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Original research article

Critical success factors for implementation of an incident learning system in radiation oncology department

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ABSTRACT

Aim: The aim of this study was to analyze critical success factors (CSFs) for implementation of an incident learning system (ILS) in a radiation oncology department (ROD) and evaluate the perception of the staff members along this process.
Background: Implementing an ILS is a way to leverage learning from incidents and is a tool for improving patient safety, consisting of a cycle of reporting and analyzing events as well as taking preventive actions. ILS implementation is challenging, requiring specific resources and cultural changes.
Materials and methods: An ILS was designed and implemented based on the CSF identified in the literature review. Before starting the ILS implementation, a structured survey was applied to assess dimensions of patient safety culture. After the period of implementation (7 months), the survey was applied again and compared with the initial assessment, and interviews were performed with staff members to evaluate the overall satisfaction with ILS and CSFs.
Results: Statistically significant improvements were observed in 5 dimensions (12 totals) of the safety culture survey, considering time points before and after the ILS implementation. According to interviewees, "Facilitating committee", "Efficient data collection", "Focus on improvement", "Just culture" and "Feedback to users" were the most relevant CSFs.
Conclusions: The ILS designed and implemented at ROD was perceived as an important tool to support quality and safety initiatives, promoting the improvement in safety culture. The ILS implementation critical success factors were identified and have shown good agreement between the results of the literature and the users' practical perception.
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1. Background

Considering that patient care may not achieve the desired results, risk minimization strategies should be adopted in order to improve patient and professional safety. In radiation oncology, due to the multidisciplinary characteristic of various stages of the treatment process and the complexity of the technology involved, there are numerous sources of error that can reduce the therapeutic success. A strategy for risk reduction used in high reliability organizations (e.g. aviation and nuclear power plants) is to implement an incident learning system. An incident learning system (ILS) is a set of organizational skills that allows useful information to be extracted from events and used to improve organizational performance over time.[1,2]

The ILS involves technical and social aspects and it is not yet clear whether it results in effective improvements in patient safety, since there is no direct measure to evaluate a cause and effect dynamic. Other studies that implemented ILS presented improvements through indirect measures, such as positive impact on the professionals' perception,[3] decrease of high severity incidents.[4–6] and improvement of safety culture.[6,7]

The implementation of an ILS represents a considerable challenge, since it requires additional resources such as procedures, people, and time, as well as cultural changes. So, it is important to facilitate the effective participation of the staff involved in the process in order to make activities flow as efficient as possible, especially leveraging analysis and learning practices.[8,9] It is also important to consider and plan management control factors that can influence the success of the implementation. The Critical Suc-

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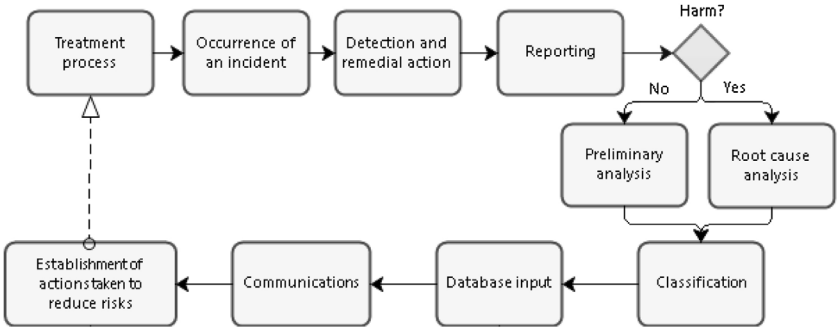

Fig. 1. ILS workflow of activities.

cess Factors (CSFs) are elements or activities that have a direct and serious impact on the success of a project. If there is a better control over these factors, the chance of success in the implementation of an ILS is higher. The concept of CSFs was first developed by D. Ronald Daniel, in his article "Management Information Crisis" (Harvard Business Review, 1961) and popularized by John F. Rockart almost two decades later.[10]

2. Aim

This study aimed to analyze the critical success factors considered most relevant for implementation of an incident learning system in a radiation oncology department and evaluate the perception of the team along this process.

