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A Tool for Reporting and Evaluation of Incidents in External Beam Radiation Therapy

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Abstract The number of cases of cancer has significantly increased in the world and the use of ionizing radiation produced by large clinical linear accelerators plays an important role in the treatment of tumors. Although radiotherapy is considered a safe medical practice, it may bring some risks for the patient and in some extreme cases even her/his death. Over the last decades, the learning with incidents there has been a powerful way to prevent them to turn to happen. In this work a digital tool was developed for recording and evaluation of incidents in external beam radiation therapy. The tool was designed to function in an intranet environment, but it can also be used in the offline mode and is based on a set of sequential forms filled by the user (e.g. medical physicists, medical dosimetrists, radiation oncologists, radiotherapy technicians). The software was firstly applied in a radiation oncology department of a public Institution in Rio de Janeiro, Brazil. The software has proved to be an important and promising tool to improve the healthcare quality of patients undergoing radiation therapy.

Keywords: *Radiotherapy, Radiation protection, Incidents, Patient protection, Quality management*

1. Introduction

According to the World Health Organization by the year of 2040 the estimated number of incidence cases of cancer is 29.5 million [1]. In this scenario, the external beam radiation therapy with the use of large medical linear accelerators plays an important role in the treatment of cancer, provided that approximately 50% of patients will undergo radiotherapy in some stage of the treatment [2]. Although radiotherapy is considered a safe medical branch, it may bring some risks for the patients and in some cases even their death as has been occurred with a man overexposed in New York City [3]. This event was not a unique and isolated accident but as it appeared in the frontpage of a popular newspaper the radiation oncology community was put into the scene. In order to discuss the errors and malfunctions in radiotherapy and their impact on the protection of patient an important initiative was the meeting "Safety in Radiation Therapy: A call to Action" held in Miami in 2010 and sponsored by the American Association of Physicists in Medicine (AAPM) and the American Society of Radiation Oncology (ASTRO) [4]. After many discussions a list of recommendations was stated, and it was recognized that the development and use of incident learning systems plays an important and fundamental role on the improvement of safety and quality of the patient healthcare [4]. In this context an "incident" can be defined as "An unwanted or unexpected change from a normal system behavior which causes or has the potential to cause an adverse effect to persons or equipment" [5]. Another important concept is the "near miss" defined as

"An event or situation that could have resulted in an accident, injury, or illness but did not either by chance or through timely intervention." [5]. The learning with incidents refers to all cycle of feedbacks reported by users and analysis and development of actions in such a way that incidents could be prevented. We find in literature several healthcare studies and/or recommendations for radiation therapy that include incident learning systems [4-16] and is also available a recent review on incident learning in radiation oncology [17].

The incidents that occur in radiation therapy leading to unintended exposures to the patients are in general related to the values of doses different from that prescribed by the radiation oncologist; radiotherapy treatment delivered to a wrong patient or to a wrong anatomic location, and an accidental dose delivered due to malfunction or failure of the equipment [10].

To avoid these errors in the treatment that may result in unwanted doses, various organizations recommend an establishment of specific programs for incident learning in radiotherapy [8,18-21]. In this sense, it is important to discuss the incidents that have been occurred in order to look for lessons of how to prevent them to happen again and is also important the use of tools that allows us to learn and share informations on incident learning [22,23].

In Brazil there are few studies performed on this kind of approach in radiation therapy and on the other side there is a remarkable increasing of the practice of radiation oncology, due to the constant increase of the number of new cases of cancer. Thus, there is a need for the development of systems for reporting and evaluation of incidents in order to promote improvements in the attendance, efficiency in the treatment and also to provide the enhancement of the institution staff, which would directly contribute to diminish the incidents. Furthermore, the formulation of a system for record and evaluation of incidents, within the reality and characteristic of brazilian radiotherapy facilities, may aid to point out various questions in radiation healthcare that would be unnoticed and, added to several factors, may cause incidents.

