RADIATION SAFETY ASSESSMENT OF COBALT 60 EXTERNAL BEAM RADIOTHERAPY USING THE RISK-MATRIX METHOD.

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Abstract. External beam radiotherapy is the only practice in which humans are placed directly in a radiation beam with the intention to deliver a very high dose. This is why safety in radiotherapy is very critical, and is a matter of interest to both radiotherapy departments and regulatory bodies. Accidental exposures have occurred throughout the world, thus showing the need for systematic safety assessments, capable to identify preventive measures and to minimize consequences of accidental exposure. Risk-matrix is a systematic approach which combines the relevant event features to assess the overall risk of each particular event. Once an event sequence is identified, questions such as how frequent the event, how severe the potential consequences and how reliable the existing safety measures are answered in a risk-matrix table. The ultimate goal is to achieve that the overall risk for events with severe consequences should always be low o very low. In the present study, the risk-matrix method has been applied to an hypothetical radiotherapy department, which could be equivalent to an upper level hospital of the Ibero American region, in terms of safety checks and preventive measures. The application of the method has identified 76 event sequences and revealed that the hypothetical radiotherapy department is sufficiently protected (low risk) against them, including 23 event sequences with severe consequences. The method has revealed that the risk of these sequences could grow to high level if certain specific preventive measures were degraded with time. This study has identified these preventive measures, thus facilitating a rational allocation of resources in regular controls to detect any loss of reliability. The method has proven to have an important practical value and is affordable at hospital level. The elaborated risk-matrix can be easily adapted to local circumstances, in terms of existing controls and safety measures. This approach can help hospitals to identify vulnerable aspects and improvements required and regulatory bodies to improve the quality of their inspections.

KEYWORDS: safety assessment; risk analysis methods; radiotherapy.

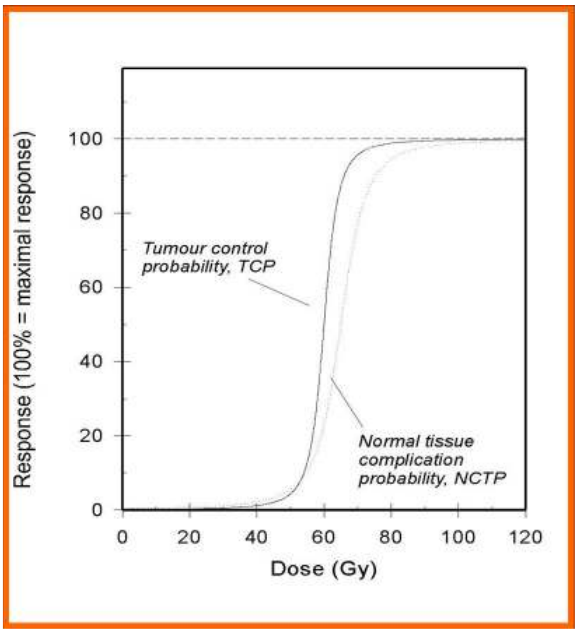
1. Introduction

Curative or palliative radiation therapy has three major concerns: efficacy, quality of life, and safety. From the point of view of radiation safety, radiotherapy is a very special application of radiation because it is the only one in which high doses of radiation is deliberately given to people (typically from 20 to 80 Gy).

Errors in radiotherapy, both overdosage and underdosage can be lethal or very severe. Figure 1 shows the principle of radiotherapy: the TCP curve represents the probability of tumour control and the NTCP curve shows the probability of normal tissue complications as a function of radiation dose. At low doses TCP and NTCP vary slowly with an increase in dose. From a given dose value both TCP and NTCP increase steeply but NTCP increases somewhat slower. For an extremely high dose both curves reach the value of nearly P=1 or 100%, i.e., both tumour and part of normal tissue are completely destroyed.

From this picture, a therapeutic window becomes apparent. At a given tumour dose (in this example, around 60 Gy) a probability of 80% for tumour control can be achieved with 20% normal tissue complication probability. Figure 1 also shows that the window is usually very narrow, hence the importance of accuracy and precision in dose delivery. This point is also crucial to safety, because equipment faults and human errors in the treatment process causing a 25% higher dose, for example, lead to a substantial increase of life threatening normal tissue complications. On the other hand, a 25% lower dose can cause a drastic decrease in tumour control probability.

