	An incorrect examination was performed or an incorrect anatomical object was imaged	Human error during the performance of the examination
	Failed examination or an excess exposure related to the examination	Erroneous or deficient instructions
		Human error during the performance of the examination
Extraordinary exposure, other events		
Patient	Failed examination or an excess exposure related to the examination	Isolated case of equipment failure
		The high likelihood of errors in equipment, an auxiliary appliance or system*) as a contributing factor
	Examination repeated unnecessarily	No information available on earlier similar examination, or results from earlier examination not available
Patient and worker	Worker also exposed due to the abnormal event mentioned above (when the worker's exposure is not significant)	
Worker	Worker exposure (when the exposure is not significant)	
	Other event:	
Unintended exposure of the foetus		
Foetus	Pregnant person exposed	The pregnancy is at such an early stage that it cannot be verified
		The possibility of a pregnancy was not considered before the procedure

*) A high likelihood of errors refers to the poor usability of equipment or a system, allowing extraordinary radiation exposure to be caused by a human error that can occur easily.

3. RESULTS

Numbers of abnormal events from year 2010 to year 2017 in different classes are presented in Table 2. Figure 1 shows the temporal distribution of human errors. There were statistically significant differences between weekdays. The other errors were distributed as presented in Figure 2. There were statistically significant differences between weekdays. In all cases the exact date of abnormal event was not available. Those cases were excluded.

TABLE 2. Numbers of abnormal event in different classes in years 2010-2017.

Year	Events related to the referral	Isolated case of equipment failure	Human error	Other
2010	0	0	1	1
2011	2	1	4	5
2012	8	8	25	9
2013	8	6	21	14
2014	14	7	22	16
2015	8	5	12	10
2016	10	13	18	14
2017	3	2	11	4

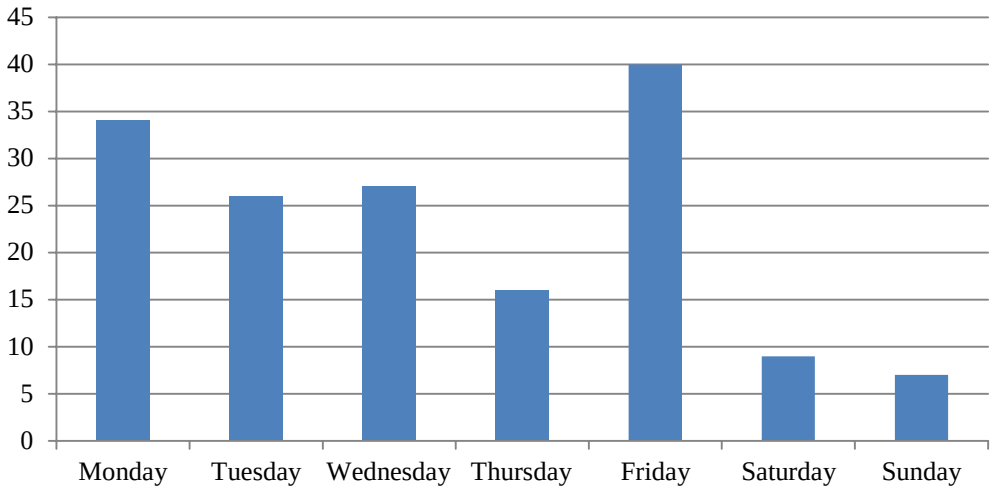

FIG. 1. The temporal distribution of human errors.

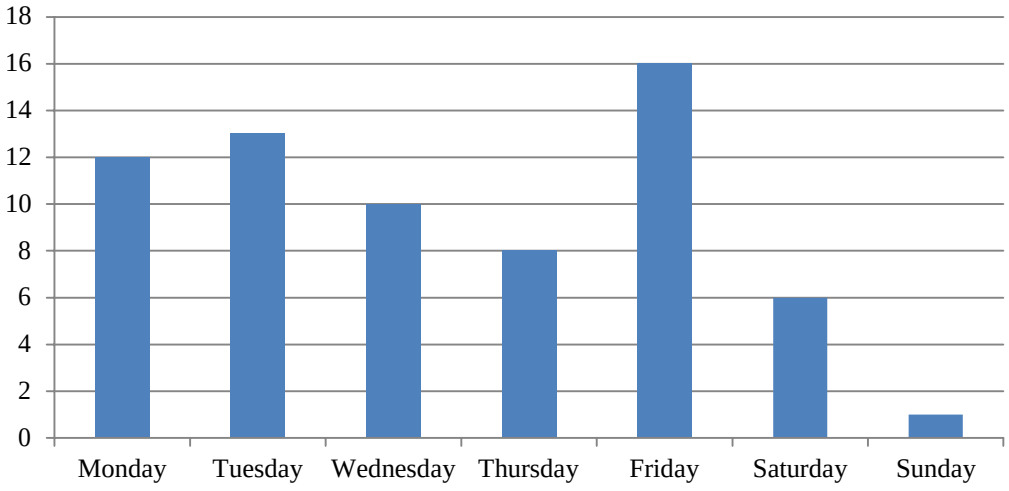

FIG. 2. Chart showing the temporal distribution of abnormal events that are not human errors.

4. DISCUSSION

The number of abnormal events per year varies greatly (Table 2). The growth in number of reported abnormal events in years 2010-2012 may be explained by active guidance. During those years STUK was promoting the importance of reporting abnormal events.

Figure 1 agrees with the first hypothesis. Indeed, temporal distributions of human errors is not uniform. Saturday and Sunday differ from the other days most probably because of the lower number of X-ray examinations conducted during those days. Even if Saturday and Sunday are neglected number of abnormal events in Thursday differs significantly. Monday and Friday are the worst days. The results shown in Figure 2 are nonintuitive and suggest that the second hypothesis should be rejected. However, the rejection is in line with the previously published finding that there is a minor day-of-the week effect in computer failures [2].

Based on the results the role of the human factor is evident, and therefore the reasons for differences in Figure 1 should be investigated. Is the work load greater on Mondays and Fridays? Could we learn good practises from Thursdays? Can we implement a day-of-the-week-based approach such as total number of human errors decreases? Until further studies these questions remains to be answered, but from risk management point of view the present results are useful. Resource allocation decisions can benefit by knowing how risk varies across time.

CONCLUSIONS

Based on the results we propose a day-of-the-week-based approach as a tool to decrease number of abnormal events. This could be a part of self-evaluation process in healthcare units.

References

[1] L. Salehi, P. Phalpher, and R. Valani, “LO54: A descriptive analysis of ED length of stay of admitted patients ‘boarded’ in the emergency department,” *CJEM*, vol. 19, no. S1, p. S46, May 2017.

