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Analisi del rischio clinico del percorso del paziente in un centro di radioterapia avanzata mediante metodologia F.M.E.A.

Clinical risk analysis of the patient's path in an Advanced Radiotherapy Center (A.R.C.) through F.M.E.A. method

Autori / Authors: C. Pobbiati, M. Monturano, A. Vavassori, M. Gerardi, M. Sarra Fiore, E. Rondi, E. Borghetti, F. Castellini, V. Scroffi, C. Arrobbio, F. Castelluccia, V. Gandellini, S. Greco, A. Leppa, B. A. Jereczek-Fossa

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Contatto autori / Corresponding author:

Claudio POBBIATI, c.pobbiati89@gmail.com

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Clinical risk analysis of the patient's path in an Advanced Radiotherapy Center (A.R.C.) through F.M.E.A. method

Pobbiati Claudio[1], Monturano Massimo[2], Vavassori Andrea[1]
Gerardi Marianna[1], Sarra Fiore Massimo[1], Rondi Elena[3]
Borghetti Enrica[1], Castellini Fabio[1], Scroffi Valerio[1], Arrobbio Camilla[1]
Castelluccia Fabiana[1], Gandellini Valeria[1], Greco Saverio[1]
Leppa Assuntina[1], Jereczek-Fossa Barbara Alicja[1,4]

[1] *Radiotherapy Division, European Institute of Oncology, IRCCS, Milan, Italy*

[2] *Patient Safety and Clinical Risk Management, European Institute of Oncology, IRCCS, Milan, Italy*

[3] *Unit of Medical Physics, European Institute of Oncology, IRCCS, Milan, Italy*

[4] *Hemato-oncology and Oncology Department, University of Milan, Italy*

Corresponding author: Claudio POBBIATI - c.pobbiati89@gmail.com

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Abstract

Starting from the increasing requirement of efficient access to healthcare, the study aims to assess the current standard procedures in order to optimize safety and quality.

The decision to study the patient's process in Radiotherapy (RT) by FMEA methodology (Failure Mode and Effect Analysis), in order to identify and manage the risks for patients, arose from an interest of both the Radiotherapy Division and the Management of the European Institute of Oncology (IEO) IRCSS of Milan (Italy) in consideration of its high activity and of the volume of patients treated. The department has undergone a remarkable change in the last seven years, by increasing the number of accelerators and the number of patients treated, which rose from 2.197 (2011) to 3.194 (2017).

Treatment modalities and timing of each session have changed: nowadays the majority of the patients receive highly complex treatments (intensity-modulated radiotherapy, image-guided radiotherapy, stereotactic radiotherapy, etc.).

Purpose

The purpose of this study is to define an instrument of practical use and maintenance, for the proactive management of clinical risk by analysing the patient's care path in RT: from his medical examination to the discharge and the next follow-up visits.

The instrument was tested by handing it out to employees in the form of a questionnaire, trying to involve a significant pool of professionals.

Materials and methods

Starting from previous Institutional experiences of FMEA studies in other clinical areas, we decided to:

- make-up several multidisciplinary working groups (with one or two members of each professional level) in order to define the sub-processes, the failure mode and the impact of potential damage.
- propose the participation of radiotherapy professionals in defining the frequency of the failure mode in their experience, using questionnaires and scales of predefined values.

To define the value "potential damage" and the attribution of the frequency of occurrence of the various failure modes, we sought to minimize a potentially non-voluntary effect of mitigating the risk due to the awareness of the correlations between frequency of occurrence and damage.

Therefore, the professionals involved were not aware of the results.

Results

The study was carried out with great participation from the professionals involved in the patient's path (88,6% of the staff involved in the study responded to the questionnaires administered in the first part of the study; 69,7% was the rate of participation in the second part). This result allowed to overcome the subjective limitations due to the low numerical representation and the lack of objective epidemiological data concerning the near miss. Forty-four criticalities were found (14% of all the failure) and required intervention planning.

