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Abstract

Background and purpose. The potential for unintended and adverse radiation exposure in radiotherapy is real and should be studied because radiotherapy is a highly complex, multistep process which requires input from numerous individuals from different areas and steps of the radiotherapy workflow. The 'Incident' (I) is an event the consequence of which is not negligible from the point of view of protection or safety. A 'near miss' (NM) is defined as an event that is highly likely to happen but did not occur. The purpose of this work is to show that through a systematic reporting and analysis of these adverse events, their occurrence can be reduced.

Materials and methods. Staff were trained to report every type of unintended and adverse radiation exposure and to provide a full description of it.

Results. By 2018, 110 worksheets had been collected, with an average of 6.1 adverse events per year (with 780 patients treated per year, meaning an average incident rate of 0.78%). In 2001–2009, 37 events were registered (13 I and 24 NM) the majority of them in the decision phase (12/37), while in 2010–2013, 42 (1 I and 41 NM) in both the dose-calculation and transfer phase (19/42). In 2014–2018, 31 events (1 I and 30 NM) were equally distributed across the phases of the radiotherapy process. In 9/15 cases of I some check point was introduced.

Conclusion. The complexity of the radiotherapy workflow is prone to errors, and this must be taken into account by encouraging a safety culture. The aim of this paper is to

present the collected incidents and near misses and to show how organization and practice were modified by the acquired knowledge.

Keywords: radiotherapy, risk management, accidental exposure

1. Introduction

Radiotherapy (RT) is one of the primary treatment options in cancer management, effectively saving and prolonging lives while preserving quality of life. The best available practices indicate that more than 50% of oncologic patients should receive RT at least once during the treatment of their cancer. RT is widely recognised as one of the safest areas of modern medicine, and incidents in RT are very rare [1,2]. However, when incidents do occur, consequences can be severe and may affect large numbers of patients, being harmful or even fatal in the worst cases. The potential of unintended and accidental exposure in RT is real and should be studied because RT is a highly complex, multistep process which requires input from many professionals belonging to a variety of areas during both the planning stage and the delivery of treatment [3,4].

"Minimization of the likelihood of unintended or accidental medical exposure in radiation therapy can be brought about by: (a) the introduction of safety barriers at critical points identified in the process, with specific quality control checks at these points. Quality assurance should not be confined to physical tests or checks on radiological equipment, it shall include actions such as checks of the treatment plan or dose prescriptions by independent professionals; (b) actively encouraging a safety culture of always working with awareness and alertness; (c) providing detailed protocols and procedures for each process; (d) providing sufficient staff educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput;

(e) continuous professional development and practical training as well as training in applications for all staff involved in the preparation and delivery of radiation therapy; (f) clear definition of the roles, responsibilities and functions of staff in the radiation therapy facility as understood by all staff" [5].

Two international and one national databases are currently ongoing, investigating unintended and accidental medical exposure in radiation therapy: SAFRON (Safety in Radiation Oncology) [6], ROSIS (Radiation Oncology Safety Information System) [7] and PRISMA-RT (Prevention Recovery Information System for Monitoring & Analyses) [8].

"According to the International Atomic Energy Agency (IAEA) safety standards, 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 potentially 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.

International safety guidelines have been developed and are regularly updated to deal with radiotherapy errors related to equipment and dosimetry" [9]. There is no consensus yet on the best strategy to deal with errors not covered by regular system quality assurance checks. After analysing the first 36 accidental events by means the Human

Factors Analysis and Classification System (HFACS) [10], this department kept collecting errors and analysing them in order to find weak spots in the procedures. The aim of this paper is to present the collected incidents and near misses and to show how organization and practice were modified by the acquired knowledge.

2. Materials and Methods

This radiation therapy department was opened at the end of the '50s with Rontgen-therapy equipment; in the '60s it was equipped with cobalt therapy, and in 2001 with two 3D conformal radiotherapy linear accelerators (3DCRT). Since 2013 linear accelerators with VMAT (Volumetric Modulated Arc Therapy)/IGRT (Image Guided Radiation Therapy) have been available.

The collection activity was performed over a long period (2001-2018). 17 years in which there were considerable changes in the department. The observational time was divided in three periods: 2001–2009 was the transition period from 2D to 3D; 2010–2013 was the period of complete informatization of the department; 2014–2018 was the period of paperless activity and the introduction of IMRT (Intensity Modulated Radiation Therapy) -VMAT techniques. We choose these three periods because they represent three deeply different way of working for the personnel according to different RT techniques and organization.

In Table 1, the distribution of health professionals in three periods is shown. The needs of the department staff were calculated in accordance with ISTISAN 02/20 [11], 04/34 [12], and Italian Quality Assurance guidelines [13].

