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Design of a local incident learning system in radiotherapy based on SAFRON

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Independently of reporting events to general incident learning systems, a local incident learning system is required. With these local systems, events can be analysed and specific actions can be designed and adapted to the specific workflows and technologies available in each Service. The design of these local systems involves a significant effort and must be carried out in such a way that it is easy to report and that the necessary information is recorded for subsequent analysis. In this work, the design of a local incident learning system based in a web form with the SAFRON structure is presented, showing the advantages compared to other possible options.

Key words: ILS, Incident learning system, SAFRON, safety in radiotherapy.

Introduction

A fundamental principle of the healthcare system is patient safety. In fact, one of the main precepts taught to every medical student is "primum non nocere" or "first do no harm". However, morbidity and mortality due to errors in hospitals[1] remains a major concern. In radiotherapy, although most errors are minor, errors with fatal consequences for patients can and do occur and are widely followed by the media.[2,3]

A fundamental tool for improving safety and learning from errors (or near misses) is the use of Incident Learning Systems (ILS) in radiotherapy. An ILS consists of a cycle of reporting, analysis and incorporation of preventive actions. Its implementation actively promotes safety culture, but it is a challenge that requires specific resources, cultural changes and in which an adequate design is essential.

The European Directive 2013/59/Euratom[4] and its transposition into Spanish legislation[5] establish that "an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures" must be implemented. It is also included in the Patient Safety Strategy of the National Health System[6] and in European recommendations.[7] Our legislation[5] states that the undertaking or the organisation responsible "shall implement the appropriate measures to reduce as far as possible the probability and magnitude of accidental or unintentional exposures". Therefore, regardless of the existence and need for external ILSs, it is necessary to have a local ILS, which allows the design of the specific measures to reduce the probability and magnitude of accidental exposures, and to which both errors ("events involving") and near misses ("or potentially involving") can be reported.

There is a clear need for local, national and international ILS in radiotherapy[7,8] with the same basic objective, but each oriented to a different audience and needs. Thus, although for all ILSs the main objective is to learn from errors and near misses, in local ILSs the analysis should lead to the design of defences adapted to the local configuration and processes to avoid the repetition of the event; national or international ILSs have much larger databases, which allows learning from the events of other departments, learning from errors that occur more rarely and the massive statistical mining of the reported data. Being all types of ILSs necessary, if there is correlation between the structure of a local ILS with the national or

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international ILS, the possibility of sharing information between local ILSs and a national or international ILS is greatly facilitated.

Our hospital did not have a radiotherapy-specific ILS. There is a general hospital ILS for events that affect patient safety, but it does not have a structure with radiotherapy-specific fields that characterize the site of the process where the event is associated with or where it is discovered, the severity, modality, contributing factors, or measures to reduce the likelihood of repetition of the event. This lack of specificity in the fields for data collection, together with the difficulty in analysing a specific radiotherapy event by a hospital patient safety group without adequate representation of the professionals involved in the radiotherapy process, makes the use of these systems for radiotherapy very difficult.

This paper discusses the design of a local ILS based on a web form and with the structure of the SAFRON[9] system, as well as the reasons for choosing this option. SAFRON (SAFety in Radiation ONcology) is a voluntary and anonymous ILS maintained by the International Atomic Energy Agency (IAEA) since 2012. It has more than 1300 reported events and powerful tools for learning from reported events and near misses.

Material and Methods

The characteristics of different radiotherapy ILSs have been studied, trying to find the common features and the characteristics that a specific local ILS for radiotherapy should comply with in the design. For this purpose, SAFRON,[9] ROSEIS,[10] Hospital incident reporting system (CISEMadrid[11]), SiNASP,[12] ASN-ANSM[13] and PRISMA-RT[14] were studied. The characteristics studied in these ILSs were whether:

- The system is local or has a wider geographical coverage.
- Notification to the system is voluntary or mandatory.
- The system is anonymous (the reporter does not reveal his or her identity at any time), confidential (the identity of the reporter is not revealed outside the group in charge of analyzing the reported events) or, on the contrary, all information is public.
- To make a report, a prior registration as an ILS user is required or not.
- The system has a general structure to accommodate any type of medical event or, on the contrary, it is specific and has a structure especially oriented to radiotherapy events.
- All types of events can be reported or only those with certain characteristics, e.g. significant events.
- Individual events can be queried to learn from them, or it does not allow querying.

In the design of any ILS we can differentiate between the structure (set of fields and their interrelationships) and the management tool (software and policies for access by the reporter and the analysis group). In this study, the reasons for emulating as far as possible the SAFRON structure, but with a management tool (web form) different from SAFRON, are analysed. The advantages and disadvantages of the proposed solution are discussed, analyzing the critical factors identified in the literature for the successful implementation of ILSs.