[2] R. Showcase, @ Cmu, B. Schroeder, G. Gibson, and G. A. Gibson, “A Large-scale Study of Failures in High-performance-computing Systems (CMU- PDL-05-112) A large-scale study of failures in high-performance computing systems,” 2005.

[3] R. C. Schwing and D. B. Kamerud, “The Distribution of Risks: Vehicle Occupant Fatalities and Time of the Week,” *Risk Anal.*, vol. 8, no. 1, pp. 127–133, Mar. 1988.

[4] M. R. Gibbons and P. Hess, “Day of the Week Effects and Asset Returns,” *J. Bus.*, vol. 54, no. 4, pp. 579–596, 1981.

[5] P. Glasner and M. Leitner, “Evaluating the Impact the Weekday Has on Near-Repeat Victimization: A Spatio-Temporal Analysis of Street Robberies in the City of Vienna, Austria,” 2016.

LEARNING FROM IONISING RADIATION DOSE ERRORS, ADVERSE EVENTS & NEAR MISSES IN UK CLINICAL IMAGING DEPARTMENTS.

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Abstract

Since 2008, there has been a successful standardised method for classifying and reporting radiotherapy errors (RTE) and near misses within the UK. All RT departments support the voluntary collection of anonymised RTE data to Public Health England (PHE). General opinion in the UK states that a similar national standard reporting framework should be developed for UK Clinical Imaging departments for staff to use to code and report errors, adverse events and near misses. Under the auspices of the UK Clinical Imaging Board (CIB), a joint professional body working group was established to develop a framework. The Coding Framework details relevant taxonomies, coded to fit both the UK Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R) duty holder roles and the relevant steps of the patient pathway. A standard Reporting Template has been created and the pilot phase is complete with a guidance document soon to be in place. Reviewing errors and near misses must be done locally to ensure learning takes place. It is also important that national reporting with anonymised data being shared is published for learning purposes across the UK. The paper will update delegates on this CIB partnership work - involving IPEM, SCoR, RCR, PHE and the Care Quality Commission.

1. INTRODUCTION

In 2008 a joint Royal College of Radiologists (RCR), Society and College of Radiographers (SCoR), and Institute of Physics and Engineering in Medicine (IPEM) document was published offering guidance to the radiotherapy community on the categorisation of radiotherapy errors (RTE) [1]. This was, and continues to be, well received, and has become the definitive process for reporting errors and near misses in UK radiotherapy departments. The main recommendation was that each department must have a system for reporting and analysing errors. The lessons learnt should be fed back to the staff in multidisciplinary meetings. The radiotherapy community have adopted this methodology to the extent that all RT UK departments now support the voluntary collection of RTE data. This data is analysed to identify when and at what point in the patient pathway the RTE occurred with the aim of highlighting regular patterns of practice activities that may have contributed to these errors / near misses. Recognising and reviewing these patterns supports staff to learn from them with the overall aim to enhance patient safety. This document has been widely accepted as a national resource in coding & classifying RTE and near misses, with many departments regularly using the classification system to support local and national discussions. Detection & prevention of errors / near misses is, of course, useful in improving the quality of services to patients and overall patient safety. Quality improvement is further enhanced by the voluntary reporting of errors and near misses and the UK National Reporting & Learning System (NRLS) receives voluntary data submissions. The multidisciplinary Public Health England (PHE) "Patient Safety in Radiotherapy Steering Group" was established with the aim of reviewing data analyses and supporting the dissemination of learning across the UK via biannual reports, newsletters [2].

Since then, it has become apparent that similar guidance on the standard coding of errors and near misses would also benefit the UK radiology and nuclear medicine (NM) community. The preparation of relevant professional body guidance (similar to TSR) could help to support staff in preventing and minimising further radiation dose errors. The safe and accurate delivery of diagnostic clinical imaging services is the responsibility of all staff involved in the clinical imaging patient pathway. Of course, annual IR(ME)R Inspectorate reports such as those from the Care Quality Commission (CQC) in England, go a long way in identifying patterns of reportable errors and have a place in supporting the community to review local procedures with the aim of changing practice if required. A robust radiation safety culture involving radiation dose error / near miss reporting within local departments is imperative in fostering patient safety and ongoing quality improvement of imaging services. It is also, arguably, the national sharing of the learning from such errors, which ultimately highlights and helps to support the potential need for procedural change.

The UK Clinical Imaging Board (CIB), comprising the RCR, the SCoR, and the IPEM commissioned a joint professional body working party to develop guidance to support the UK clinical imaging community in the methodology of identification, classification, coding and reporting of radiation dose errors and near misses. The first meeting took place July 2015.

The working party (Table 1), chaired by Maria Murray (SCoR), is supported by colleagues from PHE and the CQC and includes a Patient Representative. Regular progress reports are delivered to CIB members.

The working party have developed two main tools to be used by staff in clinical imaging departments to categorise and record errors and near misses. Guidance to support radiology and NM staff to understand and implement the standard coding & reporting system is nearing completion. Importantly, the analysis of patterns of incidents is supported with recommendations for staff feedback to ensure that learning takes place.
The paper explains the principles behind the factors that could potentially affect the occurrence of errors and near misses in clinical practice, details of the standard coding taxonomy and reporting tool created by the working party as well as recommendations for their future implementation across the UK.
For the guidance to be user friendly for all staff groups, scenarios have been included to provide examples and advice on practical issues relating to the coding and reporting systems. The advice given is wide-ranging and does not undermine an employer's legal responsibilities for reporting radiation incidents "much greater than intended" to the appropriate authority [3].

2. METHODS

Working party members undertook a review of the global literature pertaining to errors, adverse events and near misses. Much of the literature stems from the commercial sector (4) and it was apparent that there is a dearth within the healthcare sector, let alone from radiology and nuclear medicine services. In terms of healthcare delivery, many of the contributions to learning from errors and near misses relate to radiotherapy practice [5] stressing the importance of the higher patient safety risks from those high dose exposures. Radiology and NM errors and near misses and the learning from them has not evolved as much as those in radiotherapy suffice to highlight the compulsory notification of defined errors to national bodies [6] but the issues have been raised in several books [7]. However, a national Radiology Events Register (RaER) was developed in Australia [8] designed to undertake systematic data collection and analysis of adverse incidents and discrepancies in radiology to support quality improvement and patient safety.

It is evident that a multitude of websites available to the public exists [9, 10, 11, 12]. The National Patient Safety Agency (NPSA) developed a framework [13] for categorising the factors that could contribute to the occurrence of errors and near misses, which must also be taken into consideration when analysing patterns of errors. Root cause analysis (RCA) is a method of problem solving used for identifying the root causes of faults or problems [14]. It may be applied to methodically identify the root causes of events, rather than to simply address the symptomatic result and is typically used as a reactive method of identifying event(s) causes, revealing problems and solving them. Although many people are treated safely and successfully daily in the UK NHS, when incidents do happen, it is important that lessons are learned to prevent the same incident occurring elsewhere. Root Cause Analysis investigation is a well-recognised way of doing this and whilst analysis is normally undertaken after an event, it can be a pre-emptive method to predict events.

