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 patient's safety in radiation oncology.

1. INTRODUCTION

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 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.

2. MATERIALS

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 to partially or totally change a procedure, 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.

3. RESULTS

Up to 2016 were collected 101 worksheets. 34 in breast treatments (trt), 21 Head&Neck, 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 profesional 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 ACCORDING 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 procedure; retrospective ones which 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 referr 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 here was a turn-over of prsonel 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 beahviours and the procedures. The number of incidents was lowered from the beginning to le more recent periods, and patterns of errors were significant different according to sites, professionals and steps of radiotherapy pathway.

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