In this work we present a computational tool that was developed for reporting and evaluation of incidents in external beam radiation therapy within the reality of facilities in Brazil. The software was designed to function in an intranet environment in that cases where an institution has one or more subsidiaries, but it can also be used in offline mode. In a first stage the software was applied to a unique radiotherapy department of a facility in Rio de Janeiro state to be validated with test-case scenarios. In a second stage, after the initial test application of SPIRad, it is intended the tool be available to be applied in others institutions abroad the country to prove that it can contribute to the improvement of healthcare quality of patients undergoing radiation therapy.

In this work, we analyze data obtained from an Institution in the state of Rio de Janeiro that offers a high complexity radiotherapy practice due to the large variety of techniques of treatment, to the number of equipments dedicated to therapy and to the existence of a multidisciplinary team. In Brazil there is a legal requirement to establish a systematic methodology of investigation of adverse events that reach the patients, and on the other hand the reporting and learning with incidents in radiotherapy have been frequently questioned in talks and specific workshops to the oncology radiation community with the participation of representatives of institutions spread across Brazil. In this way, the conditions were favorable to the implementation of tools focused on the safety and quality treatment of patients treated with ionizing radiation.

2. Methods

The digital tool was developed for record and analysis of incidents focused on the characteristics of the radiotherapy facilities in Brazil. Of these characteristics, usually found in developing countries, are the great number of patients per day, which implies in a large clinical workload to the personnel and means less time to report incidents. In this manner the system should to be simple and user-friendly.

The software was conceived to work by means of a private network, which is based on a suite of internet protocols (intranet), and the proposal is the clinics that use it can share important informations about events. In designing of the tool (informally named as Standardized System of Incidents in Radiotherapy - SPIRad) was necessary the use of resources such as HTML + CSS3 and PHP to make it a digital page, and the MySQL to implementation of the database. The system is constituted by three sequential forms:

i Incident Summary

ii Analysis of the Incident

iii Response Form

In Figures 1 to 3 are depicted some parts of the above forms. Figure 1 presents the form of Incident Summary where we can find the date and hour of the incident; the date of report and discovery of the incident; type of incident (actual or near-miss); person affected; number of dose fractions incorrectly delivered; name of the physician; type of treatment, and name and function of staff member that has reported the incident.

In Figure 2 is shown a part of the Analysis of the Incident form and we can find informations such as the location and profile of the facility (number of clinical linear accelerators, number of patients per day, number of medical physicists, etc.); age and gender of the patient; notification to the patient and his physician; type of disease and anatomic location of the tumor; total and fractioned prescribed dose; treatment technique used and current phase of treatment; type of image used to locate the region to be treated; function of who discovered the incident; number of patients treated and staff in the date of incident; types of error and severity metric; reportable event to responsible organization; type of the severity and period of evaluation; description of the incident given by the person that evaluate the incident; causes and factors to the incident, and so on.

Figure 3 shows how the Response form looks like. This third form is the form where the person responsible by the evaluation of the incident reports the actions taken on the incident and may be filled by the same user responsible by the Summary and Analysis form. This last form contains the scales of clinical action related to the idea of severity of harm, from A (lower) up to D (higher), according to the guidelines of AAPM [5]; a pull-down menu with the type of intervention taken; free text boxes with the safety barriers, and corrective, preventive and learning actions.