One very important point , apart from the learning from previous errors and near misses, is the requirement to be open and honest with patients when something goes wrong [15]. All healthcare professionals have a duty of candour – a professional responsibility to be open and honest with patients when things go wrong. This is articulated through various professional *"Code of Conduct"* or specific professional guidance documents [16]. - Professions regulated by the Health and Care Professions Council (HCPC); Standards of conduct, performance and ethics: Standard 8 [17]

A Coding Taxonomy is one of the tools created by the working party which consists of an excel spreadsheet detailing each aspect of the patients' journey through a radiology / nuclear medicine or an interventional radiology department. This Coding Taxonomy (CT) is the detail for coding errors and near misses that may occur during that journey – the codes begin with the identification of the radiation exposure type; the imaging modality used and the UK IR(ME)R duty holder roles:

- Employer
- Referrer

- Practitioner
- Operator
- None

Further sub categories exist within the taxonomy to support the identification of the root cause of the error / near miss e.g. wrong anatomy / side.

To indicate the severity level of the incident, a classification code was created:
Severity (1 - 3)

Level 1 – Error / adverse event notifiable to the appropriate authority
Level 2 – Error – not notifiable
Level 3 - Near miss

Error

Tier 1 – Primary Code - the point in the pathway that the error first occurred
Tier 2 – Secondary Code - What went wrong? The detail of the error

Finally, the Coding Taxonomy was further enhanced by the addition of Contributory Factors (CF). The working party elected to include contributory factors when developing the error coding taxonomy as an element of their remit to provide a process for the classification of errors and near misses in clinical imaging. It was felt that inclusion of the contributory factor taxonomies would enhance subsequent error / near miss trend analysis. Future work on the analysis of diagnostic imaging and nuclear medicine errors would seek to improve the learning from these events, subsequently improving patient safety.

Root cause and contributory factor
Incidents and errors often involve a complex chain of events. Whilst an oversight or certain action may be viewed as the immediate cause of an incident, subsequent analysis will often expose a series of events or deviations from safe practice. These events are described as root cause and contributory factors.

Root cause – identified event that leads to an occurrence or incident … the what. (The primary point on the pathway coding -Tier 1&Tier 2).
Contributory factor – weakness that causes the apparent basis of an event to happen ... the why. (The contributory factors (CF) coding).

With the use of the Coding Taxonomy (CT), following the internal reporting of an incident, an alphanumeric code can be produced which could then be entered into an IT system to support the identification of patterns of errors and near misses. The working party created another tool (an basic IT system) to record the alphanumeric code – namely, the Reporting Template (RT) which is presently a basic excel spreadsheet with drop down boxes for each element of the final alphanumeric code. This Reporting Template should, in clinical practice, be a "live" document that would allow the sharing of data locally and nationally.

The full standard coding system (the CT and the RT) could also be used to further support data benchmarking.

3. RESULTS

To test the validity, reliability and reproducibility of the two "tools", a pilot study took place towards the end of 2016 and was completed early 2017. Seventeen clinical imaging centres from throughout the four countries of the UK, were invited to participate.

Each centre was asked to

- Use Coding Taxonomy (CT) to code six control scenarios (coded and consistency checked by working party members)
- To code ten recent radiation incidents from their own department to retrospectively test the CT.
- To then insert the final alphanumeric codefor each of the sixteen incidents into the Reporting Template (RT)
- To complete the Pilot Participation Form to highlight any ambiguities / difficulties encountered in using the two tools.

Twelve centres responded – mostly positively.

Some of the resultant comments from the various centres were:

As a department we already hold a similar database. This would provide a consistent approach across all Trusts that could be filtered for trends etc.

I like the idea of collating this sort of data; a lot of errors tend to slip under the radar because they are non-reportable, so having a way to log these could allow analysis of trends etc. on both a local and national level. The coding took a bit of getting my head around at first.

Excellent piece of work, this project will allow a national coding system for radiation incidents which can be understood across all sites. Initially it does take a little time to understand the coding framework.

The coding is too detailed and adds up significant time to our already busy schedule.

Further to the pilot study, the working party have made slight alterations to both the Coding Taxonomy and the Reporting Template. The original Contributory Factors element required substantive changes. It was felt necessary to introduce sample scenarios and resultant codes for the CF section to be included within the final guidance document to support a deeper understanding for the future user.

4. DISCUSSIONS

5. CONCLUSIONS

The primary aim of the forthcoming guidance is to help UK Radiology staff to minimise future potential ionising radiation exposures errors / near misses whilst enhancing ongoing patient safety. The guidance is intended to provide a practical approach to implementing the standard coding system for the identification of errors and near misses - this includes the primary process coding (Tiers 1 and 2 of the Coding Taxonomy) and any Contributory Factors (CF). It involves a clear objective methodology for highlighting, categorising and recording radiation dose errors and near misses that may occur during any phase of the clinical imaging patient pathway.

The guidance will include recommendations for implementation of the standard coding system as well as the jointly agreed taxonomies and reporting methodologies that have been developed to mirror the various stages of the clinical imaging patient pathways for radiology, nuclear medicine and interventional radiology practices.

6. TABLES

Table 1

Member	Organisation
Ms Claire Skinner	IPEM
Ms Aida Hallam	IPEM

Ms Catrin Ferioli	IPEM (from Oct 2016)
Ms Alison MacDonald	SCoR /Ramsey Health
Ms Sarah Durkin	SCoR (till end 2016)
Ms Sue Johnson	SCoR (till end 2016)
Ms Lynda Johnson	SCoR (from early 2017)
Mr Philip Plant	SCoR (Lay representative)
Ms Gail Woodhouse	PHE
Ms Rachael Ward	CQ
Ms Sarah Peters	C
Mrs Maria Murray	CQ

7. REFERENCES

[1]. *RCR, BIR, NPSA, IPEM, SCoR: Towards Safer Radiotherapy, (2008) Accessed October 2017* *http://www.rcr.ac.uk/docs/oncology/pdf/Towards_saferRT_final.pdf*

[2]. *Public Health England, Patient Safety in Radiotherapy Steering Group. Accessed October 2017* *http://webarchive.nationalarchives.gov.uk/20140505133515/http://www.hpa.org.uk/ProductsServices/Radiation/Radiotherapy/PatientSafetyMonitoring/*

[3]. *Department of Health (2017) Guidance on investigation and notification of medical exposures much greater than intended. Accessed October 2017* *https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/583637/MGTI_guidance_Jan_17.pdf*