Results

Table 1 provides a comparison of the characteristics of the ILSs studied. As can be seen, a Competent Authority ILS (as is the case of ASN-ANSM or the one to be implemented by the health authority in Spain to comply with article 14.2 of RD 601/2019[5]) is mandatory, is reserved for significant events and usually is not anonymous. These systems address the need to provide institutional accountability for significant events. ILSs where the only objective is to learn from errors are normally anonymous or confidential, voluntary, and open to all types of events (although there are systems such as PRISMA-RT that are designed to work only with near misses, thus avoiding the problems associated with real incidents, such as legal liability, embarrassment or fear of reporting). None of the systems studied use paper forms as a reporting system and all systems are now web-based.

None of the systems studied fully meet the characteristics we would wish for a fully functional local ILS for a variety of reasons:

1. The geographical range of the system does not include events occurred or reported in Spain (which makes us discard PRISMA-RT and ASN-ANSM) or it is not implemented in all the Autonomous Communities (such as the SiNASP system, promoted by the Ministry of Health and implemented in some communities, but not in the Community of Madrid).
2. The system is not specific for radiotherapy, i.e., it is too generalist to contemplate the particular characteristics of the radiotherapy process, the contributing factors or specific measures to be implemented, which makes data collection and

Table 1. Comparison of the characteristics of the studied ILSs.

Feature	SAFRON	ROSEIS	CISEMadrid	SiNASP	ASN-ANSM	PRISMA-RT
Local (L), External (E)-Geographical area	E/L Global	E/L Global	L Madrid	E Spain	E France	L/E The Netherlands
Voluntary	✓	✓	✓	✓	✗	✓
Anonymous-Confidential	✓	✓	✓	✓	✗	✓
Registration required	Yes	Yes	No	Yes	Yes	Yes
Specific for radiotherapy	✓	✓	✗	✗	✓	✓
Reportable events	Any	Any	Any	Any	Significative	Near misses
Possibility to search incidents	✓	✓	✗	✗	✗	✓
Summaries/Safety Notes	✓	✓	✓	✓	✓	✓

subsequent analysis difficult. This leads us to discard CISEMadrid and SiNASP.

3. The system does not allow direct and anonymous reporting by any unregistered person in the system, at any time, using any medium (PC or mobile). If we consider these characteristics as fundamental, none of the possibilities proposed would be valid, including the systems that are specific for radiotherapy, can be used from Spain and have the possibility of using the system as a local ILS, as is the case of SAFRON or ROSEIS.

Therefore, none of the systems met our desired needs to function effectively as a local ILS. In addition, there are very few commercial solutions available for event reporting. Probably the best solution would be the possibility to design them as part of Oncology Information Systems, but in the meantime, if we want all the above-mentioned features, we are forced to design our own local ILS. This has, a priori, the advantage of designing a specific system adapted to the particular characteristics of each Service, the disadvantage of using a significant amount of resources in the design and, depending on how it is designed, it may involve difficulties in combining, comparing and sharing data with other Departments or general ILS that have a different structure.

The International Atomic Energy Agency (IAEA) has an ILS for educational purposes specific to radiotherapy called Safety in Radiation Oncology (SAFRON), which is a world reference and whose structure has been used in the design of our hospital's local ILS for radiotherapy. The local ILS developed not only serves to identify, learn from events, and reduce the likelihood of repetition, but can also respond to the need to comply with current legislation.[5] The SAFRON structure includes fields for entering free text for the event description and a complete system for classifying events. This classification is based on the process described in various publications of recognised prestige.[15–17]

In SAFRON, it is possible to filter reported events from the reporting department so that, at least theoretically, it could be used as a local ILS. However, there are two problems (in the tool, not in the structure) that make it difficult to use it for this purpose:

1. To be able to notify to SAFRON, the radiation oncology department must be registered with a single notifier per department. This means that notification cannot be made freely, easily, and anonymously by any professional in the department. A radiation oncology department may decide that different users use the department's credential. However, this would go against the IAEA policy in SAFRON. IAEA requires a single authorised user per department, who is the department's point of contact, who knows the system and who serves as a filter to assess what is reportable and in what form.

2. Internal agreement and permission to be able to send data to an external ILS can be difficult to obtain, as event reporting can have media and even legal implications. There is reluctance to send sensitive data of this type to a system outside the hospital, even though the IAEA considers personal details, or those of the particular radiation oncology department, to be confidential and therefore will not be disclosed to any regulatory authority, media, other facilities and any other third party.