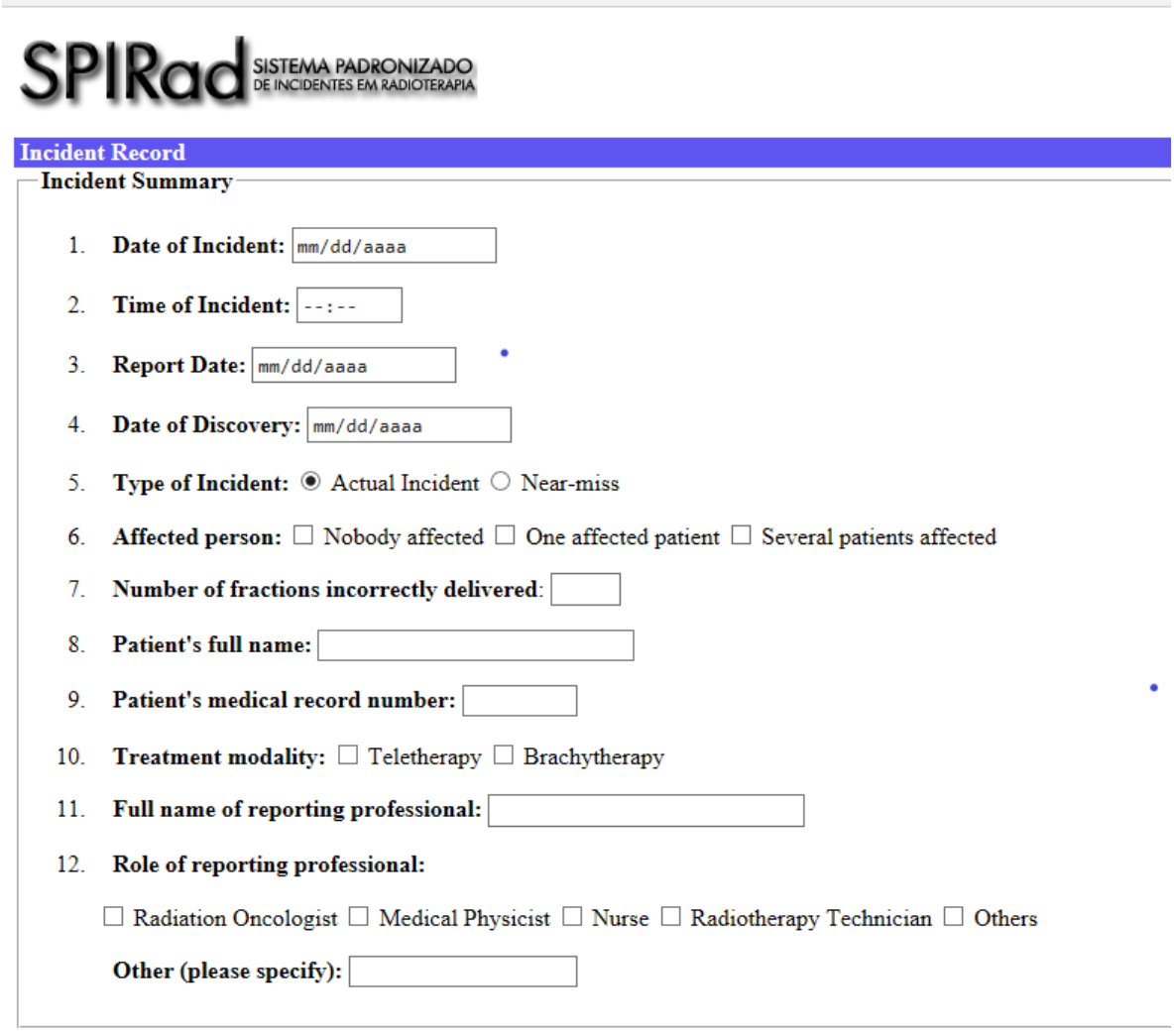

Figure 1. Incident Summary screen.