Figure 1: Curves showing the variation of tumour control probability (TCP) and normal tissue complications probability (NCTP) as a function of the dose [1].



In addition, from the prescription to the delivery of a radiotherapy treatment, a team of professionals from a number of disciplines is involved in a large number of steps. In the case of external beam radiotherapy, a treatment is usually delivered with 20 to 40 fractions or sessions, each requiring a large number of machine and patient parameters, all of them similar but different from one patient to the next. For all these features radiotherapy has been receiving special attention in safety standards, in particular the International Basic Safety Standards for the Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) [2], which establish requirements to investigate accidental medical exposure and to adopt corrective measures to avoid reoccurrence.

There is substantial amount of literature with detailed reports on major accidental exposure [3, 4, 5], and the lessons learned from them, which help identify measures to avoid similar accidental exposures in future. In spite of these efforts, accidental exposures continue to happen, some time showing new weaknesses, which were not identified by safety assessments traditionally performed for radiotherapy. In this situation more proactive approaches to risk analysis are gaining attention.

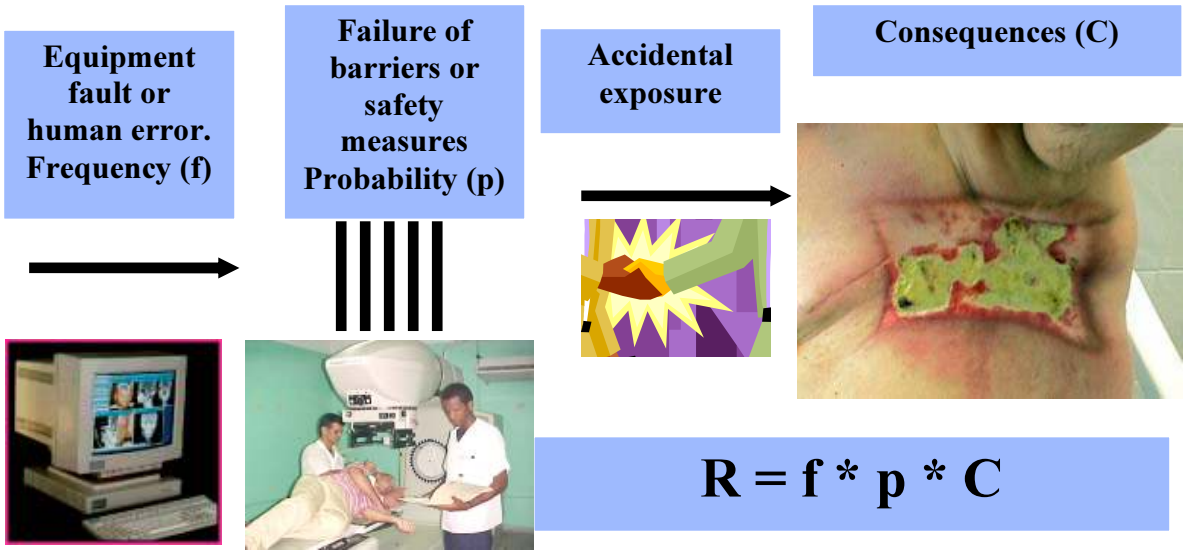
Probabilistic Safety Assessments (PSA) is a comprehensive and structured approach, which has been recently used to evaluate risk in radiotherapy. Results of the application of risk analysis methods have been published in [6]. However, the complexity of this method and the unavailability of human resources that can be devoted to this task in radiotherapy departments, have prevented its use on a wider scale. In this work a safety assessment of ^{60}Co external beam radiotherapy treatments using the risk matrix approach, as proposed in [7], has been carried out for a ^{60}Co treatment unit with pneumatic control source drawer.

2. Safety assessment of cobalt 60 external beam radiotherapy using risk-matrix method

2.1 Technical basis for the risk matrix method.

In order to understand the risk matrix method it is necessary to follow the event sequence leading to the accidental exposure. Figure 2 shows a simplified scheme of the event sequence.

Figure 2: Simplified scheme of an accidental sequence



A fault or error (initiating event), which can lead to an undesired outcome, occurs at a given frequency (f), depending on the type of fault or error. The problem can be detected and corrected if certain elements (interlocks, alerts or alarms, or double checks procedures) are in place in order to prevent the accidental exposure. These elements are called "barriers". However, there is a certain probability of failure of these barriers in which case, the accidental exposure with its consequences (C) will be inevitable, affecting the patient, workers or the public.

