APPLICATION OF THE RISK MATRIX APPROACH IN RADIOTHERAPY: AN IBERO-AMERICAN EXPERIENCE

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Abstract.

The "Risk Matrix" method has been used extensively for safety assessments in the risk industry. The method is characterized by being systematic and simple, features that allow considering its application in hospitals. The practice of radiotherapy, where fatal accidents have occurred, needs to apply methodologies to anticipate and prevent potential accidents. The Ibero-American Forum of Radiological and Nuclear Regulators (FORO) has adapted and applied this methodology of risk matrices in teletherapy (Co-60 equipment and linear accelerators) and brachytherapy (high and low dose rate). A large list of possible human error and equipment failure that could trigger accidents was analyzed. The main defenses (interlocks, alarms and procedures) that could prevent, detect, monitor and mitigate potential accidents were identified; finally, the accident sequences with highest risk were established and the measures to reduce risk in such sequences have been proposed. This work confirmed the importance of radiation protection of patients in the practice of radiotherapy and showed that the risk matrix approach is a useful tool to reduce the risk of accidental exposure.

1. INTRODUCTION

The safety of the practice of radiotherapy is a major issue today and the experience of past accidents [1, 2] shows the need to strengthen the safety of this practice. The risk analysis methods are tools to analyze systematically all those equipment failures and human errors that could potentially cause an accident. Some of the risk analysis methods with high precision and prestige (e.g. probabilistic safety assessment) are extremely complex and laborious, and this has limited its application in radiotherapy services. The methodology of risk matrices has the advantage of being relatively simple and easy to implement, although it does not allow numerically quantifying the risk. The present work shows the criteria taken into account by the FORO to adapt the methodology of risk matrices to radiotherapy treatments. We present the main results of the method in radiotherapy services that are representative of this practice in Latin America.

2. MATERIALS AND METHODS

The methodology of "Risk Matrix" is based on the logical sequence of occurrence of accidents (Figure 1). A certain human error or equipment failure (initiating event) occurs with a certain frequency (f). Probably there are barriers in radiotherapy services (interlocks, alarms or procedures) that can detect and correct the malfunction or failure and therefore prevent the initial event becoming an accident. However, there is always some probability (p) that these barriers could fail. In this case the accident will occur and leads to particular consequences (C). The quantity characterizing the sequence of occurrence of accidents is the risk (R) that can be calculated as shown in Figure 1. The method of the risk matrix is based on subdividing the independent variables of the risk equation into four quality levels [3] (e.g. high, medium, low, very low) and through all the possible logical combinations four risk levels were also obtained as a result (very high, high, medium and low) as shown in Table I.

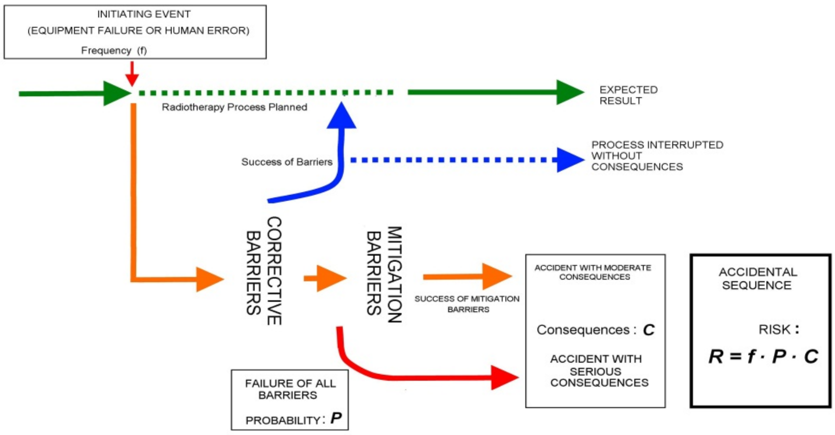

Fig. 1. Logical sequence of occurrence of accidents

Table I is also used to make a more detailed analysis (second screening) of unacceptable risk accident sequences taking into account the strength of barriers and reducing as shown in [4].