[4]. *Douglas A. Wiegmann & Scott A. Shappell (2003). A Human Error Approach to Aviation Accident Analysis: The Human Factors Analysis and Classification System. Ashgate Publishing, Ltd.*

[5]. *Clark B, Brown R, Ploquin J, Kind A, Grimard L. (2010) The management of radiation treatment error through incident learning. Radiotherapy and Oncology*

[6]. *DATIX - http://www.datix.co.uk/*

[7]. *Romano, Luigia, Pinto, Antonio (Eds.) Errors in Radiology. Accessed October 2017* *http://www.springer.com/gp/book/9788847023383*

[8]. The Radiology Events Register (RaER) (Australia) http://www.raer.org.au/

[9]. *NHS Healthcare Improvement Scotland Learning from adverse events through reporting and review A national framework for Scotland: Second edition (2015) Accessed October 2017* *http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx*

[10]. *NHS Healthcare Improvement Scotland (2016) Learning from adverse events Learning and improvement summary: Accessed October 2017* *http://healthcareimprovementscotland.org/news_and_events/news/news_adverse_events_report.aspx?iru=E93GDEHRM2*

[11].AuntMinie.com *Accessed October 2017* http://www.auntminnieeurope.com/index.aspx?sec=sup&sub=xra&pag=dis&itemId=613132

[12]. *Department of Health.(2000) An organisation with a memory. Report of an expert group on learning from adverse events in the NHS. Accessed October 2017* *http://www.aagbi.org/sites/default/files/An%20organisation%20with%20a%20memory.pdf*

[13]. National Patient Safety Agency: (2010) National framework for reporting and learning from serious incidents requiring investigations. Accessed October 2017 https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

[14]. Wilson, Paul F.; Dell, Larry D.; Anderson, Gaylord F. (1993). Root Cause Analysis: A Tool for Total Quality Management. Milwaukee, Wisconsin: ASQ Quality Press.

[15]. The UK Government (2014)The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Accessed October 2017
http://www.legislation.gov.uk/uksi/2014/2936/pdfs/uksi_20142936_en.pdf
[16].The College of Radiographers (2013); The Code of Professional Conduct. Accessed October 2017
https://www.sor.org/learning/document-library/code-professional-conduct
[17]. The Health and Care Professions Council (HCPC), (2016) Standards of conduct, performance and ethics. Accessed October 2017
http://www.hcpcuk.org/aboutregistration/standards/standardsofconductperformanceandethics

8. BIBLIOGRAPHY

[1]. Sommer K. (2003) Learning from Errors. Applying Aviation Safety Concepts to Medicine. European Urology.
[2]. Catchpole K, Bell D, Johnson S. (2008) Safety in anaesthesia: a study of 12606 reported incidents in the UK
[3]. National Reporting and Learning System. Anaesthesia. Accessed October 2017
http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2007.05427.x/pdf
[4]. Incident reporting and learning in radiation oncology: Need of the hour. J Med Phys. 2014 Oct-Dec; 39(4): 203–205
[5]. Helmreich R. (2000) On error management: Lessons from aviation. British Medical Journal. Accessed October 2017 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1117774/
[6]. (2014) Incident reporting and learning in radiation oncology: Need of the hour. Journal of Medical Physics. 39(4): 203–205
[7]. Kotre C J, Walker A. (2014) *Duty of candour and the definition of moderate harm for radiation overexposure and exposures much greater than intended in diagnostic radiology.* British Journal of Radiology

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VOLUNTARY REPORTING OF ERRORS IN RADIOTHERAPY
Errors collection in radiotherapy

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Abstract

A reporting worksheet was developed in 2001 to collect the errors discovered in the department. The worksheet comprised the following variables : body site, machine and energy, phase of RT procedure, description of incident, how discovered, date of incident, date of discovery, staff member involved in incident and staff member who discovered it (only qualification). The personnel was required reporting events explaining the importance of safeguarding patients and assuring that no disciplinary trial would be opened. Up to 2016 were collected 101 worksheets. 34 in breast treatments , 21 Head and Neck (H&N), 9 Chest, 19 Pelvis, 13 bone metastases (MTX), 5 brain. In 2001-2009 were collected 37 events, 24 Near Miss (NM), 13 Incident (I), 2 of them harmful. In 2009-2012 42 NM, no I, 2014-2016 22 events, 21 NM and 1 incident. In 2001-2009 majority of the errors was made in prescription phase (12/37), in 2009-2012 in dose-calculation phase and transfer phase (19/42). In 2014-2016 the events were balanced in all the phases. Although voluntary reporting of errors does not discover all the errors, it permits to improve the procedures and to increase a positive culture towards errors. Their distribution among sites of treatment, professionals and steps of the treatment pathways is significant different in the three periods considered. Collection and analysis of errors may improve patients safety in radiation oncology.

INTRODUCTION

According to the International Atomic Energy Agency (IAEA) safety standards, in Radiation Therapy (RT) an “incident” is any unintended event which includes:
- operative errors
- equipment failures
- initiating events
- accident precursors
- near misses or other mishaps
- malicious or non-malicious unauthorized acts
- the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

A “near miss” is defined as a potential significant event that could have occurred as the consequence of a sequence of actual occurrences, but did not occur owing to the plant conditions prevailing at the time [1]. International safety guidelines [2] have been developed and are regularly updated to deal with radiotherapy

errors related to equipment and dosimetry. There is no consensus yet on how to best deal with errors not covered by regular system quality assurance checks.

After analysing the first 36 erros by means the Human Factors Analysis and Classification System (HFACS) [3] the department kept collecting errors and analysing them in order to find weak points in the procedures.

METHODS

The staff involved in the Radiation Therapy Department and in the Medical Physics Department was invited to highlight every type of incident, committed by him/her-self or other colleagues, and to provide a full description of it. The entire staff was assured that no blame or liability would derive from incident detection. A reporting worksheet was developed in 2001 to collect the errors discovered in our center. The worksheet comprised the following variables : body site, machine and energy, phase of RT procedure, description of incident, how discovered, date of incident, date of discovery, staff member involved in incident and staff member who discovered it (only qualification). For each incident, after analysis with the Head of the Medical Physics Department, the Head of the RT Department recorded any dose deviation, avoidance of a harmful incident, the need of partially or totally change of procedures, or occurrence of harm and its communication to the patient. Once discovered, events were classified according to the possibility of: errors avoiding a major incident “Near misses”, (NM) or "Incident" (I) the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

The collection activity was performed in three periods (2001-2009; 2009-2012, 2014-2016). The three period were choosed because the 2001-2009 was the period of passage from 2D to 3D, 2009-2012 was the period of complete infomatization of the process, 2014-2016 the period of paperless process and IMRT-VMAT techniques.