The global parameter which characterizes a given accidental sequence is the risk or detriment[1] (R), which expresses the combined probability of harm.

As shown in figure 1,

$$R = f * p * C. \qquad (1)$$

With the risk matrix method each of the variables of equation (1) is evaluated for each initiating event, assigning to f, p, C one of four levels previously established, and obtaining in each case one of the four levels for the resulting risk (R), as shown in Table 1.

[1] The risk is used in this context is broad as human or health risk, which includes the more specific term "detriment", in this case from the accidental exposure, which is the result of two events: fist, the occurrence of the accidental exposure and second the appearance of the associated harm. The associated harm to be considered when the end points are assessed includes death or serious localized harm from deterministic effects, cancer and hereditary harm due to stochastic effects.

Table 1: Complete risk matrix containing all combinations of the four levels of frequency of occurrence of the initiating even (f), the four levels of probability of failure of the set of safety measures (P) and the four levels of severity of consequences (C), if the initiating event results in an accidental exposure.

f_H	p_H	C_{VS}	R_{VH}
f_M	p_H	C_{VS}	R_{VH}
f_L	p_H	C_{VS}	R_H
f_{VL}	p_H	C_{VS}	R_H
f_H	p_M	C_{VS}	R_{VH}
f_M	p_M	C_{VS}	R_H
f_L	p_M	C_{VS}	R_H
f_{VL}	p_M	C_{VS}	R_H
f_H	p_L	C_{VS}	R_H
f_M	p_L	C_{VS}	R_H
f_L	p_L	C_{VS}	R_L
f_{VL}	p_L	C_{VS}	R_L
f_H	p_{VL}	C_{VS}	R_H
f_M	p_{VL}	C_{VS}	R_L
f_L	p_{VL}	C_{VS}	R_L
f_{VL}	p_{VL}	C_{VS}	R_L

f_H	p_H	C_S	R_{VH}
f_M	p_H	C_S	R_H
f_L	p_H	C_S	R_H
f_{VL}	p_H	C_S	R_H
f_H	p_M	C_S	R_H
f_M	p_M	C_S	R_H
f_L	p_M	C_S	R_H
f_{VL}	p_M	C_S	R_L
f_H	p_L	C_S	R_H
f_M	p_L	C_S	R_H
f_L	p_L	C_S	R_L
f_{VL}	p_L	C_S	R_L
f_H	p_{VL}	C_S	R_L
f_M	p_{VL}	C_S	R_L
f_L	p_{VL}	C_S	R_{VL}
f_{VL}	p_{VL}	C_S	R_{VL}

f_H	p_H	C_{MO}	R_H
f_M	p_H	C_{MO}	R_H
f_L	p_H	C_{MO}	R_L
f_{VL}	p_H	C_{MO}	R_L
f_H	p_M	C_{MO}	R_H
f_M	p_M	C_{MO}	R_L
f_L	p_M	C_{MO}	R_L
f_{VL}	p_M	C_{MO}	R_L
f_H	p_L	C_{MO}	R_L
f_M	p_L	C_{MO}	R_L
f_L	p_L	C_{MO}	R_L
f_{VL}	p_L	C_{MO}	R_L
f_H	p_{VL}	C_{MO}	R_L
f_M	p_{VL}	C_{MO}	R_L
f_L	p_{VL}	C_{MO}	R_{VL}
f_{VL}	p_{VL}	C_{MO}	R_{VL}

f_H	p_H	C_{mn}	R_L
f_M	p_H	C_{mn}	R_L
f_L	p_H	C_{mn}	R_L
f_{VL}	p_H	C_{mn}	R_L
f_H	p_M	C_{mn}	R_L
f_M	p_M	C_{mn}	R_L
f_L	p_M	C_{mn}	R_{VL}
f_{VL}	p_M	C_{mn}	R_{VL}
f_H	p_L	C_{mn}	R_{VL}
f_M	p_L	C_{mn}	R^{VL}
f_L	p_L	C_{mn}	R_{VL}
f_{VL}	p_L	C_{mn}	R_{VL}
f_H	p_{VL}	C_{mn}	R_{VL}
f_M	p_{VL}	C_{mn}	R_{VL}
f_L	p_{VL}	C_{mn}	R_{VL}
f_{VL}	p_{VL}	C_{mn}	R_{VL}

2.2. Criteria to assign levels to frequency of initiating events, (f), probability of barrier failure (p) and consequences (C).