Table 1: Distribution of Health professional in three periods

PERIODS	HEALTH PROFESSIONALS	NUMBERS
2001-2009	RO	4-->5
	P	2-->3
	RTP	6-->8
	N	2
	SOCIAL WORKERS	1
	CLERK	1
2010-2013	RO	5-->6
	P	3
	RTP	9-->11
	N	4
	SOCIAL WORKERS	1
	CLERK	1
2014-2018	RO	5-->6
	P	3-4
	RTP	11-->15
	N	5
	SOCIAL WORKERS	1
	CLERK	1

RO= Radiation Oncologist; P= Physicist; RTP= Radiation Therapist; N= Nurse.

According to the internal organization, each patient visits six different checkpoints, from the first visit to the beginning of the treatment. Each patient meets the nurses three times and a doctor three more times before starting treatment, to make up for shortcomings in medical records but also to intercept any possible event along the chain of actions (concomitant treatments, missing informed consent, abnormal blood tests, altered plan parameters, etc.). Before starting treatment, the Radiation Therapist (RTP) checks that the Monitor Units (MU) correspond to those provided in the treatment plan.

After each accidental event, all the professional figures (P, RTP, RO, N) of the department meet together with the members of the risk management office to discuss the case and to evaluate whether and how procedures could be improved to avoid the occurrence of similar events. The informed consent was signed by digital pads. All the steps of radiotherapeutic workflow are described in the manual procedure of the department. A picture is taken of each patient. Patients were identified not only by name, but also with two unique identification numbers (ID): one is used for the medical records and the other one is used for calling the patient from the waiting room. A double check by ID and name/surname was used to call patient before entering in the treatment area. If a homonymy exists, the patient is informed.

The staff involved in the RT Department and in the Medical Physics Department was trained to report all types of adverse events and to provide a detailed description of it. The entire staff were assured that no blame or liability would derive from incident reporting. A reporting worksheet was developed in 2001 inspired by ROSIS [7]-(figure 1).

Figure 1: Incident detection work sheet.

Incident Detection Work Sheet

Patient ID	Irradiation Site
Machine and Energy 1 Linac 6 MV 2 Linac 15 MV 3 Linac Electons 4 Brachitherapy	Step in Which Incident Occurred Planning Informed Assent Dose Prescription Conturing Dosimetry Set-up Portal imaging Check-up during Treatment Discharge Follow-up
Incident escription:	Check Date: Incident date:
Discover Modality	Data Collector Radiation Oncologist Medical Physicist Radiation Therapist Nurse

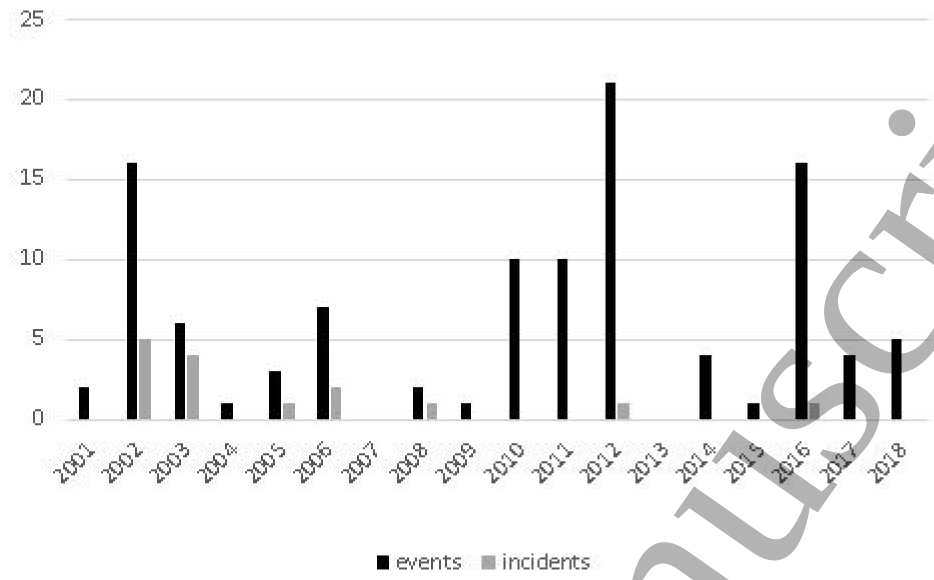
When discovered, the unintended and accidental medical exposures were classified into near misses (NM) or incidents (I). The characteristics of the events were registered and analysed, alongside the procedures when considered useful.

3. Results

Up to 2018, 110 reporting worksheets were collected with an average of 6.1 accidental events per year (with a mean of 780 patients (pts) treated per year, an average incident rate of 0.78%).