Therefore, we have worked on using the SAFRON structure and integrating it into a Microsoft Forms web form. Microsoft Forms is the web application for forms

Fig. 1. Screen of the notification system as seen through a mobile phone or PC.

and surveys contained in the ©Microsoft 365 package included in the digital platform of our hospital and is associated with an institutional email account. This web form can be voluntarily accessed anonymously via a url (or a QR code), either through any PC or mobile phone at any time (see fig. 1). The application allows the statistical management of data and the review of individual notifications, as well as the setting of alarms each time a new notification occurs via email to the associated institutional account.

The SAFRON structure, incorporated with slight adaptations in the local ILS, has the following features:

- Determination of the consequences of the event with 5 levels of dose deviation, 6 levels of severity and number of patients or professionals affected.
- How, by whom and when the incident was discovered.
- Two treatment modalities:
  - External radiotherapy, in which the equipment, mode of treatment is determined, and a complete taxonomy is given for the stage associated with the event and the stage at which the event was discovered, with 3 phases (non-clinical, pre-treatment and treatment). Each phase has categories and subcategories for a total of more than 100 classification options.
  - Brachytherapy, with the same 3 phases and a tree with more than 100 modality-specific categories and subcategories to classify the stage.
- Free text field for a description of the incident.
- Classification of the causes of the event into work factors (18 options), systemic or management factors (15 options), personal factors (10 options) and natural factors (5 options).
- Selection of the barriers that failed, detected or could have detected the event, with 20 options.
- Free text field to describe the factors that contributed to the event.
- Free text field to describe the proposed corrective actions.
- Free text field to describe the suggested preventive actions.

From the 10-level structure of the World Health Organisation's International Classification for Patient

Safety,[18] the SAFRON structure has fields for all of them, i.e. type of event, consequences, patient and event characteristics, contributing factors/hazards, outcomes for the organisation, detection, mitigating factors, improvement actions and measures taken to reduce the risk. In addition, compatibility with the fields of the hospital's general internal reporting system has been verified.

Discussion

Critical factors identified in the literature[19] for the successful implementation of reporting systems include:

1. The implementation of a safety culture that makes reporting perceived as safe.
2. The establishment of a working group to analyse and implement action.
3. The use of a standardised taxonomy.
4. Efficiency in data collection.
5. Feedback of results to all staff.
6. Voluntary reporting.
7. Emphasis on improvement.
8. Efficiency in analysis and response.
9. Compatibility with other systems.
10. Anonymous reporting.

The proposed system design is not a guarantee of success, but directly affects critical factors 3, 4, 6, 9 and 10:

- 3. Since the standardised SAFRON taxonomy is used.
- 4. A web application is used that allows for quick and anonymous data collection from any PC or mobile phone.
- 6. Access from any device facilitates voluntary reporting.
- 9. The system has a SAFRON-compatible structure, the web form developed can be used in any department that chooses to use the same solution and the data can be exported for analysis in Excel. In addition, there would be no problem in making the data compatible with hospital ILSs based primarily on text field descriptions.
- 10. Voluntary access from any device, inside or outside the hospital, without the need for identification, ensures anonymous reporting.

In addition, the proposed design contributes to critical factors 5, 7 and 8:

- 5. the possibilities for automatic statistical analysis of responses can serve as a first level of feedback to professionals.
- 7. The reporting structure allows the recording of how the event was detected (i.e. what defense acted to enable detection, the root causes as seen by the reporter, and the measures to prevent the event from recurring in the future.
- 8. The possibility of having a very detailed structure where not all questions need not be answered, but only those necessary based on answers to previous questions, together with the possibility of alerts to the analysis group after each report, facilitates efficiency in analysis and response.

The effective use of the reporting tool further contributes to and involves the remaining factors:

- 1. the availability of an anonymously accessible reporting form, with a structure that guides the reporter in a first quick analysis of the event and the possibility to feedback statistical results from a collection of reports, contributes to building a safety culture in which reporting is perceived as safe.
- 2. The tasks of a working group are facilitated by a tool that allows the possibility of alerts, exporting data to Excel and automatic statistical analysis.