A key step is the assignment of levels to each of the independent variables of the risk matrix in (1). It is done starting from an expert judgment by various specialists participating in the assessment (physicians, physicists, dosimetrists and technologists). This method of assignment provides higher objectivity. Although the four levels of the independent variables are obtained in a qualitative manner, the use of quantitative criteria as reference in the assignments, justifies to call the risk matrix approach a "semi quantitative" method. In the following sections the quantitative reference criteria are given.

2.2.1 Frequency of occurrence of initiating events.

The frequency of initiating events (IE) can be obtained directly from the historical records of equipment faults and human errors existing at a given facility. However, there are no reliable records of faults and errors available in the region. The annual frequency, f, can be estimated as the probability of occurrence of the fault or error (P^{IE}), each time an action or task is performed, multiplied by the number of times that the task is done in a year (N^E). In [8, 9] values of probability of equipment faults and human error can be found, although they are not specific for radiotherapy, they can be used with acceptable approximation for the purposes of this study. The number of times that a given task or action is performed each year can be calculated from the radiotherapy department records (for example, from the annual number of patients, average number of sessions per patient, number of treatment fields per patient). In this way the frequency can be estimated from equation (2).

$$f = P^{IE} * N^E \qquad (2)$$

The estimated value of the frequency of occurrence of each initiating event IE (f) is then compared with table 2, from which the frequency interval or level, required by the risk matrix, can be assigned.

Tabla 2: Annual frequency intervals of initiating events in number of times per year.

Qualitative frequency	**Abbreviation**	**Annual number of events (considering 500 patients per year)**
High	f_H	$f \geq 50$
Medium	f_M	$1 \leq f < 50$
Low	f_L	Between 1 per year and 5 in 100 years $0.05 \leq f < 1$
Very low	f_{VL}	Less than 5 every 100 years. $f < 0.05$

2.2.2 Potential consequences.

Assignment of consequence levels (C) is done assuming that the initiating event has occurred and all existing barriers have failed, i.e. the accidental exposure has occurred. Considering that consequences are different for patients than for workers and members of the public, two different tables are proposed.

2.2.2.1 Consequences for patients.

The following scale has been used

1- Catastrophic or very severe, (C_{VH}): accidental exposures affecting many patients and causing multiple deaths or irreversible handicap injuries.

2- Severe (C_S): accidental exposure causing death or irreversible handicap injuries to one single patient.

3- Moderate (C_{MO}): accidental exposures affecting a single patient for one session, with low deviation in the total dose.

4- Minor (C_{mn}): Loss of defence in depth, not causing any significant deviation in dose.

2.2.2.1 Consequences for workers and the public.

1- Catastrophic or very severe (C_{VS}): fatal or life threatening consequences, severe deterministic effects, irreversibly reducing the quality of life.

2- Severe (C_S): non life-threatening, reversible consequences, not affecting quality of life

3- Moderate (C_{MO}):: anomalous exposure (not included in normal exposure), exceeding dose constraints and limits, below thresholds for deterministic effects

4- Minor (C_{mn}): Loss or degradation of defence in depth not causing any significant exposure

2.2.3 Failure probability of the set of barriers.

There are different kinds of barriers (interlocks, alarms, procedures) and their strength depends on many factors. When applying the risk matrix, failure probability for the set of barriers is conservatively estimated by taking only the number of barriers into consideration. All barriers are assigned the same individual probability, at the highest expected level.

After completing the risk matrix and screening off the event sequences of low and very low risk, a deeper probability analysis for the set of barriers is carried out in order to reassign the level in a more realistic manner.

The first, conservative, assignment, based on the number of barriers only, follows the rules below:

1- High (p_H): there is no safety barrier.
2- Medium (p_M): there is only one or two safety barrier in the set
3- Low (p_L): there are three safety barriers in the set
4- Very low (p_{VL}): There are four or more safety barriers in the set.

2.3. Step sequence in the application of the risk matrix method

2.3.1 List of initiating events.

An important warning is that any initiating event, which is not postulated, will not be analyzed and will remain as a potential event, not evaluated and therefore hidden. The first step is, therefore, to identify all equipment faults and human errors that may lead to one of the four levels of postulated consequences.

