SAFRON
Improving Safety in Radiotherapy

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***Abst*ract-Safety incidents occur in radiotherapy. If we do not acknowledge that there is need to collect information on safety incidents, this may lead to a lack of understanding or learning from these incidents. In an effort to promote safety improvements in radiotherapy, the IAEA has developed an incident reporting and learning system. The Safety in Radiation Oncology(SAFRON) reporting and learning system is a voluntary, non-punitive, anonymous reporting and learning system on the Internet, aimed to enable global sharing of information on safety related events and safety analysis in order to improve the safe planning and delivery of radiotherapy. SAFRON contains over 1230 reports of incidents from around the world. It allows the viewer to search for information that might be helpful in enabling the safe use of radiation in radiotherapy centres.**

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I. Overview

Safety incidents (or near misses and minor incidents) are key indicators of a medical facilities safety performance. The goal in reporting and evaluating safety incidents is to improve awareness by recognizing unsafe conditions and acting on these events before they escalate into severe accidents. Near miss and incident analysis can also be used to identify themes and trends that the radiotherapy center should focus on to improve patient safety and manage risk. Radiotherapy centers may have problems in identifying potential serious errors if they are not aware of near misses or minor incidents because they fail to capture the information. The term "incident" refers to any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.[1]. Incidents are an outcome of organizational failures that should have been addressed [2]. However, learning from incidents should not only focus on preventing recurrence, but also on making the radiotherapy processes in a facility inherently safer. Identifying the unwanted deviations and learning from them leads to safer and more reliable processes, which will result in fewer incidents, thus safer radiotherapy and potentially improved outcomes [3]. This paper presents the Safety in Radiation Oncology (SAFRON) learning system developed by the International Atomic Energy Agency. Its purpose is to address the need to learn from incidents and implement this learning in practice. It is a system that can be used to report, review, analyze and learn about events within the individual radiotherapy center and also share and learn from information in the larger international radiotherapy community.

II. Background

Patient safety is a comparatively new discipline that has rapidly risen to star status. This rise began in the late 1990s, with eye-opening report that documented the potential scale of harm caused by medical errors, "To Err is Human" [4] that addressed patient safety issues in the United States. The publication outlined significant improvements that could be made in patient safety. One such recommendation was to identify errors and learn from them. To accomplish this, there must be a comprehensive strategy to create an environment that encourages organizations to identify errors, evaluate causes and take appropriate actions to improve performance reducing the chance for future errors. Participating in external reporting systems extends the learning from just one radiotherapy center to the community of centres allowing others to also learn from the event.

The British Institute of Radiology, et al [5] published "Towards Safety Radiotherapy" in 2008, outlining specific improvements that could be made in patient safety including recommending "each radiotherapy department to have a system for reporting and analyzing errors". The lesson learnt should be fed back to the staff in an effort to learn from errors. The recommendations from this publication was for a reporting system to be effective, it should be separate from any enforcement authority; be able to receive reports in which centres can be identified but treated with total confidentiality; be able to maintain patient confidentiality; and have the formal endorsement of stakeholders through professional bodies. This would lead to a specialty-specific voluntary system

of reporting, analysis and learning from radiotherapy events.

In 2012, the American Society of Radiation Oncology (ASTRO) published a response to the 2010, US Congressional Hearing on Safety in Radiation Oncology [6]. "Safety is no Accident," encouraged employees to report both errors and near-misses. [7] The reporting of near-misses was recognized as a powerful tool for identifying problems in the work flow process before they reach the patient and contribute to an error.

In parallel to the activities taken by healthcare professional and radiotherapy professional organizations, the International Atomic Energy Agency (IAEA) Steering Panel of the International Action Plan for Radiological Protection of Patients in 2008 recommended the IAEA develop a reporting system for radiotherapy. This recommendation led to a Consultants Meeting on the Development of an Educational Reporting System for Radiotherapy (CS-160) in December 2008. [8]

The CS160 report recommended the following attributes to be considered in creating a reporting and learning system:

- The ability to report both incidents and near incident;
- Ability to lean from the incidents and near incidents;
- Be dynamic;
- Be applicable to a wide range of settings;
- Be able to integrate new technology or processes;
- Enable feedback;
- Support education and training;
- Ability to easily share information;
- Ability to integrate retrospective reporting with prospective risk analysis;
- Ability to integrate with existing systems complementing national and mandatory systems;
- Ability to assist in patient safety assessment;
- Incorporate safety of medical workers in radiotherapy;
- Ability to influence safety culture and improve outcomes; and
- Enable research.