The structure implemented in the local ILS (see fig. 2) has a total of 704 options, 1193 connections between these options and only 15 required fields. Thus, there is a very detailed event classification taxonomy, but with a limited number of required fields to avoid as far as possible under-reporting due to an excessively high complexity of the system. There are 4 text fields and only the event description field is mandatory. The selection of one option often means the elimination of many other options that pendent on alternative selections, so that, assuming that all questions are answered, the longest path in the structure means, at most, 50 options to answer out of the 704 available. The SAFRON structure has been slightly adapted in 6 of the options to specify the names of equipment in the Department or to include

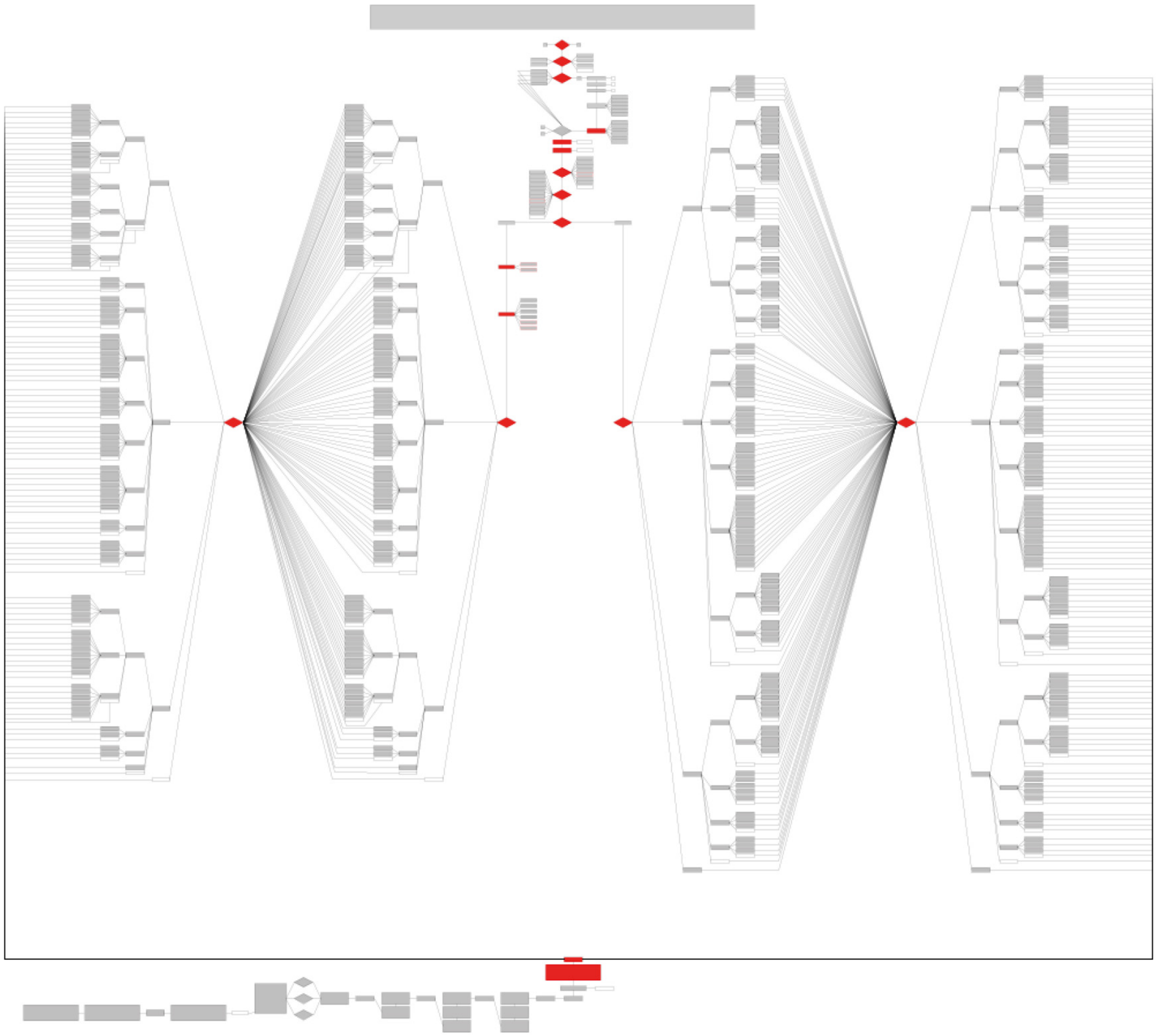

Fig. 2. General diagram of the structure of the notification system based on the SAFRON structure. Mandatory fields are highlighted in red.

options not included in the SAFRON structure such as the availability of SGRT or techniques such as SBRT or radiosurgery.