3. Materials and methods

The radiation oncology department (ROD) considered is in a cancer hospital in Brazil. During the period of the study, there were 108 members: 15 administrative staff, 4 dosimetrists, 2 nurses, 7 medical physicists (2 residents), 18 radiation oncologists (8 residents), 13 nurse auxiliaries and 48 radiation therapists. There were 5 linear accelerators (2 of them without multi-leaf collimators installed), 1 high dose rate (HDR) unit and 1 CT simulator, and modalities available were: conventional radiotherapy (2D), 3D conformal radiotherapy (3DCRT), intensity modulated radiation therapy (IMRT), fractionated stereotactic radiotherapy (SRT) and radiosurgery (SRS), gynecological and prostate brachytherapy. During the period of the study, there were no new treatment modalities implemented at ROD.

The research method used was action research, a qualitative methodological approach guided by action, appropriate when the members of the organization and researcher aim to solve a practical problem applying existing theory and creating knowledge through the collaboration between the researcher and participants.[11] The researcher, a member (medical physicist) of the ROD team, acted as a facilitator and leader for the implementation of the ILS. A Radiation Oncology Quality Committee (ROQC) was set up consisting of a multidisciplinary team of eight members: medical physicist (researcher and leader of the ROQC), radiation oncologist, dosimetrist, radiation therapist, nurse, system analysts (IT), receptionist (scheduling responsible) and secretary.

Considering radiation oncology area, we selected publications through a systematic bibliographic review. The keywords used in the searching were: (ïncidentÖR "event") AND (ïearningÖR ïeporting¨) AND (ïadiation oncologyÖR ïadiation therapy¨), limited to the years 2010–2019. We found 107 papers in the PubMed®. Analyzing the abstracts, we found 10 studies describing institutional ILS in details and 2 papers with general recommendations to ILS structure. These papers were read and by cross reference we found other 3 papers, and we concluded the review.[4,5,8,12–23]

From the analysis of these publications (15 papers), we identified (when explicitly cited in publications) a list of ten CSFs to guide the ILS development. To select these CSFs, we used the number of citation of each CSF in the papers. The CSFs and some practices associated with the implementation of ILS are also listed (Table 1).

An event was considered either an incident (an unwanted or unexpected change from normal system behavior which has the potential to cause an adverse effect to persons or equipment) or near miss (an event or situation that could have resulted in an accident, injury, or illness but did not either by chance or through timely intervention), which was consistent with the AAPM definitions (in this study we use "incident" in this more specific sense of an event that reached the patient although it should be clear that "incident learning" also includes near misses, not reaching the patient).[8,17]

The ILS was developed by the ROQC, seeking greater adherence with the ROD, considering customization and sense of creation,[20] with a clearly defined flow of activities (Fig. 1) and standardized taxonomy (CSF: "standardized terminology and procedure"). The ILS proposed also combining elements of different ILSs described in the literature such as SAFRON,[25] ROSIS,[26,27] RO-ILS,[28,29] NSIR-RT[30] and seeking compatibility with hospital reporting system. The "focus on improvement" and "just culture" are intangible elements, but they were present in the attitudes of the leaders and ROQC members.

Every member of the ROD was able to report an event by electronic or paper forms anonymously (CSF: "anonymous reporting") and voluntarily (CSF: "voluntary reporting"). The electronic forms (home made using Microsoft Access®) were available in every desktop in the ROD and ten boxes (Fig. 2) were placed in different locations to allow staff members to complete the paper forms and deposit them in the boxes (CSF: "efficient data collection"). Event reports were collected twice a week and after a screening by the leader, they were distributed to a ROQC member to investigate the incident (CSF: "analysis and response efficiency"). The leader trained all the members in how to investigate and analyze an incident (CSF: "facilitating committee"). The events were presented by a member responsible for the investigation to the ROQC, discussed, classified and risk mitigation actions were suggested for implementation in the process (for example, changing layout patient chart, establishing training to team, standardizing procedures, checklists and so on). Furthermore, a brief report was presented monthly in an easily accessible ROD mural presenting the main events reported and analyzed, and the risk mitigation actions implemented (CSF: "feedback to users"), closing the ILS improvement cycle.

During the period of the study (7 months), 127 event reports were analyzed (13% in paper forms and 87% in electronic forms), with an average of 4.2 reports analyzed per week. The events analyzed were classified according to the categorization proposed by AAPM[8,17]: 93 (73.2%) Ñear missesänd 34 (26.8%) Ïncidents, most of these events (38%) occurred in the "Treatment" step of the ROD process. The group of professionals who recorded most events

Table 1
Critical success factors (CSF) in ILS implementation.