Reporting systems are designed to meet two purposes. They are designed to meet regulatory requirements where the administration of the radiation varies from the planned or prescribed dose. The mandatory reporting usually focuses on the failure to follow the physician's orders. These reports do not imply harm to the patient. In many instances they result in administrative fines, increased regulatory oversight and in very serious events to "cease and desist orders". Such systems ensure a response, hold medical facilities accountable for maintaining safety, respond to the public's right to know, and require changes to the internal safety environment that should reduce the likelihood of such events occurring.

The second purpose is the use of voluntary reporting systems that are non-punitive and confidential, which can also be used to improve safety. Voluntary reporting systems generally focus on a much broader set of errors including near misses in an effort to detect system weaknesses before the occurrence of serious harm. Near misses can provide a wealth of information to radiotherapy facilities in support of their quality improvement efforts. The goal of these reporting systems is to analyze the information gathered and identify ways to prevent future events. Most important for both types of reporting systems is that the collecting of reports by either system while not sharing the information leads to little value when aiming to improve patient safety.

III. Development of SAFRON

In 2010 the development and testing of an international safety learning system in radiation oncology began at the IAEA. The system incorporated many of the recommendations for the CS160 report and Figure 1 below describes the flow of information. As the diagram demonstrates, the feedback to the external group is essential to encourage support for safety improvements. The name SAFRON was chosen as an acronym for SAFety in Radiation ONcology and followed the naming features of other projects within the IAEA.

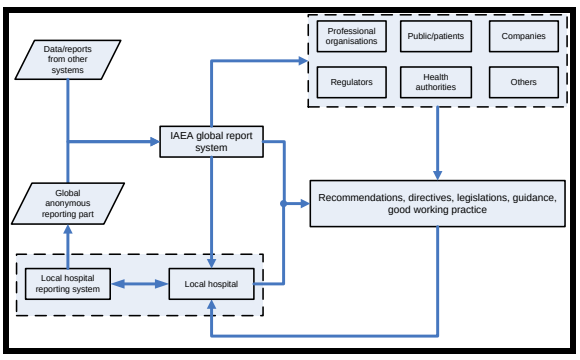


Figure 1 Flow chart outlining the information flow between the reporting institutes, the IAEA global safety reporting and learning system and other targeted groups, and indicating how this may influence decision makers, regulators, best practice development, etc.

The system was designed in English. The reports are anonymous. The reports are confidential for both the event data and registered user. The system is protected under the IAEA NUCLEUS gateway from intruders who may edit, add or delete information or contaminate the database.

The input of reports has been designed using limited free text fields. The narrative of the description of the event is free text and a response to "other" in the collection of data is free text. The remaining information is provided with the use of drop down menus, check boxes and charts where multiple selections can be made. This supports the easy use of the system and ability to perform data analysis.

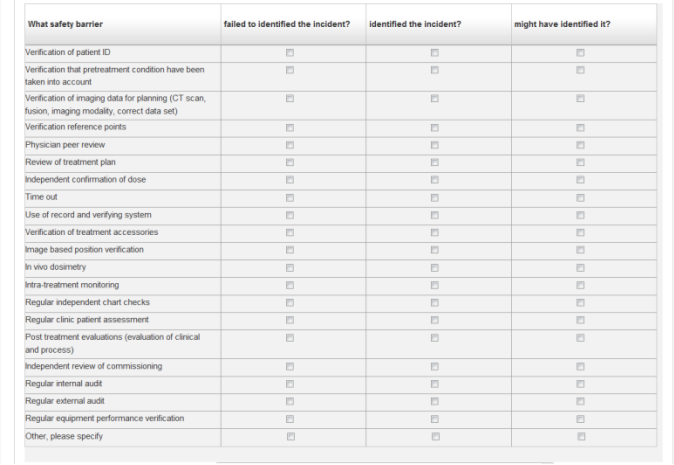
The order of the reported data is based on radiotherapy process steps. The process steps used in SAFRON were derived from the World Health Organizations Radiotherapy Risk Profile [9] as well as the British Institute of Radiology, et al [5] publication "Towards Safety Radiotherapy". This allows the entire process to be analyzed readily identifying corresponding steps which the failure is associated with and where the failure was identified. For those unfamiliar with the process steps there is help screen information.