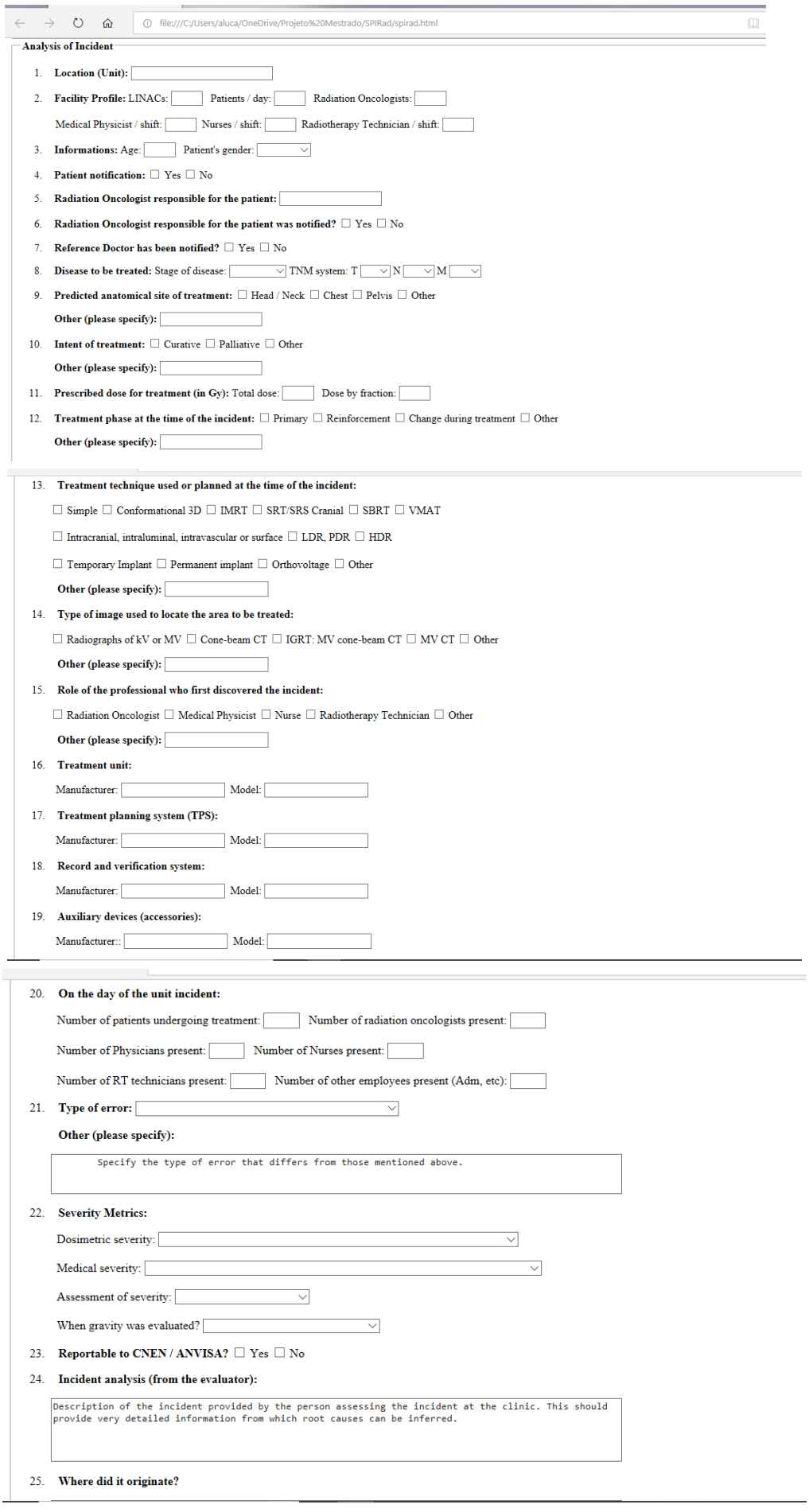

Figure 2. Analysis of the Incident screen.