In this work the list of initiating events was taken from [10], considering that that study was done on a ^{60}Co unit of the same type and for the same hypothetical radiotherapy department of the Ibero American region. The list of initiating events was thoroughly reviewed and was also checked against the lessons learned from reported accidental exposures [2, 3, 4, 11], applying the principle that any event that has already occurred must be included in the analysis. As many as 76 initiating events from all stages of the treatment process were identified.

2.3.2 Potential consequences from the postulated initiating events.

The consequences from each initiating event is analyzed, by assuming first that after it has occurred there is no barriers in the way towards an accidental exposure. At this stage, possible elements that could reduce the consequences are considered (consequence reducers). These reducers are not like barriers, i.e., they can not avoid the consequences but can mitigate them.

In this work, the level of consequences was estimated by following expert judgment, considering the deviation in radiation dose from each initiating event and the characteristics of the accidental exposure (affecting one fraction, or the whole treatment or all patients). In this study there was no need to make calculations or simulations to confirm the magnitude of deviations in dose, but this is also an option that can used if needed.

2.3.3 Frequency of the initiating events

First the number of times that an initiating event occurs in a given time is assessed, usually the annual frequency. It is important to use the records of equipment faults and human errors that may exist in the radiotherapy department. At this stage, frequency reducers are also identified. These elements act always before the initiating event.

For this work no reliable records were available to estimate the frequency, so the assessment was based on published data and on applying equation (2).

2.3.4 Existing safety barriers and probability assignment to the failure of the barrier set.

All existing barriers are identified, i.e., all technical or organizational measures established to avoid the consequences from the initiating events. Barriers usually belong to one of the following types:

1. Interlocks: technological devices responsible for a safety function, able to automatically detect an unsafe condition and remove it or stop the irradiation.

2. Alarms: audible or visual signals to alert people on the need to take action or make a decision; they require, therefore, human action.

3. Procedures: written instructions or standardized practices, to avoid or detect errors and deviations in the various tasks of a given process.

At this stage, only direct barriers are considered, i.e., those that when called upon by an initiating event acts to avoid the postulated consequences.

Barrier set failure (p) is analyzed by estimating the combined probability of failure of the whole set of barriers, relevant to the initiating event. As stated in 2.2.3, this estimation, at first, is very conservative since it only considers the number of barriers, without taking barrier strengths into consideration.

2.3.5. Resulting risk levels from the risk matrix

Once the independent variables (f, p, C) with their respective levels have been entered into table 1, the matrix provides the resulting risk level as very high, high, low or very low.

This process is done for each accidental sequence. It is important to understand that, as a result of the methodology, risk levels are obtained and no risk values. Two initiating events with the same risk levels do not necessarily have equal risk.

2.3.6. Result analysis.

At first, all event sequences whose resulting risk level falls into the "low" or "very low" category are screened off and a more detailed analysis focuses on the remaining event sequences, i.e., those identified by the matrix as level "high" or "very high" risk. In this analysis, all frequency and consequence reducers and barrier strengths are brought to consideration.

Sequences identified by the matrix as low or very low risk can be excluded from further analysis, considering the conservative features of the preliminary analysis and the risk management criteria shown in table 2 below.

Table 2: Risk management criteria

Risk interval	**Risk acceptability**	**Actions**
Very high (R_{VH})	Unacceptable	It would be sensible to stop the practice or the relevant treatments until measures to reduce the risk have been implemented
High (R_H)	Unacceptable when consequences are very severe (catastrophic) or severe	Immediate measures are required to reduce risk or the practice would need to be stopped
	Acceptable temporarily under certain conditions if the consequences are low or very low.	Measures of risk reduction need to be implemented without unnecessary delay
Low (R_L)	Acceptable from the cost-benefit point of view	Potential improvements should be explored but implementation should only proceed from cost-benefit view point.
Very low (R_{VL})	Negligible.	No action is required

In this work the analysis proceeds by asking the following questions:

A1-Are the existing barriers robust enough as to justify a reassignment of failure probability to a lower interval (for example from "high" to "medium" or "low")?
A2-Can the frequency of the initiating event be reduced, using identified frequency reducers?
A3-Can consequences of the initiating event be reduced, using identified consequence reducers?
A4-Can additional barriers or measures be introduced to reduce the overall risk?