The reports include information on severity of the event using the severity scale developed by the Alberta Heritage Foundation for Medical Research. [10] This severity scale has been used at radiotherapy centres in Canada.

The report also requests the contributor to evaluate causality of the event using a systematic table identifying job factor, systemic/management factors and personal factors described in the document "A Reference Guide for Learning from Incidents in Radiation Treatment". [10] The contributor is also able to provide the corrective action proposed by the center to prevent the reoccurrence of the event. Special consideration was given to the design of the data to allow the participant to complete the process in a few minutes.

To build the system and test its "usability", data from the Radiation Oncology Safety Information System (ROSIS) [11] and IAEA reports [12] were "mapped" into SAFRON. The information was manipulated, reviewed and searched using the available parameters in the system. A pilot study was conducted by 10 radiotherapy professionals who entered data and performed search queries on the system. The results of the pilot program indicated that the system was operational. The pilot participants requested the addition of safety barrier information. This was added to SAFRON in an effort to capture information on barriers that failed to identify the incident, barriers that identified the incident and barriers that might have identified the incident if the barrier would have been available. This is a unique feature of SAFRON.

Information on safety barriers was not available for the ROSIS or IAEA reports prepopulated for the pilot study but are being collected from contributors in the recent submittals.



What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	☐	☐	☐
Verification that pretreatment condition have been taken into account	☐	☐	☐
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	☐	☐	☐
Verification reference points	☐	☐	☐
Physician peer review	☐	☐	☐
Review of treatment plan	☐	☐	☐
Independent confirmation of dose	☐	☐	☐
Time out	☐	☐	☐
Use of record and verifying system	☐	☐	☐
Verification of treatment accessories	☐	☐	☐
Image based position verification	☐	☐	☐
In vivo dosimetry	☐	☐	☐
Intra-treatment monitoring	☐	☐	☐
Regular independent chart checks	☐	☐	☐
Regular clinic patient assessment	☐	☐	☐
Post treatment evaluations (evaluation of clinical and process)	☐	☐	☐
Independent review of commissioning	☐	☐	☐
Regular internal audit	☐	☐	☐
Regular external audit	☐	☐	☐
Regular equipment performance verification	☐	☐	☐
Other, please specify	☐	☐	☐

Figure 2 Information on Safety Barriers in the SAFRON reporting and learning system.

IV. SAFRON TODAY

SAFRON was launched on December 12, 2012, and currently contains 1231 reports. [13] These are combinations of actual incidents and near misses from ROSIS, IAEA reports and SAFRON participants. Participation in SAFRON includes facilities in all regions of the world with diverse radiotherapy capabilities from single-unit Cobalt teletherapy centres to centres with protons or advanced 12 linear accelerator centres. SAFRON participants estimate they will treat 64, 319 new patients each year. In addition to participating centres, there are two government organizations that contribute to SAFRON, the French Nuclear Safety Authority (Autorité de Sûreté Nucléaire), ASN and the Conference of Radiation Control Program Directors These reports are on incidents that met the regulatory threshold for notification to the government authorities.

Participants are encouraged to report near misses since they provide information of the adequacy of the safety infrastructure in place. Corrective actions and causality are also considered in each report, thus the opportunity to learn from the incident or near miss. There are several participants that use the SAFRON system as their own internal reporting system. To do so, they can track their own submissions by changing the parameters for the dataset contributor to review their own events by using a drop down menu that allows them to see only the events they have added to the system. The institute also has full access to all reports on the website allowing the participant to benchmark against international reports.