Conclusion

This work led to the definition of a model with analytical description and quantification of the clinical risk for all the failure modes by "Risk Priority Number" (RPN) of all the sub-processes of the patient's path. Starting from the significant result of the areas requiring intervention, we could identify several improvement actions to reduce clinical risk. The model allows a dynamic management of clinical risk linked to a specific process and it could be exported to other Radiotherapy Centers.

Key words

FMEA, radiotherapy, process, sub-process, Risk Priority Number-RPN, Clinical Risk, failure mode.

Introduction

The Radiotherapy Division of the European Institute of Oncology – IEO, IRCCS of Milan (Italy) is made up by many professionals (Radiation Therapists - RTTs, Radiation Oncologists and Radiation oncology residents, Medical Physicists and Medical physic residents, Nurses, Biomedical Engineers, Social-Healthcare Operators, Administrative Operators, Data Managers) who work in synergy to guarantee the best therapy and the highest standards of care that a patient requests.

The department has undergone a remarkable change in the last seven years, increasing the number of accelerators and the structure: from three conventional Linacs (Linear Accelerator - 2100®, 600®, Trilogy® by Varian Medical System®, CA, Palo Alto, USA) to six new generation Linacs:

- Three Tomotherapy® (Accuray® Sunnyvale, CA, USA);
- One CyberKnife® (Accuray® Sunnyvale, CA, USA);
- One Vero® (Mitsubishi Heavy Industries®, Ltd., Japan and BrainLab AG®, Feldkirchen, Germany);
- One Trilogy® (Varian Medical System®, CA, Palo Alto, USA).

and the subsequent transition to Advanced Radiotherapy Center - ARC.

This change brought to an important variation in the type of treatments, from conventional to advanced radiotherapy techniques which can be performed by Trilogy®, Vero®, Tomotherapy®

and CyberKnife®: this situation requires a different vision and perception of the daily risks, and the re-evaluation of each patient's care path in RT.

The number of patients treated increased from 2.197 (2011) to 3.194 (2017).

Due to the high volume of patients treated, we undertook this FMEA study (Failure Mode and Effect Analysis) to assess whether the prevention systems for patient safety are still valid in the daily activity or if it was necessary to elaborate new ones.

Risk Management originated in the financial and military area, and represents a structured methodological approach that studies all the risks that a company may face, with the aim of reducing them to the lowest level, analysing all business management aspects: "strategies, market, processes, financial and human resources, technologies" [1].

Every action of a healthcare professional involves a certain amount of risk, and as a result of this, healthcare can be considered more complex than any other sector due to the interaction between many factors such as cooperation between health professionals and high technological component [1,2]. Similarly to other complex systems, such as aeronautics and nuclear power stations, accidents and errors can happen in healthcare, and can be more or less serious and avoidable [3].

This study focused on the Clinical Risk Management.

When we talk about Risk Management, we must use a terminology as common and shared as possible, to avoid ambiguity [1]. The scientific community has defined Risk as "a condition or a potential event, intrinsic or extrinsic to the process, which can change the outcome of the process itself". We measure it by probability and consequences: the product between the Probability of the event's occurrence (P) and the Damage (D) that results from it. Moreover, the risk factor considers the human ability to detect a potentially harmful event (K factor) [3,4].

Radiotherapy, or Radiation Therapy (RT), utilizes ionizing radiation to treat cancer, sparing healthy tissues [5,6,7]. We can use it as an exclusive treatment (curative), in combination with other medical treatments, or in a palliative setting, to relieve symptoms [7].

The application of radiotherapy in cancer patients has considerably increased in the past few years, with a consequent improvement of the patients' quality of life [5,8].

The accidental exposure to ionizing radiation in Radiotherapy can be caused by a lot of factors, such as:

- equipment selection and maintenance;
- calibration of the treatment beam;
- treatment planning;
- treatment simulation;
- treatment delivery;
- cooperation between different professionals [3,8].