Basic reducers can be found in the following way:

- Reducers of the frequency of initiating events are usually associated to maintenance policies for equipment, and keep human errors as low as possible by selection and qualification of staff, moderating workload and improving the working environment to invite concentration and avoid frequent distraction and bad habits, i.e. a safety culture approach.
- Reducers of consequences of initiating events are those associated to quality control programmes and compliance with procedures for patient following up.
- Reducers of the probability of failure of barriers include the introduction of new barriers or strengthening existing ones, in order to make them more robust and reliable.

2.3.6. Drawing recommendations

Once new barriers, frequency and consequence reducers are identified, drawing recommendations follows. Recommendations should be tailored to help hospital administrators and managers to do a rational, risk-informed, prioritized allocation of human and material resources with a higher impact on the risk.

4. Conclusions

Risk matrix is a systematic simplified method, derived from the more complex probabilistic safety assessment (PSA) techniques, which can be easily applied by staff not necessarily specialized in PSA. This method, although it does not quantify risk with the accuracy of a PSA, helps identify priorities in a structured manner, without a more detailed quantitative study. The risk matrix method can be used by radiotherapy departments as well as by regulatory bodies.

The risk matrix approach has been applied to ^{60}Co external beam radiotherapy treatments and evaluation 76 event sequences of a hypothetical radiotherapy department, has been done. The study has corroborated that this hypothetical department is protected against "severe" and "very severe" consequences from initiating events identified as having an overall risk at "high" and "very high" level.

This hypothetical department has the highest level of safety that can be expected in the region, with a reasonable number of barriers and good safety practices. It should, therefore, not be assumed that all radiotherapy departments in the region are protected against all these initiating events. The preliminary application of the risk matrix, without the result analysis described in 2.3.6 (questions A1, A2, A3), identified 23 accident sequences with "severe" or "very severe" consequences, which were preliminary rated as "high" risk level. These risks could be reduced to low level, by considering the robustness of barriers and reducers. It is particularly important to monitor these barriers and reducers, since their failure can compromise life of one or multiple patients.

Five event sequences were identified as having "medium" level consequences associated to an overall "high" risk. No additional barriers were identified for these initiating events, because they occur just before daily treatment. It is essential, therefore, to implement reducers of frequency of the initiating event and supervise their effectiveness in a systematic manner.

In a more general sense, for all event sequences evaluated, supervision of effectiveness of barriers and reducers is essential so that effectiveness is maintained over time. Otherwise risks identified as low and very low may increase as well. External audits should address these elements specifically.

The study has revealed the need for additional barriers to reduce failure probability, in particular the following barriers should be considered:

- New patient planning conference as proposed by AAPM TG 40. These meetings contain a number of frequency reducers.
- In vivo dosimetry. Although other documents, such as AAPM TG 40; TECDOC-1151 [12, 13,] recommend them, it is not a generalized practice in countries of the Ibero American region.
- Two technologists per treatment machine and per shift, one of them verifying compliance with procedures.
- External audits before start clinical use of equipment and periodically during operation. It is important that audits include supervision of barriers and reducers as identified in this study.

The study has revealed that frequency and consequence reducers are very important to reduce risk, and in this sense the following reducers are mentioned:

- Training of radiation oncologists, medical physicists, dosimetrists and technologists, including the lessons from accidental exposure and the result of proactive study similar to this work.
- Standardized forms and protocols for prescribing, planning and reporting treatment information.
- Keeping workload to a moderate level.
- Programme of preventive maintenance.
- Implementing policies and measures to keep a working environment that stimulates work with attention, due thought, full knowledge and a proper sense of accountability (safety culture). This applies also to design (for example placing the control console on a place not readily accessible to other people).
- Having sufficient trays with fixed blocks for the whole treatment of a given patient.
- Weekly patient follow-up.
- Quality control of equipment parameters.

One of the difficulties detected by the risk matrix method was that of assigning frequencies to initiating events. This is due to scarce records on events that have occurred in the hospital. In this respect, hospital administrators and managers should create a non-punishing, stimulating atmosphere favouring reporting and recording these events.

When discharging regulatory duties of licensing, inspection, regulators have the possibility of including key aspects with impact on risk, identified in this study.

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