CSF and definitions	Practices	% citations	Articles
JUST CULTURE: Establishment of an atmosphere that staff members feel safe to report any event (without fear of negative consequences) and commitment of leadership. Punishment is applied only when negligence, recklessness or malpractice take place.	• Attitudes focused on improving the understanding of the event and the training of those involved • Use of a culpability decision tree	87%	4,5,8,12,14–18,20–22,24
FACILITATING COMMITTEE: Existence of a multidisciplinary committee trained for all ILS activities, mainly to analyze and classify events.	• Multidisciplinary committee trained and coordinated by an ILS expert • Weekly meetings	80%	4,5,8,12,15–17,19–23
STANDARDIZED TERMINOLOGY AND PROCEDURE: Clear rules, workflow, taxonomy and scope of the ILS, facilitating staff members to report an event and committee members to analysis and classify the reports.	• Elaboration of a written reference guide	80%	4,5,22,23,8,12,15–17,19–21
EFFICIENT DATA COLLECTION: Reports must be quickly accessible and easily completed by any staff members.	• Registration forms containing the definitions of the events to be included, with examples • Preparation of a report form that is easy and quick to be accessed and completed by any staff member	67%	4,5,12,16–20,22,23
FEEDBACK TO USERS: The results of each analysis should be communicated to staff members so that participants perceive the changes in their work routine.	• Disclosure to all staff members of a monthly summary of the reports made (or the main ones) in a specific period, communicating mainly the improvement actions carried out from the reports	67%	4,5,8,15–17,19,20,22,23
VOLUNTARY REPORTING: Staff members are not required to report events using ILS system.	• Department leaders do not require staff members to use ILS, they just encourage them • Staff members could report directly to their superior or using the hospital's reposting system, not necessarily the radiation oncology ILS	67%	4,5,8,12,13,16,17,20–22
FOCUS ON IMPROVEMENT: Emphasis in quality and safety of the reporting system to get good support for improvement actions (including near-misses events)	• When interviewing members to investigate events, emphasize that the ILS objective is to continuous improvement processes • Improvement actions more focused on process changes than on people (for example, classify the proposed actions, according to the hierarchy of effectiveness)	60%	4,5,14,16–19,22,23
ANALYSIS AND RESPONSE EFFICIENCY: Resources (people, time, instruments) suitable to allow analysis and response process after reporting as fast as possible (organizational support).	• Availability of the ROQC members to analyze events and participate on weekly meetings • Participation in meetings by committee members	33%	5,16,17,22,23
COMPATIBILITY WITH OTHER SYSTEMS: ILS specifically designed for radiation oncology, but allowing harmonisation with external systems (hospital's general or national/international reporting system), allowing to compare the results.	• Use of classification item from standards • Share monthly summary to quality hospital committee.	27%	8,16,17,20
ANONYMOUS REPORTS: Allow users not to identify yourself when completing a report (psychological safe).	• Allow a report to be submitted without requiring the author to identify themselves	13%	8,16

were medical physicists (41% of total reports), radiation oncologists (30%) and radiation therapists (25%).

The main contributing factors identified, according to Lawton et al.[31] classification framework, were: "Individual factors" (10.8%), "Communications systems" (10.8%), "Staff workload" (10.1%), "Policies and procedures" (9.8%) and "Team factors" (9.5%). The number of contributing factors identified (296) was greater than the number of event reports (127). Thus, on average, 2.3 contributing factors were identified per event reported. This result emphasizes that an event is generally caused by a combination of more than one system failure ("Swiss Cheese Model").[32]

To evaluate the perception of the team related to ILS, two techniques were used. The first applied a survey developed by the Agency for Healthcare Research and Quality (AHRQ)[33] to evaluate aspects of the safety culture. There are 42 questions grouped into 12 dimensions. In addition to the dimensions, the survey includes two questions that ask respondents to provide an overall grade on patient safety for their work area/unit and to indicate the number of events they reported over the past 12 months. Each question has five possible answers, two indicating negative perceptions of the respondent about the safety culture, two indicating positive perceptions and one neutral, and was associated with one safety culture dimension and the favorable frequency of each dimension was calculated by the ratio between the number of positive responses and the total number of responses obtained.