RESULTS

Up to 2016 were collected 101 worksheets. 34 in breast treatments (trt) , 21 Head&Neck (H&N), 9 Chest, 19 Pelvis, 13 bone palliation, 5 brain. In 2001-2009 were collected 37 events, 24 Near Miss (NM), 13 Incident (I), 2 of them harmful. In 2009-2012 42 NM, no I, 2014-2016 22 events, 21 NM and 1 incident. In 2001-2009 majority of the errors was made in prescription phase (12/37), in 2009-2012 in dose-calculation phase and transfer phase (19/42). In 2014-2016 the events were balanced in all the phases.
Table 1 shows the distribustion in three periods of the errors according to the treated site (chi-square statistic is 51.9102, the *p*-value is < 0.00001)

TABLE 1 ERRORS DETECTED PER SITE OF TREATMENT AND PER PERIOD

	2001-2009 N(%)	2009-2012 N(%)	2014-2016 N(%)
BREAST	12(32)	15(36)	7(32)
H&N	11(30)	6(14)	4(18)
CHEST	6(16)	3(7)	
PELVIS	6(16)	10(24)	3(14)
BRAIN	1(3)	3(7)	1(5)
BONE MTX	1(3)	5(12)	7(32)
	37(100)	42(100)	22(100)

Table 2 shows the incidents during the time according to the professional role who made them (chi-square statistic is 50.7575. The *p*-value is < 0.00001)

TABLE 2 ERRORS ACCORDING TO PROFESSIONAL WHO COMMITED THEM AND PERIOD

	2001-2009 N(%)	2009-2012 N(%)	2014-2016 N(%)
Radiation oncologist	16(43)	5(12)	6 (27)
Physicist	10(27)	21(50)	10(45)
Technologist	11(28)	12(28)	4(18)
Nurse			2(9)
Technical failure		4(9)	
	37(100)	42(100)	22(100)

Table 3 shows the incidente during the time and for each phase or group of phase of the radiotherapy procedure (chi-square statistic is 22.1531, he *p*-value is .001136)

TABLE 3 ERRORS ACCORDIG TO THE PHASES OF TREATMENT AND PERIOD

	2001-2009 N (%)	2009-2012 N(%)	2014-2016 N(%)
Prescribing treatment protocol	12(32)	6(12)	7(32)
Planning and treatment information transfer	10(27)	21(50)	8(36)
Position and immobilization/ simulation imaging and volume determination	8(22)	5(12)	3(14)
Patients set up and treatment delivery	7(19)	10(24)	4(18)
	37(100)	42(100)	22(100)

4. DISCUSSION

Reducing the rate of errors occurence is an important activity in order to maximize safety of patients. There are several methods to improve quality of radiotherapy treatment by means of reducing errors: proactive ones which analyze the processes and try and renforce the weaker point of the procedures; retrospective ones collecting and analizing errors tray and correct the procedures.

The department were coached to deal with errors considering them a source of infomation about malfuntioning in the acivity. Operators were always invited not to hide error or malfunctioning but to refer them to the master of the department.

Risk analysis by means of HFACS showed that a majority of incidents were due to inadequate supervision (unsafe supervision level), while others were due to a deficiency in the rules (resource/acquisition management level) and required correction of some procedures. [3] Obviously system of errors collection cannot intecept all the errors, while failure mode and effects analysis (FMEA) associated with incident learning can reduce much more the errors and incidents occurrence.[4] A systematic collection and analysis od inicident among different centers may result in reducing errors over the time. [5]

The most significant result of activity has been the change in culture of the staff which accepted to freely report incidents without fear of reprisal.

The three period were choosed because the 2001-2009 was the period of passage from 2D to 3D, 2009-2012 was the period of complete infomatization of the department, 2014-2016 the period of paperless activity and IMRT-VMAT techniques introduction. In 2009-2012 there was a turn-over of personel among the physics and medical staff. In the first period the number of I was higher (13), nothing in the intermediate period and 1 in last period. Considering that the analysis may bring to change procedure if it appears unfit or weak to avoid a new similar error, the fall of incident number could depend on the increased skill of the staff during the years and on the improvement of the procedures ought to errors analysis.

The statistical analysis shows a significant difference in the distribution of the errors among sites of treatment, professionals and steps of the therapeutic pathway over the time.

5. CONCLUSIONS

The monoinstitutional experience of incident learning during sixteen years shows that collection and analysis of errors may improve the safety of patients in radiotherapy, reducing incidents and stimulating a safety culture in the staff. The practice shows a modification of pattern of detected errors suggesting a sort of pressure of the activity of collection and analysis on the personnel behaviours and the procedures. The number of incidents was lowered from the beginning to more recent periods, and patterns of errors were significant different according to sites, professionals and steps of radiotherapy pathway.

REFERENCES

[1] IAEA safety glossary: Terminology used in nuclear safety and radiation protection. 2007 Edition. [2] Thwaites D, Scalliet P, Leer JW et al. Quality assurance in radiotherapy. *Radiother Oncol* 1995;35:61-73.
[3] Portaluri M. el al Collection and Evaluation of Incidents in a Radiotherapy Department.Strahlenther Onkol 2010 Dec;186(12):693-9
[4] Yang F. et al Validating FMEA output against incident learning data: A study in stereotactic body radiation therapy Med. Phys. 2015 42 (6), 2777-2785,
[5] Clark BG et al. Patient safety improvements in radiation treatment through 5 years of incident learning Practical Radiation Oncology 2013 3, 157–163

THE MARR PROJECT, INVOLVEMENT OF THE REGULATORY BODY WITH THE STAKEHOLDERS: AN APPROACH TO RAISE "AWARENESS" AND IMPROVE OF PATIENT SAFETY IN RADIOTHERAPY

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Abstract

The MARR project (Risk Matrix in Radiotherapy), shows an approach to develop a National Program on risk analysis with the involvement of all parties to raise awareness and improve the patient safety in the radiotherapy process. The risk matrix methodology developed by the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) is a method for assessing risk in radiotherapy services. It is based on analysing all potential human errors and equipment failures (initiating events) and their associated barriers. With all the stakeholders, the list of initiating events and barriers and the associated software tool (SEVRRA) from the FORO projects was adapted to the Spanish medical practice and a risk matrix application guide was written to facilitate the application of this risk analysis methodology in any Spanish radiotherapy service. As part of the project, a training course was developed and conducted by the MARR coordinating group with the support of the professional bodies to provide training to the radiotherapy professionals.

1. INTRODUCTION

Radiotherapy is a multi-step process subject to increasing complexity, with many different professional groups involved and abounding human-machine interactions. Given that the main cause of initiating events is human error, Quality Control might not be enough to guarantee safety in radiotherapy.