Therefore, the SAFRON structure can be used in local ILSs. The use of Microsoft Forms as a management tool has, in our case, advantages as it is a solution included in the institutional software package and to which the hospital's security levels apply. Similar solutions can be developed with other web-based survey tools such as Google Forms or Alchemer that would also allow web access, statistical analysis, and customisation of the ILS. Each department can choose one tool or another depending on the availability and degree of support in each hospital. Different web tools imply different implementations of the reporting structure with the SAFRON base, but the number of possible tools is rather limited and the development of one hospital can be shared with many other centres that need to use the same tool, so that the work in developing the management tool does not need to be repeated. Thus, for example, the solution proposed in this work with Microsoft Forms could be used in all public hospitals in the Community of Madrid.

Regardless of the tool, as the structure would be maintained, further external reporting of the data to SAFRON would be fairly immediate, as there would be a 1:1 correspondence between the local ILS data and SAFRON data. Therefore, considering the advantages and disadvantages, the solution can be a win-win strategy for the centre and for SAFRON as summarised in table 2.

Table 2. Advantages for the radiation oncology service and for SAFRON of the design of a notification system as presented in this work.

	For the Department	For SAFRON
Advantages	• ILS structure already developed and widely endorsed. • Possibility of customisation with specific attributes of the department. • More direct notification with any type of device and without the need for registration. • Translation into local language, eliminating the language barrier. • Possibility to share the notification system as a template without data, so that the effort to develop the local notification system tool is reduced.	• The more local systems have the SAFRON structure, the more likely it is to notify SAFRON, since the notification is simpler and more straightforward, with direct field-to-field correspondence. • Contribution to the standardisation of SAFRON taxonomy at international level, allowing for direct comparisons and aggregation of data.
Disadvantages	• Need to develop the web form with the SAFRON structure or contact a centre that has previously developed it to share it.	• Notification to SAFRON is not direct, but would be done in a step after the use of the SAFRON structure for local notification.

Conclusions

The SAFRON structure can be used in local ILSs without the limitation of prior registration and access limited to a single registered person per radiation oncology department. This requires the integration of the structure into a software that is chosen depending on availability, support and security. The solution designed provides advantages for both the Department and SAFRON. This type of solution can be shared as a template without data to be implemented in other Departments, thus reducing the workload necessary for the development of a tool needed to improve patient safety and legally required in our legislation.

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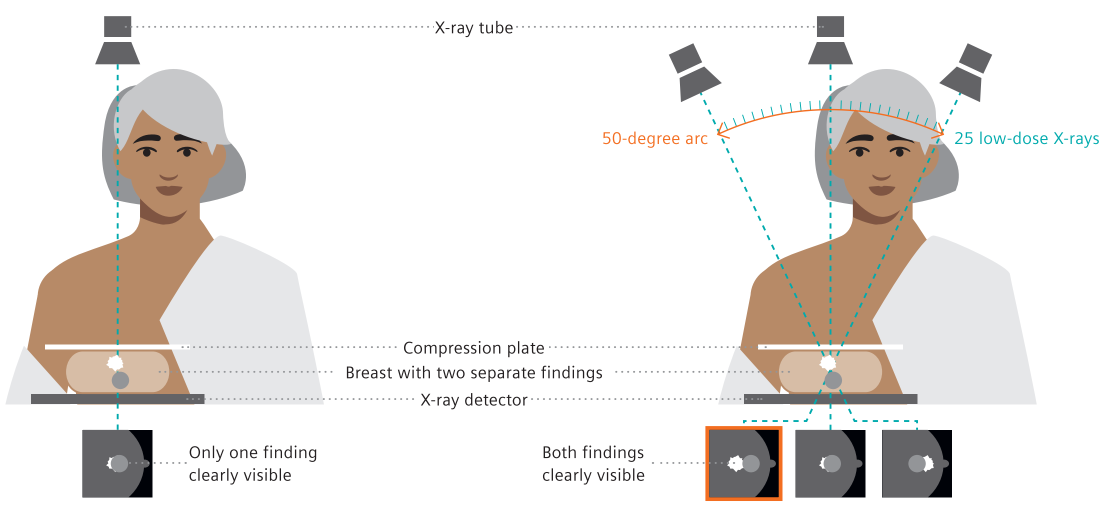

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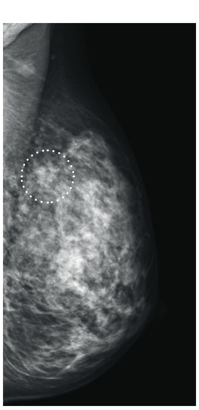
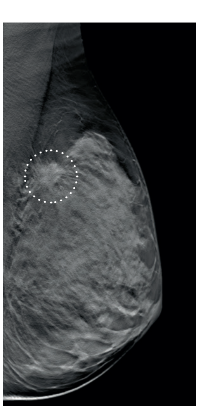


Finding is hard to see on 2D mammography scan



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