The second technique was a series of semi-structured interviews with 19 team members (randomly chosen, but involving at least one representative for each group) at the end of the study period. During the interviews, participants were asked to answer three questions:

1 Do you think the Incident Learning System (ILS) is an important tool for the ROD? Why?
2 What were the main ILS negative points (criticisms and difficulties) that you have observed? Make suggestions if you wish.

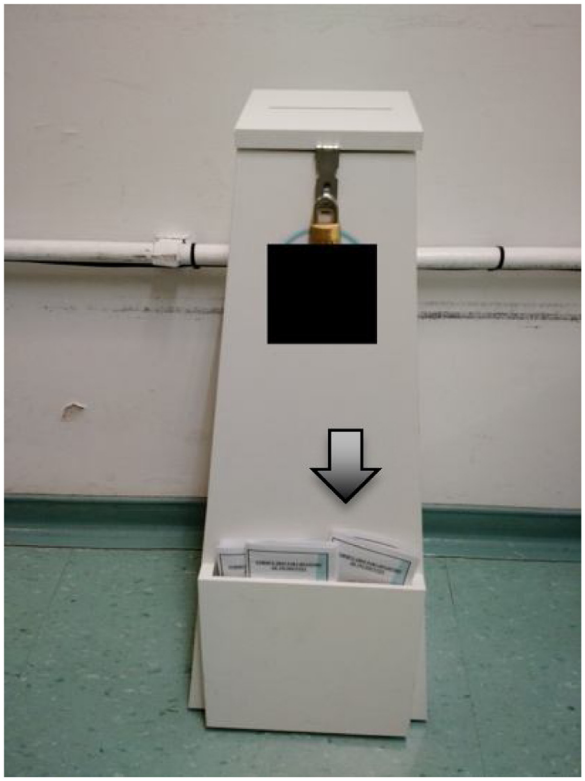

Fig. 2. Urns to collect paper forms (arrow) in different locations of the ROD (protected by padlock to maintain confidentiality).

3 What were the main ILS positive points (compliments and motivators) that you have observed?

In addition, a list of ten critical success factors adopted to implement the ILS was provided to participants and they were asked to choose the five most important ones according to their perception.

4. Results

The AHRQ survey was applied before and after the period of ILS implementation and the response rates were 71.9% and 53.8%, respectively. There is no clear reason for the decrease in the number of respondents in the second period; however, the response rate was still representative and at least one member of each group of professionals answered the survey in both periods. In the beginning, ILS was a novel system for the members of the committee. As the implementation kept going, they understood its importance and the central role of CSFs, and they decided to conduct the implementation until the end. Fig. 3 presents the variations in overall composite frequency (*f*), ratio of the number of positive responses to the total number of positive, neutral and negative responses of each dimension. The p-values are associated with the differences of *f*, using Exact test, according to Fisher, between the two time points of application of the questionnaire.

Seven of these twelve dimensions had a statistically significant change ($p < 0.05$) with ILS implementation, with five of them (Ḟrequency of reported events, Ġeneral safety perceptions, Örganizational learning - continuous improvement, Ṡtaffing - adequate number of professionals, "Non-punitive response to errors") showing an increase of frequency of positive evaluation and two (Ṫeamwork between service unitsänd Ïnternal transfers and shift changing) showing a decrease (the causes of reduction in this perception were not clear).

The mean number of events reported in the previous and post-implementation period presented a statistically significant increase ($p < 0.01$), evidencing a greater willingness and confidence to report events. The safety assessment, obtained by one specific question within the AHRQ survey ("Please give your work area/unit in this hospital an overall grade on patient safety" - not included in the dimensions analysis), was ëxcellent/goodïn 76.8% and 85.0% of the sample, before and after ILS implementation ($p = 0.22$), indicating general good safety perception with little improvement, but without statistical significance. This may indicate that sharper improvement in safety perception may require more time and results that are more concrete.

One of the survey questions assessed how many incident reports had been performed by the staff in the last 12 months. Fig. 4 illustrates the frequency responses in the time when the survey was conducted. Using Fisher's exact test, it is concluded that there was a statistically significant improvement ($p < 0.01$).

While practicing the second research technique, personal interviews were conducted with 19 professionals (17.6% of the total) after the implementation of the ILS, including at least one member of each group (administrative staff, dosimetrists, nurses, nurse auxiliaries, medical physicists, radiation oncologists and radiation therapist) for a better scope of the result. Everyone considered ILS an important tool for improving quality and safety, with emphasis on perceptions: the implemented ILS allows the solution of problems of the work routine, avoids recurrences of errors and improves communication among professionals.