This concern is addressed in the international requirements gathered in the International Atomic Energy Agency Basic Safety Standards (IAEA BSS). IAEA BSS requirements have been adopted by European Directive 2013/59/Euratom and risk analysis to reduce the likelihood and magnitude of radiotherapy accidents has been included. It is remarkably important that once the European Directive is transposed at a national level, risk analysis in radiotherapy will be mandatory.

Some of the risk analysis methodologies are highly complex, specific to each service and needing a group of risk specialists who require months to complete the analysis. The chosen method should be more adequate, affordable and no high training-demanding.

The methodology chosen in Spain to address the risk analysis was the radiotherapy risk matrix and its SEVRRA software tool, developed by the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies (FORO) [1, 2] of which the CSN is part of it.

This method consists in analysing all potential human errors and equipment failures (Initiating Events) that would lead to an unintended outcome in the treatment process if the measures put in place to avoid it (barriers) failed. The risk is then defined as a function of three independent variables: the frequency of the initiating event, the probability of failure of the barriers and the severity of the consequences.

The risk matrix methodology has since been proved in 44 radiotherapy services of 7 different countries. The MARR project adapted the methodology to the Spanish radiotherapy medical practice. This radiotherapy adapted risk matrix methodology offers an alternative because:

— It provides an already analysed risk model of the radiotherapy process that includes a listing of potential human errors, equipment failures, safety barriers, frequency reducers and consequences.
— An associated software tool (SEVRRA) is available to facilitate its use.
— It does not require a great prior knowledge about risk analysis, therefore it can be applied by the professionals themselves.
— And finally it promotes safety culture.

2. METHODS

The MARR project was carried out with the collaboration of all the stakeholders at national level. While it was coordinated by the Spanish Nuclear Safety Council (CSN), all the professional associations were involved. As well it had the support of the Ministry of Health. This collaboration (Fig.1) was of paramount importance for the success and development of the MARR project.

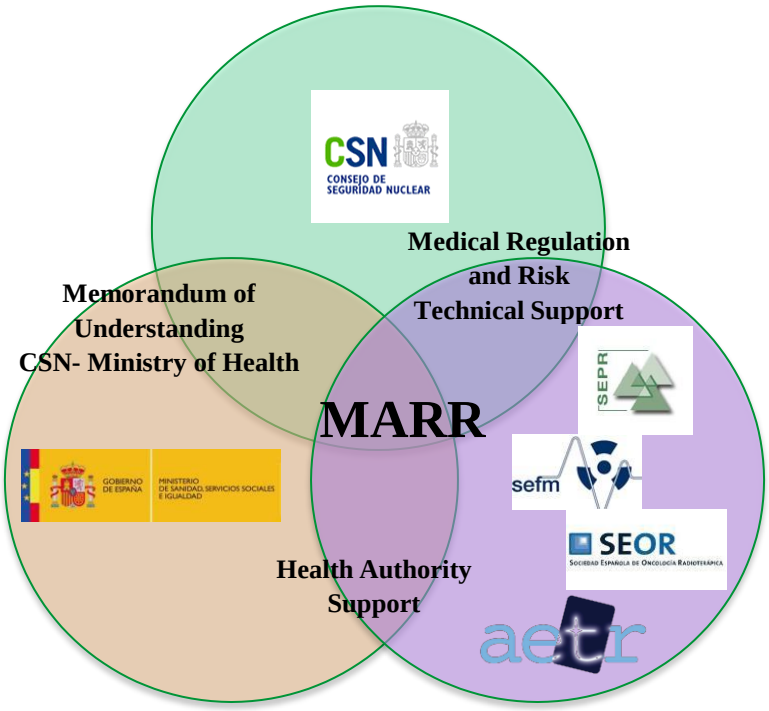

FIG. 1.MARR Project framework.

Collaboration of all the stakeholders at hospital level was also promoted, so that at least one representative of all groups of professionals (Radiation Oncologists, Medical Physicists, and Radiation Technologists) were involved. A pilot application involving 12 Spanish Hospital radiotherapy departments was also part of the project.

The MARR project involved several stages:

(a) Reviewing the FORO work in order to adapt the risk model to the current radiotherapy practice in Spain.
(b) Training the professionals in the working team, composed by a Radiation Oncologist, a Medical Physicist and a Radiation Technologists from each hospital, in the risk matrix methodology and the use of the software tool SEVRRA.
(c) Carrying out a pilot application of the risk matrix methodology to the radiotherapy process and obtaining feedback to adapt the risk model.
(d) Developing a risk analysis guidance in order to facilitate the implementation of the method based on the results and feedback provided by the working teams.

3. RESULTS

As part of the MARR project, a survey was conducted. Its goal was to analyse how applicable the proposed risk model. According to the project participants, 70% of the provided initiating events, barriers and reducers were successfully applicable within their radiotherapy treatment process and only about 30% should need to be adapted (Fig.2). As a result of the changes implemented in the original risk model, it is expected to fit better to the Spanish (i.e. European) reality.

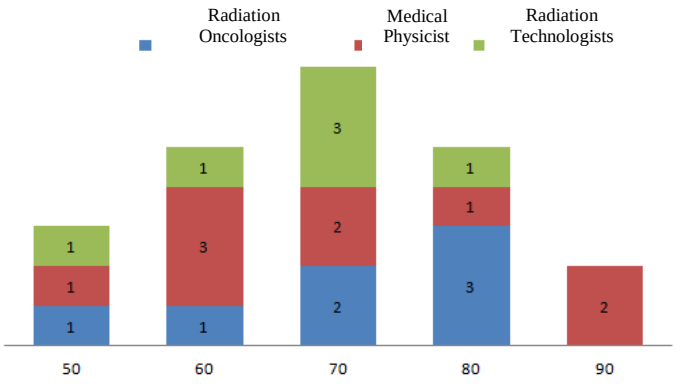

FIG.2: *Applicability of the lists of IE, B, FR y CR.*

The survey provided information of advantages and disadvantages of the adapted risk matrix methodology and its software tool SEVRRA. How useful this methodology was to perform the risk analysis in the radiotherapy process of the Spanish participating Hospitals was also analysed. The results can be found in the figure presented below (Fig.3).