The distribution of adverse events in timeline is shown in figure 2: 15 I and 95 NM. The years with the greatest number of events were: 2002 (16), 2010 (10), 2011 (10), 2012 (21) and 2016 (16). The years with I were: 2002 (5), 2003 (4), 2005 (1), 2006 (2), 2008 (1), 2012 (1) and 2016 (1)

Figure 2 Number of events in 2001–2018 period. Incidents (gray), Near misses (black)



The distribution of events detected per treatment site is shown in table 2: highest number and most serious of events occurred during breast cancer therapy. Considering the low frequency of H&N and Pelvis treatments, the events in these patients resulted considerable. In the total considered period the most treated sites were breast and bone metastases.

TABLE 2: Events detected per site of treatment.

Site of treatment	N	NM	I	Sites
Breast	38 (35%)	32 (33%)	6 (40%)	30%
H&N	22 (20%)	21 (22%)	1 (7%)	7%
Cheast	9 (8%)	7 (8%)	2 (13%)	10%
Pelvis	22 (20%)	18 (19%)	4 (26%)	14%
Brain	5 (4%)	4 (4%)	1 (7%)	14%
Bone mtx	14 (13%)	13 (14%)	1 (7%)	25%
TOT	110 (100%)	95 (100%)	15 (100%)	100%

N: total number of events; NM: near miss; I: incident. Sites: percentage of patients per treatment site .

Based on the professional category that generated the adverse event, we found that Physicist and Radiotherapist were the most involved ones (table 3).

Table 3: Events according to professional to whom it was attributed.

Professional categories	N (%)
Radiation oncologist	30 (27%)

Physicist	41 (37%)
Radiotherapist	37 (34%)
Nurse	2 (2%)
Total	110 (100%)

We divided the observational time into three periods:

- 2001–2009 37 events were collected, 24 NM and 13 I, two of which harmful.
- 2010–2013 42 events, 41 NM and one I.
- 2014–2018 31 events, 30 NM and one I.

Considering the events according to the treatment phase in which they occurred, we observed that in 2001–2009 the majority of events were made in the treatment decision phase (12/37), in 2010–2013 in the treatment planning phase (19/42). In 2014–2018 the events were balanced across the phases of the radiotherapy workflow, as reported in table 4.

Table 4: Unintended and accidental exposure according to phases of the workflow.

Phases of treatment	N(%)
Treatment decision	26 (24%)
Imaging simulation	19 (17%)
Treatment planning – plan approval – QA	41 (37%)
Radiotherapy Delivery	24 (22%)

Total	110 (100%)

Table 5 shows the 15 incidents occurred and the actions which were implemented to lower the probability of recurrence.

Table 5: list of the occurred incidents and of the adopted actions.

N	Incident description	Actions
1	controlateral breast irradiation. Side prescription error	Introduction of checkpoint at simulation and treatment phases
2	incorrect identification of pts. Irradiated another patient: breast/breast; pelvis/prostate;	Introduction of photo in electronic chart
1	incorrect dose due to incorrect normalization	Discussion only – human error – introduction double check in Treatment planning phase
1	inverted prone/supine position;	Introduction of photo of patient position
1	incorrect prescription; missing supraclavicular field in breast irradiation.	Introduction of checkpoint on prescriptions at daily meeting
1	breast standard dose on Partial Breast Irradiation contouring;	Introduction of checkpoint on prescriptions at daily meeting
1	missing bolus	Introduction of checkpoint at transfer of treatment planning to machine
1	exceeded spinal cord dose tolerance limits	Discussion only – human error – introduction of alert for previous treatment considering
1	wrong contouring	Discussion only – human error – introduction of the duty of segmentation guidelines mention
1	patient hit with the gantry	Discussion only – human error – introduction of

		the check that anti-collision is on.
1	erroneous monitor unit calculation	Introduction of checkpoint just before radiation delivery
1	missing isocenter	Discussion only – human error – introduction of double check on beam eye view.
1	shift errors; shift not made correctly or not performed	Introduction of procedure for shift from tattoos to isocenter if requested
1	lack of patient's informed consent before treatment	Introduction of checkpoint before starting treatment

4. Discussion

Reducing the rate of unintended and accidental events occurrence, it is important to improve patient safety and to achieve RT result. Two possible approaches, either pro-active or reactive, can be followed. In the pro-active approach, critical points in various steps of the existing process and procedures are highlighted [14-16]. In the reactive approach, the analysis moves backward starting from an adverse event to reconstruct the entire sequence of events. This approach permits the identification of all causal factors of an incident [17,18].

In this department, the staff were trained to deal with adverse events by considering them as a source of information about potential workflow failures. Operators were always invited not to hide events or malfunctions but to refer them to the management in charge.