From the analysis of the responses to the interviews, it was possible to identify that the perception that the ILS is an important safety tool to the ROD is unanimous. The most prominent points are: it allows for problem solving (improvement tool), prevents recurrence of errors and improves communication. In addition, the negative points (criticisms and difficulties) were highlighted: the lack of time to register incidents, the need for greater clarity as to which situations should be performed and the need for improvements in the form of feedback to users ("feedback"), in relation to the results of the analysis of the incidents and corrective and preventive actions proposed and carried out. The positive points (compliments and motivators) raised were the facility to record incidents, the non-punitive character (just culture), the perception that there are improvements in the work flow and the existence of feedback to users, despite the need to improve the way it is carried out.

Also, when applying the second technique, the interviewees ranked the five most important factors for success of the ILS implementation in a list of ten critical success factors among those from the literature that were adopted during the ILS implementation. Table 2 shows the ranking of these ten factors in order of relevance, calculating the "importance indexes" using two methods: calculating weighted sum of citations by the participants (weight 5 for the most important CSF, weight 4 for the second most important CSF, and so on)—"weighted for relevance" (first column); and calculating the arithmetic sum of the items without considering the degree of importance—"by citations on interviewees" (second column). As a comparison, the factors in order of citation in the literature review (Table 1) are presented in the third column.

Thus, the five factors perceived as the most important in the ILS implementation were the same in both methods and four of them are also among the five most cited in the literature review.

5. Discussion

During the implementation period, 33,767 radiotherapy sessions were performed, with a rate of 0.37% of event reports. These values are consistent with rates published by other authors, rang-

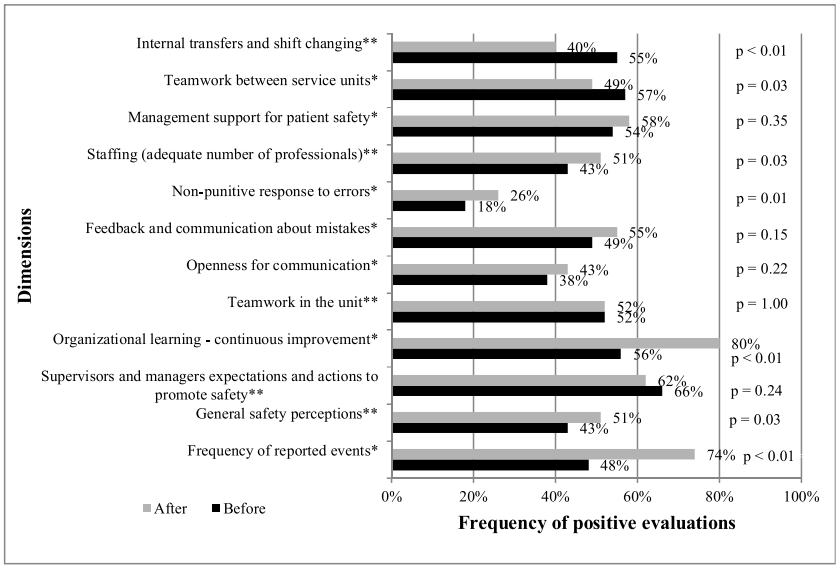

Fig. 3. Overall composite frequency evaluation before (black) and after (gray) the implementation of ILS (by dimension of AHRQ survey[34]).
*Dimensions with 3 questions; ** Dimensions with 4 questions.

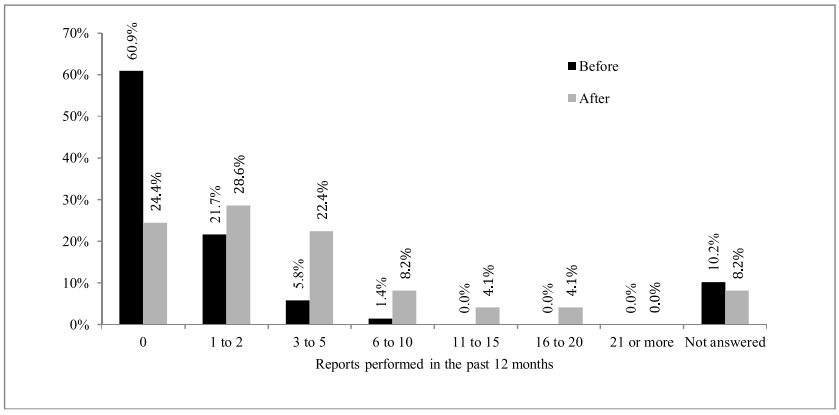

Fig. 4. Frequencies of the answers to the question Ïn the past 12 months, how many event reports have you filled out and submittedbefore (black) and after (gray) the implementation of ILS.