In the first form (Incident Summary, see Figure 1) if we choose in field 5 the option Near-miss, the three forms above transform to a unique form with the topics:

1. Date and hour of the incident;
2. Date of the report and discovery;
3. Type of treatment;
4. Name and function of the professional that reports the event;
5. Location of the unit;
6. Notification to the Radiotherapist which is responsible by the patient;
7. Anatomic location to the planned treatment;
8. Phase of the treatment and technique used;
9. Type of image used to location of the region to be treated;
10. Function of the person that initially discovered the event;
11. Technical specifications on the treatment unit, planning system and system of registration and verification;
12. Type of error;
13. Detailed description of the event;
14. Point of the flux of work that the event began;
15. List of all causes and contributing factors in the work;
16. Preventive action taken in order to prevent the event to occur again;
17. Enlightening files (images, attached documents, etc.).

Figure 3. The screen showing the Response form.

When analyzing the consequences of an incident or near-miss in radiation therapy is recommended to assign a score to account for dosimetric and medical severity. In Tables 1 and 2 are shown the dosimetric and medical scales of severity used

in this work as adapted from reference [5]. The metric scales of dosimetric and medical severity are independent each other, and the dosimetric scale ranges from <5% deviation from the prescribed dose to any structure to >100% dose deviation; the medical scale ranges from temporary side effects with no intervention indicated to premature death. In Table 1 "Not applicable" refers to an incident with no dosimetric component, as for example an equipment failure.

3. Results and Discussion

The tool described in the precedent section was applied to a radiation department of a hospital in the city of Rio de Janeiro, Brazil. The facility is a public institution and its characteristics are: the team is constituted by 20 radio-oncologists, 6 medical physicists, 17 radiotherapy technicians, and 5 nurses per shift; approximately 400 patients are treated per day in 5 linear accelerators, 1 telecobalt unit and 1 HDR. In this Institution the SPIRad pilot test application lasted approximately 5 months and during this period the records were carried out by medical physicists.

Table 1. Dosimetric severity scales used in this work [5].

Level	Dose deviation per course
9/10	>100% dose deviation from that prescribed for any structure
7/8	>25% to 100% dose deviation from that prescribed for any structure
5/6	>10% to 25% dose deviation from that prescribed for any structure
3/4	>5% to 10% dose deviation from that prescribed for any structure
1/2	<5% dose deviation from that prescribed for any structure
----	Not applicable

Table 2. Medical severity scales used in this work [5].

Level	Consequences (actual or predicted)
10	Premature death
8/9	Risk of life – intervention essential
7	Severe and permanent disability (or grade 3/4 permanent toxicity)
5/6	Permanent minor disability (or grade 1/2 permanent toxicity)
3/4	Temporary side effects – necessary treatment or hospitalization
2	Temporary side effects – intervention indicated
1	Temporary side effects – intervention not indicated
0	No damage done

After the pilot test application, it was possible to draw a profile of the Institution according to the critical success factors for the implementation of the SPIRad. The analysis allowed us to identify and make the following statements for each critical factor:

i. **Need for resources:** Due to a great workload in the Institution, the employees had a short period available to feed the system with records, associated with the short time available for the SPIRad test application resulted in a low collection of records for evaluation;

ii. **User training and pilot test:** After presenting the system and guiding how to fill the fields, the employees were encouraged to use SPIRad by migrating some previous recordings from the traditional occurrence book to the system in order to familiarize themselves with the fields present in the form, which also made it possible to answer existing questions;

iii. **Ease of recording/registration, definitions and scope:** Based on the pilot test, it was possible through feedback from employees to perform necessary updates in some fields that, until now, were generating doubts to some members of collaborating team, and it was possible a design of a more practical tool for completing it, adapting it to the reality of the Institution;

iv. **Inclusion of near-misses:** Most of the records collected for analysis were related to near-misses, and from users feedback a specific form was designed only for this type of event. Although near-misses do not reach the patient they are an important source of incident learning [12,17].