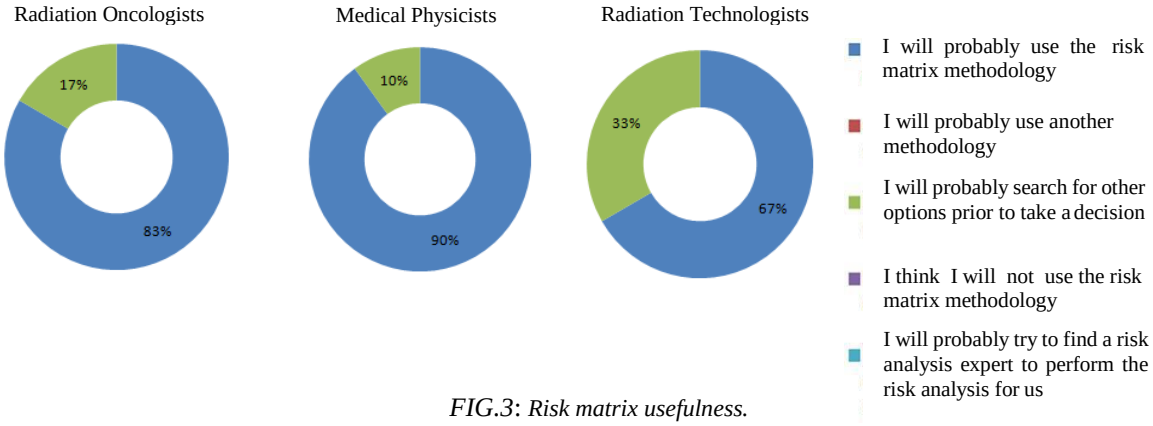

FIG.3: *Risk matrix usefulness.*

4. DISSCUSIONS

Risk analysis methodologies as well known in other areas, but hardly has just become part in radiotherapy. It requires resources and training in order to perform a risk assessment in radiotherapy departments. It is essential to find an easy tool that could be both applicable and appropriate to perform the risk analysis in those radiotherapy services.

In addition, support by the institution would be advisable. It is essential to find a way to involve all the stakeholders that could provide support to the risk group at the hospital level. Therefore, the collaboration and coordination of the stakeholders at the hospital level, professional bodies and the support of the Ministry of Health are fundamental to develop a patient safety strategy that includes risk analysis.

To address the risk analysis in radiotherapy services at national level, the MARR project chose the risk matrix methodology. This method does not require prior highly specialized expertise in risk analysis. A group of Radiation Oncologists, Medical Physicists and Radiation Technologists can apply the method themselves as it was proven in the pilot application. They just needed a training workshop and the software with the adapted risk model.

The MARR coordinating group developed a risk matrix and SEVRRA training course for radiotherapy professionals. This course, which spans for two days, includes basic concepts of risk analysis but also how to apply the risk matrix methodology and the use of the software tool SEVRRA.

Based on the feedback provided by the working teams, a risk matrix application guide [3] has been issued to facilitate the implementation of this method. The guidance can be found on the website of the different Spanish professional bodies, the CSN and the Ministry of Health. Also available on the same websites are the following resources:

- the MARR project document,
- the adapted risk model to the Spanish radiotherapy practice and
- the software tool SEVRRA.

Under the Memorandum of Understanding between the Spanish Health Authorities and the CSN regarding medical exposure, the need of the implementation of risk analysis in the Spanish radiotherapy services has been considered. As such, it has been addressed in the Health Authority Technical Document "Patient Safety Strategy for the National Health System, 2015-2020". The MARR project offers a very suitable way to fulfil this requirement.

5. CONCLUSIONS

The MARR project promoted by the regulatory body (CSN), involving all the stakeholders (at national and hospital level) with the support of the Ministry of Health and carried out with the collaboration of twelve main hospitals within the country, enabled the evaluation of the usefulness of the risk matrix methodology with the aim to be a national reference for the Spanish Radiotherapy Departments.

The risk matrix analysis, its associated software tool (SEVRRA) together with the risk matrix application guide, provides a self-assessment tool for radiotherapy services, aimed at preventing errors or failures leading to unintended and accidental medical exposures. It is, therefore, a way to improve the safety culture in radiotherapy.

The risk matrix methodology thus applied as in the MARR project may be considered as an approach to encourage the implementation of risk analysis in radiotherapy services at a national level.

REFERENCES

[1] VILARAGUT, JJ, et al., “Prevention of Accidental Exposure in Radiotherapy: The Risk Matrix Approach”. Health Physics, vol. 104, nº 2, (2013) 139–150.

[2] “Application of the Risk Matrix Method to Radiotherapy”, IAEA TECDOC No. 1685. IAEA, Vienna (2016).

[3] FORO DE PROTECCIÓN RADIOLÓGICA EN EL MEDIO SANITARIO, “Guía para la Aplicación de la Metodología de Matrices de Riesgo en Radioterapia Externa”, Madrid (2016).

REWARDS AND CHALLENGES IN PROMOTING RADIATION TREATMENT ERROR REPORTING CULTURE-A SINGLE INSTITUTION EXPERIENCE

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Abstract

Reporting of unwanted/unexpected events that may impact the treatment of patients undergoing radiotherapy in our center started in 2004. Over the past twelve years, the reporting norms have evolved. Reported events (2004-2016) were reviewed and their impacts were analyzed. The patterns of reporting have been investigated to identify activities undertaken in promoting patients' safety. Two hundred eight incidents were reported in the department for the past 12 years namely: radiation events (85%), near misses (9%), and non-radiation events (6%). There has been significant increase in reporting over the last 5 years (83%) compared to the first 7 years. From 2004-2009, all reports were related to radiation events (mostly correctible 80-90%) and made by medical physicists (80%). In 2010, the department acquired new equipment, hence, training of new staff, as well as retraining of the incumbent staff was conducted. Subsequently, lectures on patient safety, professionalism and treatment error reporting were done. Developing a reporting culture needs reinforcement of trust in the system. Good communication between hierarchical and interdisciplinary structures is one of the keys to improve patient safety. Continuous professional development is recommended in order to reinforce the human resource.

1. INTRODUCTION

To provide quality radiation oncology service and patient care, a better understanding of error reporting culture in radiotherapy facilities is vital in every step of the treatment process. Obstacles in reporting must be identified to provide awareness into potential areas for improvement. The practice of reporting unwanted or unexpected events that have the potential to impact the treatment of patients undergoing radiation therapy at the Department of Radiotherapy-Jose R. Reyes Memorial Medical Center, Manila, Philippines started in 2004.

Over the past twelve years, the types, magnitude, quality of reports and the reporting norms in the department have evolved. The general objective of this paper is to improve on the incident learning system of a small radiotherapy department with limited resources. Specifically, we aim to identify the various factors that influence the development of reporting culture in the department, and to come up with analyses and recommendations to further improve the said reporting system.

2. METHODS

A multidisciplinary team of medical physicists (MPs), radiation oncologists/residents (ROs) and radiotherapy technologists (RTTs) reviewed the documented reported events over the past 12 years. These were then classified into: 1.) radiation events (whether they are correctible or non-correctible), 2.) Near-misses (or potential events), or 3.) Non-radiation events [1].