When discussing Risk Management in Radiotherapy we not only have to talk about the clinical setting, but also about all the processes related to the patient's identity, the target volume, the irradiation technique and the quality of the radiation, the delivery dose and its distribution, the dose limits to Organs at Risk (OARs) and the therapeutic program [2].

The awareness of Failure modes, and therefore the possibility of making them, led to develop a number of safety programs:

- Quality Assurance;
- Surveillance carried out by external control bodies;
- Professionals' Training;
- Communication development between professionals;
- Error reporting [3].

The adverse event in Radiotherapy is "any unwanted event, which involves a substantial deviation from the conditions expected by medical prescription, and that may have clinical consequences [3,9]".

Various databases have been created to manage the collection of incidents in radiotherapy, and safety and prevention projects, aimed to reduce human errors, have been implemented. An example is ROSIS (Radiation Oncology Safety Information System), established in 2001 by the ESTRO - European Society of Therapeutic Radiotherapy and Oncology- which includes a voluntary collection of data about accidents (1) and near misses (2) that can be used and analysed to reduce the incidence of the error [2,8,10].

In order to improve safety, we have seen the introduction and application of the FMEA in Radiotherapy, a risk analysis technique based on double evaluation:

- Processes and sub-processes by qualitative analysis;
- Criticalities by quantitative analysis [3,8,11].

According to a study carried out by Shuller et al. (Journal of Applied Clinical Medical Physic, 2017), we observe a reduction of RPN values applying the corrective actions highlighted post FMEA, as a result of the capacity to detect an error and to reduce the probability/frequency of occurrence [12].

Materials and Methods

The study took place at Radiotherapy Division of IEO, IRCCS of Milan, from June 2016 to December 2017, and was divided into two parts. The tool used for this project is HFMEA - Healthcare Failure Mode and Effect Analysis (health-related declination of FMEA), a proactive methodology which analyses and divides a process into several sub-processes, and researches what could go wrong, the possible Failure Modes and their causes [3,11,13-17].

The HFMEA contemplates the assignment of a score from 1 to 4 for Probability (P)/Frequency of Occurrence (Table 1) and a score from 1 to 5 for Damage (D) (Table 2);

PROBABILITY/FREQUENCY (P)		
SCORE	DEFINITION	DESCRIPTION
1	Remote	One or more times a year
2	Low	One or more times a month
3	Moderate	One or more times a week
4	High	One or more times a day

Table 1. Probability/Frequency of Occurrence (P); source: Ministry of Health (adopted model) [4,11,18,19]

DAMAGE (D)		
SCORE	DEFINITION	DESCRIPTION
1	None	No effect
2	Mild	Temporary damage which requires or prolongs hospitalization
3	Moderate	Short-term disability which requires or prolongs hospitalization
4	Severe	Permanent damage of minor entity or serious damage if not treated
5	Catastrophic	Patient death – Event could cause death – Permanent disability

Table 2. Damage (D); source: Ministry of Health (adopted model) [4,11,18,19]

The Risk Priority Number (RPN) is obtained by:

$$RPN = P \; x \; D$$

where P is the Probability and D the Damage; the value 1 of RPN indicates Failures with low probability of occurrence and damage, while value 20 indicates events which present a high probability of occurrence and catastrophic outcome; we used the model proposed by the Ministry of Health (Table 3) to reduce subjectivity because detectability is based on individual perceptions [19].

The first part of the project defined an instrument (a questionnaire) able to quantify and assess the possible risks in patients' care path in RT: it was defined "Radiotherapy Process", with its related sub-processes.

Errors more likely to occur (according to the perception of professionals) have been generated and the professionals figures involved examined them. The RT staff had to answer in accordance with the professional category involved in the proposed Failure. The results were delivered to the hospital's Risk Management Service.

Figure 1. PROCESS: Patient's care path in RT

The second part of the project is an amplification of the previous study: the review and extension of the evaluation instrument, the re-administration of the questionnaire to colleagues to monitor the progress in the safety program previously implemented, and the definition of the areas requiring corrective action.