v. **Voluntary and non-punitive records:** Because it was a voluntary test application, employees could anonymously to report and there would be no identification in case of non-completion of actual incidents and near misses;

vi. **Anonymizing the data:** When analyzing the causes of events, the human error was the predominant factor to the occurrence of actual incidents as far as near misses in almost all records collected. For this reason, the employees opted for the anonymization of the patient's data and even of those who detected and reported the event;

vii. **Focus on system improvement and record quality:** Employees of the Institution were conscious that the purpose of the system is to improve quality and security in the treatment processes, but due to the great workload and lack of time for the practice of reporting they left some fields in blank, filling only the essential and without detailing;

viii. **Perception of error:** All records were performed by medical physicists of Institution, but in most of the records the radiotherapy technicians were responsible for detecting the incident, which shows the perception of errors by part of other team members;

ix. **Organizational support:** In Institution, after a meeting with medical physicists and their superiors, it was obtained the support of the top management so that it could be possible to use the facility to carry out the test application of SPIRad;

x. **Integration with the Institution's general registration system:** Contributors of Institution took advantage of the test application to officialize the reported records, and as the test application was offline they printed the events recorded and attached to the occurrence book.

When evaluating the topic concerning the severity metrics in the collected records, the following details with respect to the incidents were obtained:

- All actual incidents had a dosimetric severity scale of 1/2 (absolute dose deviation of the total prescription below 5%);
- All actual incidents had a medical severity scale of 0 (no harm);
- All actual incidents were assessed in less than 24 hours after the incident;
- The scale of clinical action in all records of actual incidents was "A" in the ratio of A to D, that is, they had a low scale.

In majority of the systems described in the literature, the group of professionals who generates most records of incidents are radiotherapy technicians, dosimetrists and medical physicists, and the participation of physicians is almost non-existent [15]. In Fact, when surveying the records, it was observed that 70% of recorded incidents were detected by radiotherapy technicians and 30% by medical physicists. On the discovery of actual incidents and near-misses, an analysis was made of fields 24 (“Analysis of the incident”) and 25 (“Where it originated”) of the second form of the SPIRad together with the field 5 of the first form where the "Type of incident" field appears. A treatment process map for external beam radiotherapy was developed for the Institution according to general guidelines, as shown in Figure 4 [5,8,18]. It should be noticed that all reported incidents were related to external beam treatment; during the initial test application of SPIRad no incident relating to brachytherapy was recorded. After the survey of data on the origin of events, both actual incidents and near misses, it was possible to identify the stage of the process where the events were detected. Thus, it can be stated that:

- 70% of reported events were detected by radiotherapy technicians in the command room during treatment, half of them were identified as actual incidents and half were near misses.
- 30% of recorded events were detected by medical physicists in treatment planning, all being near-misses.

There are several factors that can contribute to an incident and a near-miss. Considering the fields related to the causes and factors that contributed to the occurrence of the incident in the Institution, we verify that:

- 60% of the contributing factors found in the records are related to human errors;
- 30% of the factors are related to procedural failures;
- 10% of the factors are related to technical problems in equipment.

When surveying the types of errors, an analysis of the collected records was made and among the reported types of errors, the most found were:

- Wrong patient: 2 events presented this type of error at the treatment delivery stage, resulting in actual incidents that were detected by radiotherapy technicians during the process;

- Dose prescription: 2 events presented this type of error in the review and verification stage for pre-treatment, both detected by medical physicists and characterized as near-misses;
- Design error: 1 event presented this type of error in the review and verification stage for pre-treatment, and it was detected by a medical physicist and classified as a near-miss;
- Opening of wrong a treatment plan of a patient: 2 events presented this type of error in the treatment delivery stage, and they were detected by radiotherapy technicians and resulted in 1 actual incident and 1 near-miss;
- Error of conference of the treatment plans of the patient: 3 events presented this type of error in the step of delivery of the treatment, and they were detected by radiotherapy technicians and were classified as 1 actual incident and 2 near-misses.