Table 2
Critical Success Factors in order of relevance according to the interviewees.

	Weighted for relevance	By citations on interviewees	By citation on literature review
1	FACILITATING COMMITTEE	FACILITATING COMMITTEE	JUST CULTURE
2	EFFICIENT DATA COLLECTION	EFFICIENT DATA COLLECTION	FACILITATING COMMITTEE
3	FOCUS ON IMPROVEMENT	FEEDBACK TO USERS	STANDARDIZED TERMINOLOGY AND PROCEDURE
4	JUST CULTURE	JUST CULTURE	EFFICIENT DATA COLLECTION
5	FEEDBACK TO USERS	FOCUS ON IMPROVEMENT	FEEDBACK TO USERS
6	STANDARDIZED TERMINOLOGY AND PROCEDURE	STANDARDIZED TERMINOLOGY AND PROCEDURE	VOLUNTARY REPORTING
7	COMPATIBILITY WITH OTHER SYSTEMS	COMPATIBILITY WITH OTHER SYSTEMS	FOCUS ON IMPROVEMENT
8	ANONYMOUS REPORTS	ANONYMOUS REPORTS	ANALYSIS AND RESPONSE EFFICIENCY
9	ANALYSIS AND RESPONSE EFFICIENCY	ANALYSIS AND RESPONSE EFFICIENCY	COMPATIBILITY WITH OTHER SYSTEMS
10	VOLUNTARY REPORTING	VOLUNTARY REPORTING	ANONYMOUS REPORTS

ing from 0.18% to 1.0%.[5,14,35,36] The group of professionals who recorded most events were medical physicists, radiation oncologists and radiation therapists, indicating a positive aspect of the registration culture, i.e. participation of different group of professionals, with emphasis on the large participation of radiation oncologists, an unusual result in systems described in literature. Another positive result was the low number of reports submitted anonymously (2%), similar to presented in the literature.[37]

In order to evaluate the staff' perception regarding the ILS, implementation safety culture surveys and satisfaction perception interviews with team members were carried out. The results showed that the professionals' perception regarding the patient safety in the ROD was positive, as it was considered ëxcellent/goodïn 76.8% and 85.0% of the sample, before and after ILS implementation, respectively (p = 0.22). The fact that ILS exposes errors in the process and makes them known to everyone, in principle, could have a negative impact on the professionals' perception regarding the patient safety. However, there were no statistically significant changes in that respect with ILS implementation.

There was a significant improvement in the dimensions "Frequency of reported events" and "Non-punitive response to errors" although improvement in this cultural aspect is still necessary, as evidenced by the low values of *f* (positive evaluation) of this dimension at both time points of the evaluation (Fig. 3).

Considering the perception of the professionals interviewed in the radiation oncology department (Table 2), five factors stood out: "Facilitating committee", "Efficient data collection", "Focus on improvement", "Just culture" and "Feedback to users". Simultaneous consideration of several success factors to ILS implementation in radiation oncology department is essential, but it was possible to identify a sub-list with the most important ones, according to the literature review and the interviewees' perception. These factors can also be the focus of studies to develop, and evaluate, specific practices that assist in their consolidation.

6. Conclusions

The ILS was developed and implemented in a radiation oncology department. Despite its being a customized procedure, the implementation process was structured by other systems described in the literature and it was oriented by critical success factors. Through analysis and discussions of all reported events, improvement and risk reduction actions were implemented in the patient workflow and in the work environment. From the perception of the radiation oncology department team (survey and semi-structured interviews), we concluded that ILS is an important system that supports routine management, improves quality of radiotherapy treatment, and promotes the safety culture. In addition, considering the results of the citations in the literature review and the team members' perception, it was possible to identify critical success factors in the implementation of ILS in a radiation oncology department and to show their importance to ILS in radiation oncology.

Conflict of interest

None declared.

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