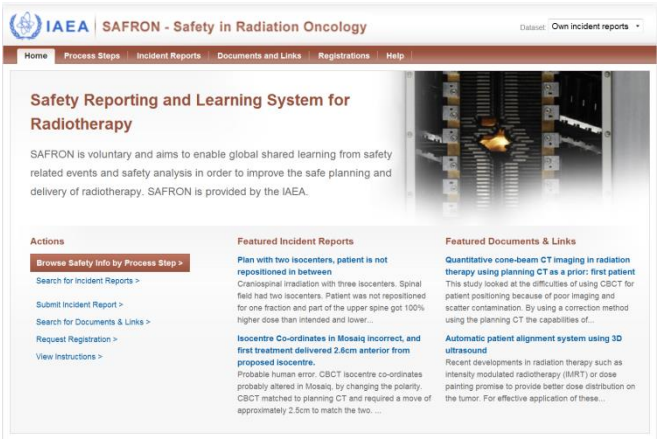


Figure 3 SAFRON for individual facility use

V. Learning from SAFRON

With 1231 reports available for analysis, early observations are available for many of the types of incidents and near misses. More importantly there are recommendations in the change of procedures from the event. An example can better demonstrate the effectiveness of the system.

In reviewing the data, the pre-treatment phase account for 615 reports. Within this process step, there are 255 reports related to the sub-process step of treatment planning. Further analysis into a finer grid of sub-processes indicates that treatment information transfer errors account for 109 reports. Evaluating these reports; 76 are identified as reports where incorrect data was entered into the treatment planning system. For the radiotherapy center, consideration should be given to adding an additional requirement for a review of the transfer of data before treatment, verifying that the correct information was submitted. Even in those institutions that have automatic transfer of data from imaging to treatment planning to record and verify, there are identified incidents where the wrong CT scan was used, the wrong patient file was used or the orientation of the patient for the imaging study was different than the treatment planning orientation. This can have significant consequence when the patient is receiving a few high dose treatments such as in stereotactic radiosurgery.

In the treatment phase, a similar review can be performed. There are 548 reports in the treatment phase. These are further defined as reports concerning treatment setup (393) treatment delivery (63), treatment verification (75), treatment monitoring (2) and other (12). Within the process step on treatment setup, reports concern the patient setup (393), treatment unit setup (154) and use of accessories (105). With a significant number of reports in the treatment phase and the potential for the error to reach the patient it may be of interest to facilities to focus corrective actions to prevent these types of incidents and near miss. A robust safety system would have barriers in place to prevent errors at the treatment setup process. Some of the recommendations provided by the participants in this area are standardization of treatment protocol, second independent review of treatment parameters and the use of time out before treatment. Something as simple as a new procedure standardizing the use reference marks could prevent a future accident.

Figure 4, an example of a SAFRON Report

VI. Safron future

Just as radiotherapy is continuing to evolve, so is SAFRON. New search features are planned as well as an expansion of capabilities to include brachytherapy and radiopharmaceutical therapy. Offering SAFRON in other languages needs to be addressed. An effort to identify qualified radiotherapy personnel to assist with translations for the text fields is under consideration. Realizing that participants have limited time and capabilities to perform essential analysis, more published information is planned. There are other radiotherapy reporting systems where coordination and sharing of information may be possible.

There is a project underway to address the feasibility of adding a prospective risk analysis feature to SAFRON. This is based on the work of medical physicists associated with the Latin American Forum of Radiological and Nuclear Regulatory Agencies (FORO). [14] SEVRRA is a software tool used to facilitate the assessment of risk levels of radiotherapy services and to standardize regulatory assessment activities in radiation safety practices. Using reports in SAFRON, the system can help participant's identify potential risk of errors.

VII. Conclusion

As important as gathering the data for learning purposes is the dissemination to external groups which

may not be in the position to enter reports but can review all the information in SAFRON. These include: some groups of healthcare professionals; educators and trainees; resource allocating organizations; institutes, clinics and hospitals; manufacturers, government authority, influencing organizations such as professional societies; patient advocacy groups; the public, media, researchers and the patients. In addition, the Agency provides information through newsletters and compiled reports summarizing, analyzing and drawing conclusions from the global safety database. As more information becomes available, best practice guidelines, directives, suggested regulations and other instruments will be made available to support improved safety in radiotherapy.

As new knowledge becomes available it will require the collective support of all groups to advancing the field of safety in radiotherapy.

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