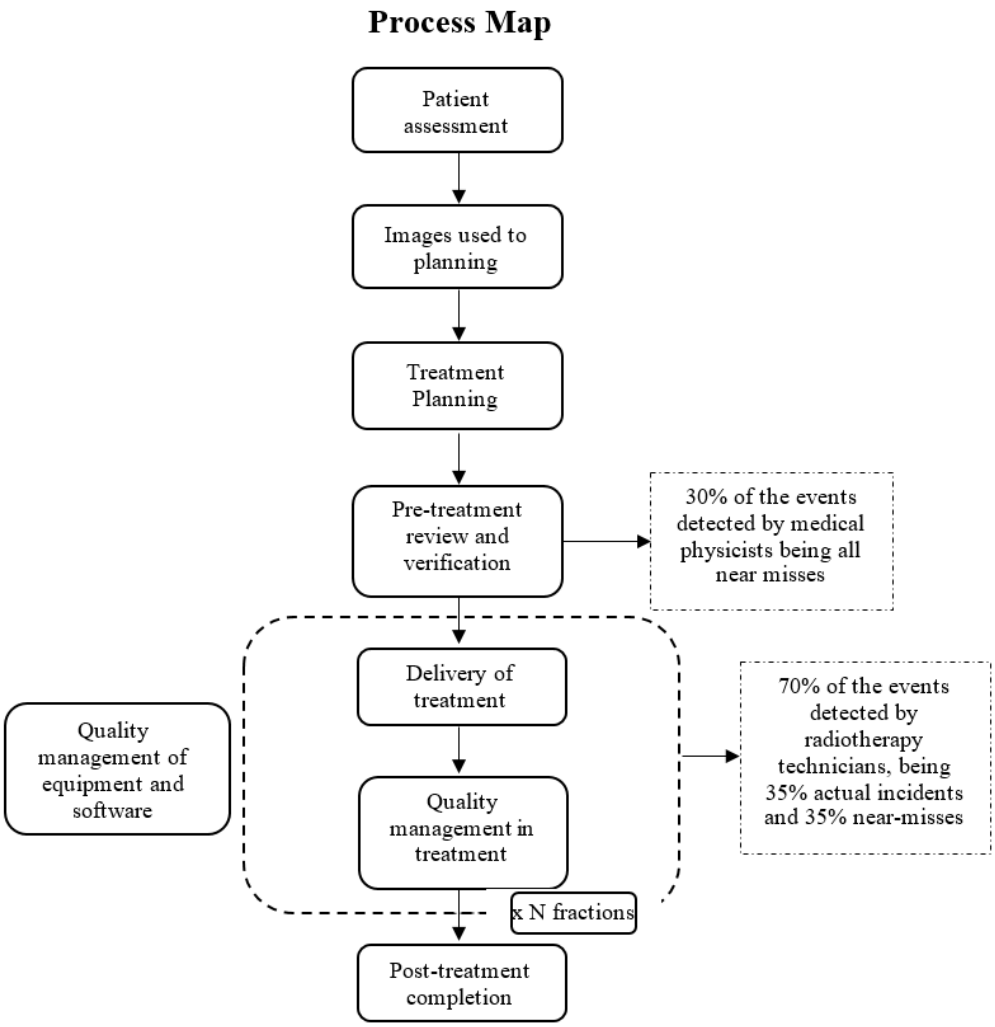

Figure 4. Map of processes for treatment with external beam with identification of the steps where the incidents were detected in the Institution.

The safety barriers ("Any process step whose primary function is to prevent an error or mistake from occurring or propagating through the radiotherapy workflow" [5]) are important critical points of control in the process map of the treatment with ionizing radiation. They are actions that at any stage of the process have as their main function to avoid errors occurring during the process and it is fundamental that they be perceived to what extent these are effective or not so that it is possible to analyze the information.

The safety barriers established in the records of the Institution were analyzed regarding the success/failure capacity in detecting actual incidents and near-misses. It is possible to verify that there exist efficient barriers in the detection of incidents. Furthermore, it is important to highlight that the barriers that did not detect an incident are not necessarily bad barriers, they only did not contribute to the detection because they are not directly related to the incident and can be considered weak barriers to the reported incident.