Risk analysis by means of HFACS showed that a majority of events were due to inadequate supervision (unsafe supervision level), while others were due to a deficiency in the rules (resource/acquisition management level) and required the correction of some procedures [19]. Obviously, the system of event collection cannot intercept all accidental medical exposures, while Failure Mode and Effects Analysis (FMEA), analysis of the effects and continuous learning from adverse events, can reduce error occurrence much more effectively [20]. A systematic collection and analysis of adverse events among various centres may result in reducing incidents and near misses over time [21]. The most significant result of this activity has been the change in staff culture, accepting to report events freely without fear of disciplinary actions.

In 2010–2013 there was a major turnover among the physics and medical staff. In the first period the number of incidents was higher, while only one was reported in the intermediate period and final period respectively. The analysis of reports may lead to a change of an operative procedure if it appears unfit or weak, so to avoid further similar errors. The decrease in the number of overall accidents and of incidents per year could depend on the increased skills of the staff during the time, on the improvement of the procedures due to the accident analysis and on the increase of the available number of professionals.

The analysis shows a difference in the distribution of events per sites of treatment, professionals and the steps of the therapeutic pathway over time. Three critical years were 2002, 2012 and 2016. The review of the possible causes identified a key point in the update of equipment and procedures. In August 2001, our new centre started with two Linear Accelerators for 3D conformal radiotherapy and one traditional simulator. In 2012, there was a complete software update and in 2016 a transition to the TC simulator and new VMAT accelerator. Comparing the percentage of the events in each treatment site with the mean percentage of the overall treated patients of the same site shows that Head&Neck and pelvis are the site where the percentage of the events is higher than that of treatments (20% vs 7% and 20% vs 14% respectively).

According to Reason [22], the occurrence of an accident is the result of a concatenation of events that have overcome all the defence mechanisms put in place. Described with the "Swiss cheese model", in which each slice represents a defensive layer of the organization, the presence of holes in different layers is not sufficient for the occurrence of an accident, which occurs only in those particular situations in which these holes align as per the so-called theory of opportunities.

In their studies, Verran [23] and Krapohol [24] show that the size of the staff has important implications for the quality of care and patient safety. In the conclusion of their study, Baiotto B. et al [25] say that although record-and-verify systems play a crucial role in the accuracy and reproducibility of radiation treatment, their inability to eradicate all errors requires surveillance by the RT and physics teams. Studies report that the recommended workload should not be exceeded [14,20,26,27] in order not to increase the risk for patients. A study from Knaus et.al. [28] in intensive care shows that a good work environment also decreases patient mortality; this could be true also in RT departments. Procedures can also improve through anonymous patient opinion or suggestions. Each patient has the opportunity to express his/her satisfaction, highlight wrong procedures, discomforts or anything he desires to communicate to the staff. These opinions are then discussed in staff meetings. A no-blame safety culture reduces the number of serious incidents in radiotherapy. Changes in complex radiotherapy regimes should always trigger extra caution.

The reduction of accidents observed over the years is probably due to greater attention to the problem, greater collaboration between operators, assimilation of step procedures, and low employee turnover. The professional preparation of all members of the staff is a very important step for high-quality radiation therapy and must be constantly increased via continuous professional training. Adequate numbers of trained staff, good collaboration between professionals and clear steps in procedures are essential to reduce the number of serious accidental events

Unusual and complex treatments should always trigger an extra warning, and staff members should be aware and alert in these situations. The use of 'time-outs', where staff take time to review what has been planned, prior to delivering treatment, should be considered. Excessive workload represents a possible contributory cause; in fact, in those years (first years of 2001-2009 period) when all the medical physics activity of the hospital (those of diagnostic imaging, radiation protection, nuclear medicine and radiotherapy) were supplied by only two physicists, the higher was the number of accidental events.

5. Conclusion

110 accidental events were identified in the 2002-2018 period with an average of 6.1

accidental events per year (with a mean of 780 patients (pts) treated per year, an average incident rate of 0.78%). 15 I and 95 NM. The years with the greatest number of events were: 2002 (16), 2010 (10), 2011 (10), 2012 (21) and 2016 (16). The years with I were: 2002 (5), 2003 (4), 2005 (1), 2006 (2), 2008 (1), 2012 (1) and 2016 (1). highest number and most serious of events occurred during breast cancer therapy.

The number of accidents lowered from the beginning compared to more recent periods, and their characteristic was significantly different according to sites, professionals and steps of the radiotherapy pathway. In this experience, systematic collection and discussion of unintended and accidental exposures with a no-blame safety culture has reduced the number of incidents.

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Declaration of competing interest

Authors declare that there are no conflicts of interest.

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Article Highlights:

- Introducing new complex treatments in radiotherapy should always trigger an extra warning.
- Both the pro-active and the reactive approach are useful and necessary to reduce

the accidental events.

- Reduction of incidents can be achieved by a greater attention to safety culture, greater collaboration between operators, assimilation of step procedures and low employee turn-over.