The impacts of these events were subsequently analyzed. The pattern of events reported and the reporting team member/s were likewise analyzed to identify related activities undertaken in the department ultimately promoting patients' safety.

3. RESULTS

In this twelve-year retrospective analysis, only 208 incidents were reported in the Department of Radiotherapy: 85% were radiation events (involving both patients and staff), 9% were near misses, and 6% were non-radiation events (Fig. 1 and Fig. 2). Of the radiation-related events, 83% were correctible and 17% were non-correctible. The latter half of the analyses resulted to a significant increase in reporting, 83% of the events were reported in the last 5 years vs 17% in the first 7 years of the reporting period.

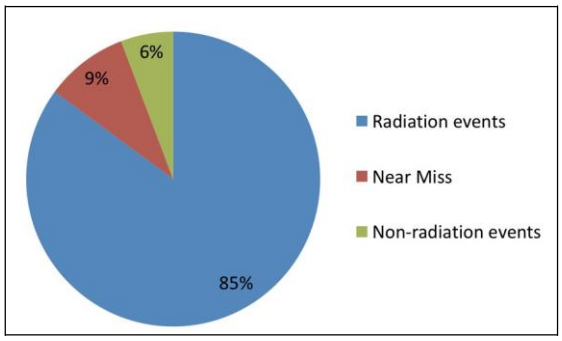

Fig. 1. Types of incidents reported (2004-2016)

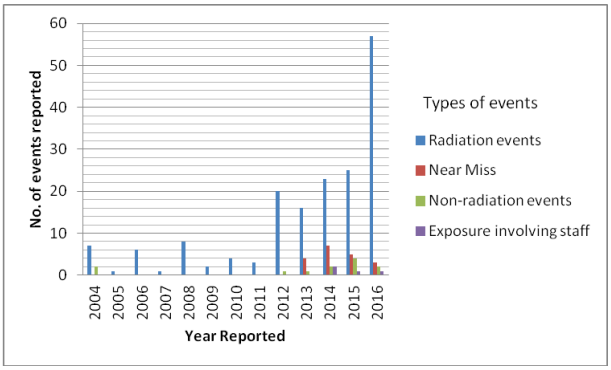

Fig. 2. Types of reported events

The medical physicists (MPs) were the most active members of the team with 42% of the events reported by this group. The radiation oncologists/residents (ROs) and the radiotherapy technologists (RTTs) on the other hand both reported 28% each of the events while the remaining 2% by the rest of the staff. It is interesting to see that the RTTs and the ROs have taken active participation in reporting, achieving 10% more events than the MPs in the last 3 year-period.

4. DISCUSSIONS

From 2004-2009, all reports were radiation-related events. Most of these were correctible events *(80-90%)* and were relayed by MPs *(80%* as shown in Fig. 3).

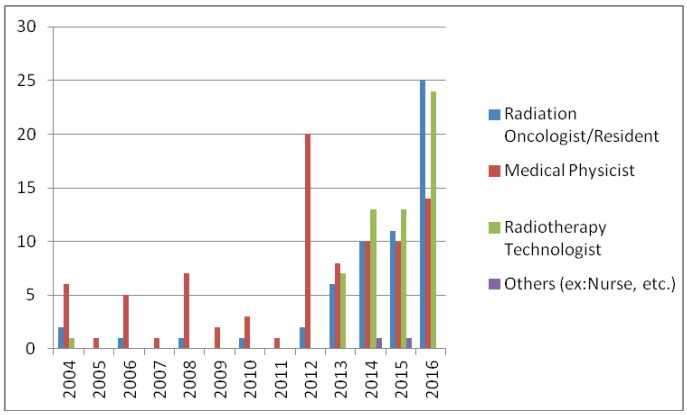

Fig. 3. Reporters of events categorized based on respective profession/discipline

In 2010, the Department of Radiotherapy acquired a new linear accelerator with a dedicated CT Simulator thru the partnership with a private institution. With the advent of this new technology, the MPs conducted a training of

new ROs and RTTs, as well as retraining of the incumbent staff on radiation safety placing emphasis on patient safety and reporting of events. Thereafter, lectures on power distance index [2], undergoing audit by the national Quality Assurance Team in Radiation Oncology (QUATRO) [3], performance testing and audit by the regulatory and participating on safety assessment [4] were undertaken.

The department has also adopted a patient safety-first dogma, and a blame-free policy to encourage team members to report errors. From 2010 to 2016, the number of events reported has increased (approximately 7x higher in the year 2016 compared to 2004). Most of these were of the less severe types and majority was reported by the radiation technologists.

Another possible factor in this trend was the simplification of treatment event reporting system. This was achieved thru 1.) adopting a common taxonomy [5] and 2.) providing each with numerical codes for direct causes, contributing factors and radiotherapy stage [6] where the event specifically occurred.

5. CONCLUSIONS

Developing a reporting culture needs reinforcement of trust in the system to eliminate any fear of retribution. Good communication between hierarchical and interdisciplinary structures is a key component to improve patient safety – the prime objective of reporting events.

Continuous professional development through trainings and workshops (both local and international) is recommended in order to reinforce the human resource aspect and minimize common causes of errors. And lastly, improved and active participation to Safety in Radiation Oncology (SAFRON) [7] is strongly encouraged to establish an institutional incident learning system.

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REFERENCES

1). British Institute of Radiology, Institute of Physics and Engineering in Medicine (2008). Towards Safer Radiotherapy. Retrieved April 18, 2017, from https://www.ipem.ac.uk/Portals/0/Images/Towards%20Safer%20Radiotherapy.pdf

2.) I.TreatSafely (2016). Retrieved April 18, 2017, from www.itreatsafety.org

3.) IAEA (2007). *Comprehensive Audits of Radiotherapy Practices. A tool for Quality Improvement by Quality Assurance Team for Radiation Oncology*. Vienna: International Atomic Energy Agency.

4.) The American Association of Physicists in Medicine. Retrieved April 8, 2017, from http://spa.aapm.org/

5). Calaguas, M.J. et.al. Adaptation of the ASTRO Framework for Quality Radiation Oncology and Care on Treatment Error Reporting: A Single Institution Experience on Error Reporting Culture and Factors. Paper submitted at ASTRO 2017 Annual Meeting.

6.) American Society for Therapeutic Radiation Oncology (2012). Safety Is No Accident: A Framework for Quality Radiation Oncology and Care. Retrieved April 8, 2017, from https://www.astro.org/uploadedFiles/_MAIN_SITE/Daily_Practice/Accreditation/Content_Pieces/SafetyisnoAccident.pdf

7.) Radiation Protection for Patients (2013). Safron. Retrieved April 8, 2017, from https://rpop.iaea.org/RPOP/RPoP/Modules/login/safron-faq.pdf