TABLE I. RISK MATRIX.

f_H	P_H	C_{VH}	R_{VH}	f_H	P_H	C_H	R_{VH}	f_H	P_H	C_M	R_H	f_H	P_H	C_L	R_M
f_M	P_H	C_{VH}	R_{VH}	f_M	P_H	C_H	R_H	f_M	P_H	C_M	R_H	f_M	P_H	C_L	R_M
f_L	P_H	C_{VH}	R_H	f_L	P_H	C_H	R_H	f_L	P_H	C_M	R_M	f_L	P_H	C_L	R_M
f_{VL}	P_H	C_{VH}	R_H	f_{VL}	P_H	C_H	R_H	f_{VL}	P_H	C_M	R_M	f_{VL}	P_H	C_L	R_M
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f_M	P_L	C_{VH}	R_H	f_M	P_L	C_H	R_H	f_M	P_L	C_M	R_M	f_M	P_L	C_L	R_L
f_L	P_L	C_{VH}	R_M	f_L	P_L	C_H	R_M	f_L	P_L	C_M	R_M	f_L	P_L	C_L	R_L
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f_{VL}	P_{VL}	C_{VH}	R_M	f_{VL}	P_{VL}	C_H	R_L	f_{VL}	P_{VL}	C_M	R_L	f_{VL}	P_{VL}	C_L	R_L

Tables II, III and IV show the criteria used to assign levels of frequency (f), consequence (C) and the probability of failure of all barriers (P), respectively. For each initiating event the levels corresponding to the independent variables of the risk equation should be evaluated, and by using Table 1 "risk matrix" we can derive the level of risk (R) for each analyzed accident sequence. By repeating this procedure for all initiating postulated events a first selection (screening) can be obtained showing those accident sequences with "very high" and "high" risk levels, which are considered unacceptable.

TABLE II. FREQUENCY LEVELS OF INITIATING EVENTS

Frequency level	Symbol	Annual frequency (for 500 patients/year)
High	F_H	More than 50/y, i.e., $f \geq 50$
Medium	F_M	Between 1 and 50/y, i.e.,$1 \leq f < 50$
Low	F_L	Between 1/y and 1 every 100 y, i.e., $0.01 \leq f < 1$
Very low	F_{VL}	Less than 1every 100 y, i.e., $f < 0.01$

TABLE III: SEVERITY LEVELS OF CONSEQUENCES

Severity level	Symbol	Description of consequences
Very high	C_{VH}	Causing multiple deaths or limiting damage to multiple patients (roughly more than 25% under- or overdosage can cause this effect).
High	C_H	Causing single death or limiting damage to multiple patients. Also deviation of 10% and 25% to multiple patients are included in this level.
Medium	C_M	No risk to patient life, only recoverable deviation affecting one or a few sessions.
Low	C_L	Reduction of defense in depth with no dose deviation.

TABLE IV. LEVELS FOR PROBABILITY OF TOTAL FAILURE FOR A SET OF BARRIERS

Probability level	Symbol	Number of barriers
High	P_H	There is no barrier at all
Medium	P_M	There are one or two barriers
Low	P_L	There are three barriers
Very low	P_{VL}	There are four or more barriers

3. RESULTS

Table V shows the results of applying the methodology of risk matrices to evaluate 3 hypothetical radiotherapy services. As it can be appreciated, human errors and equipment failures that may lead to unacceptable risk of accidental exposure (R_{VH} and R_H) have an impact on the patient and therefore, the main emphasis on safety improvements must be done to strengthen the radiation protection of patients. It can also be seen that most of the initiating events analyzed are related to human errors.

TABLE V. RESULTS OF APPLICATION OF THE METHODOLOGY OF RISK MATRIX. RISK PROFILE.

	Teletherapy with Co-60		Teletherapy with LINAC		Brachytherapy HDR	
Number of events analyzed	132		141		115	
With consequences for patients	121	92 %	132	93.6 %	92	80 %
With consequences for workers	7	5 %	5	3.5 %	16	14 %
With consequences for the public	4	3 %	4	2.8 %	7	6 %
Events linked to human error	116	87 %	111	78 %	87	75 %
Identified barriers	91		100		74	
Frequency reducers identified	41		37		62	
Consequences reducers identified	50		26		26	
Sequences with "Very high" risk	0	0 %	0	0 %	0	0 %
Sequences with "High" risk	16	12 %	5	4 %	5	4 %
At risk, "High" affecting patients	16	12 %	5	4 %	5	4 %
Sequences with "Medium" risk	110	83 %	126	89 %	107	93 %
Sequences with "Low" risk	6	5 %	10	7 %	3	3 %