In Table 3 are shown the frequencies of the safety barriers observed during the initial test application of the tool. When analyzing the reported barriers in the collected records, it was detected that the safety barriers "Treatment monitoring" and "Check of the data in the planning sheet" were the most efficient in detecting the recorded events being an actual or near-miss incident. After these two events, the barrier "Patient ID Verification", which is a redundant safety barrier, is present in virtually every step of the treatment process map. The last two barriers did not detect errors, probably because they were not necessary since the barriers that preceded them were effective in detecting the incident.

Table 3. Frequency distribution of safety barriers reported in the collected records.

Security Barriers	Frequency	Relative Frequency
Verification of patient's ID	3	0.13
Planning review by the physicist	2	0.09
Independent calculation of dose	2	0.09
Registration and verification system	2	0.09
Checking the data in the planning sheet	4	0.17
Image-guided verification	2	0.09
In vivo dosimetry	2	0.09
Treatment monitoring	4	0.17
Verification of the weekly chart by the physicist	1	0.04
Post-treatment clinical evaluation	1	0.04
Independent review of commissioning	0	0.00
Quality management in progress	0	0.00
Total	23	1.00

Finally, when the data referring to the fields of the form that focus on corrective, preventive and learning actions were collected, all 10 records presented solutions related to the incidents. The corrective action to "wrong patient" incident was the reinforcement of actions of patient identification and improvement in the organization of the treatment schedule; the preventive action was the improvement in the patient's photo requirement in the management system, and the learning action was the improvement in the communication. The incidents that presented as an error "wrong prescription" and "design error" had only preventive action, respectively, the improvement of the use of electronic prescription by the physicians in the management system and the use of structure sets for standardized delineation and the implementation of double medical check. The incidents that presented as an error "opening of the wrong patient's plan" were those that had technical problems as contributing factors, and had as a preventive action the manual insertion of the treatment parameters into the system of management, and completion of all courses of treatment after the end of treatment plan so as to make it not more available to be erroneously opened in the control room. Lastly, the incidents that presented as an error "conference of treatment plans" had as corrective action the scheduling of a new application at the end of the course of treatment to complete the treatment and as a preventive action the need for the presence of the physicist also in the phase changes of the treatment.

4. Conclusion

In conclusion, we can point out that:

i. Along this work all records obtained in Institution were filled by medical physicists, as they chose to be responsible for this function of feeding the SPIRad with the data.
ii. In this study, after a review and harmonization of all concepts, it was possible to establish structuring criteria for an incident recording platform in the collaborating Institution.
iii. The incident learning system is an important tool used in risk management in various productive sectors. As stated in the literature, the application of this methodology has been recommended by specialists in the health area and stands out in radiotherapy, as required by regulatory organizations.

iv. After completing SPIRad's digital environment and its pilot test application, it is possible to say that SPIRad can be very useful in improving treatment protocols, provided that it will be possible to report and evaluate informations that impact on the treatment, making it possible to take actions to reduce risks.

v. SPIRad allows sequential recording of actual incidents and near-misses in radiotherapy, divided into categories and processes throughout the treatment. According to some feedback from users, usefulness of SPIRad is one of its most interesting feature which can be seen in the records since there were no fill errors despite the test application was performed in the offline mode.

vi. Because it is a voluntary tool and therefore an institutional tool of instructive and non-punitive nature, SPIRad will assist in the quality management policy and patient safety culture. However, to have a good use, it is necessary to have participation and practice in reporting the events and to share the experiences obtained, be constant and embraced by the entire professional body involved with the treatment, since radiotherapy is a multidisciplinary practice.

vii. After the initial application of SPIRad and the first results obtained, next it is intended to offer the tool to be applied in other institutions that use external beam radiation as far as brachytherapy to treat patients with cancer.

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