Another important result derived from the use of the risk matrix methodology is the possibility of assessing the relative importance of different defenses (barriers, reducing the frequency and consequences), and distinguishing which of these have the greatest impact on risk reduction. Figure 2, for example, shows the 5 barriers with the highest influence over the risk reduction in the LINAC teletherapy service. Similarly, Figure 3 shows the 5 consequence reducers with highest influence in mitigating the consequences of any possible accidents in the HDR brachytherapy service. In addition to the above results obtained between 2009 and 2011, this proactive approach was applied to 44 radiotherapy equipment in 7 Latin American countries. The IAEA, through the Thematic Safety Area No. 3 – “Radiation Protection of Patients in the Medical Exposures” has developed training and advice to support the implementation of this methodology in Latin America.

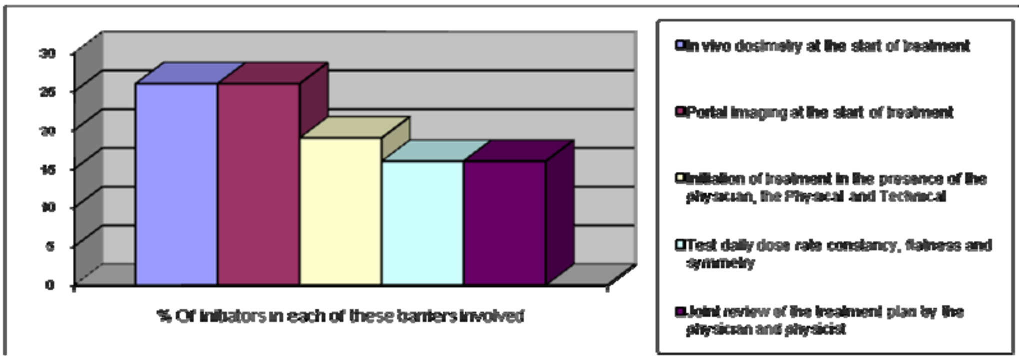

FIG. 2. Barriers with highest contribution in reducing risk at the of LINAC Teletherapy services

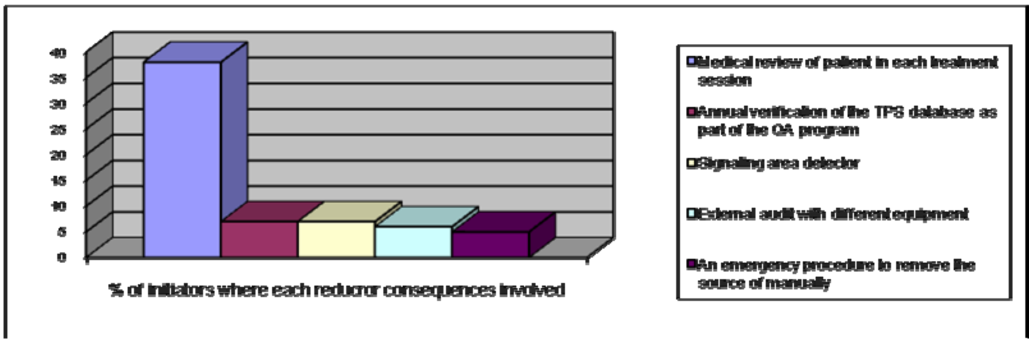

FIG. 3: Consequence reducers with highest contribution to the HDR Brachytherapy practice

An IAEA TECDOC publication, currently in printing process [5], contains extensive information about this work. All joint actions, carried out in synergy by the FORO and the IAEA on this subject, have shown the advantages inherent in the presented methodology, as an analysis tool to detect the safety weaknesses in the radiotherapy process of a particular department.

4. CONCLUSIONS

Safety assessments developed as part of the present work have shown clearly that the radiation protection of patients deserves the first priority in terms of effort to be done to prevent the occurrence of accidents in radiotherapy practice. Human error is recognized as the main cause for which accidents occur and in this regard actions should be prioritized to minimize human errors that were identified as reducing the frequency of occurrence of initiating events. The study identifies those defenses with highest influence on the practice risk profile. Such defenses should be carefully monitored by the staff of the institution as well as by the regulatory authority taking into consideration that any neglect of them could dramatically increase the level of risk of accidents.

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