We have identified two evaluation stages:

- Risk Assessment (qualitative);
- Risk Analysis (quantitative) [1,11]

The aim of the instrument is to investigate the perception of how many times a certain "Failure Mode" may occur. Four "Focus Groups" were created: two in the period from September to October 2016; and two from June to July 2017. We involved a multidisciplinary team [3,11,12,16] in order to delineate the damage value associated to each "Failure Mode" found. The team consisted of the same professionals for the four Focus Groups: two RTTs; two Radiation Oncologists; a Medical Physicist; a Moderator. The risk assessment takes into consideration two parameters: damage and the weighted frequency (probability) of occurrence [3]. These values can be put into the Risk Matrix (Table 3), which allows us to define the actions that we have to implement for each level of risk. The following tables were used for the analysis of the results:

Risk Matrix assessment (Ministry of Health's Guidelines)							
Probability	High	4	R4	R8	R12	R16	R20
	Moderate	3	R3	R6	R9	R12	R15
	Low	2	R2	R4	R6	R8	R10
	Remote	1	R1	R2	R3	R4	R5
			1	2	3	4	5
			None	Mild	Moderate	Severe	Catastrophic
			Damage				

Table 3. Risk Matrix; source: Ministry of Health (revised model to quantitative analysis) [1,17,19]

The Risk matrix used for this study was based on the guidelines of the Ministry of Health and revised for a quantitative analysis. The higher the numerical value, the higher the risk: we decided to overestimate the level of R5 and R10, considering the damage value [19].

This specific choice led us to consider as a priority an event that, even with remote probability, could have catastrophic consequences, compared to another with a higher probability of occurrence that could instead have moderate or severe consequences.

Subsequently, we focused on the search of possible corrective actions that have to be implemented due to the criticalities detected. This part of the study is called Risk Analysis [1].

	Risk level	Actions
R	Acceptable risk	No intervention
R	Low risk	Monitoring
R	Medium risk	Planning
R	High risk	Implementation of urgent corrective actions

Table 4. Intervention Matrix Level, Source: Ministry of Health (adopted model) [1,19]

The search for solutions was carried out by four multidisciplinary Focus Groups (formed by the same components), one in October 2016 and three meetings from November to December 2017.

First part of the study

The first part of the study was focused on the search for Failure Mode with a higher probability of occurrence. We submitted an evaluation questionnaire to all the professionals of the Radiotherapy Division: Medical physicists, Radiation Oncologists, RTTs and nurses, and subsequently analysed the collected results. The data obtained are sufficiently representative of the staff, since 88,6% of professionals responded (70 questionnaires filled –in out of 79).

The aim was to identify the frequency of occurrence of a specified "Failure Mode" by focusing the study on those that have a higher probability of occurrence.

The values of the damage for each "Failure mode" were subsequently defined through two multidisciplinary meetings (two Radiation Oncologists, two RTTs and one Medical physicist), discussing the seriousness of an event, and evaluating possible protection barriers. The discussion was sustained in blind mode: each participant was unaware of the result related to the weighted frequency of occurrence of the various Failures. This allowed to respond objectively to the damage value associated with the different Failure modes, avoiding any sub-estimates (mitigation effect). In fact, it had already been recorded that, when considering events with high values of weighted frequency of occurrence, the participants purposely lowered the damage value to obtain a low RPN value. Some items, even though repeated, have been evaluated with two different scores of damage, in order to intercept the error. The collection of data on the weighted frequency/probability of occurrence (P) and damage (D) was essential to delineate the value of the risk Priority Number (RPN), given by the following formula: RPN = P x D.

These data are useful to define the risk level of each "Failure mode", to recognize the areas that need:

- no intervention;
- monitoring;
- intervention planning;
- urgent corrective actions.

The Risk Matrix assessment (table 3) and the Intervention Levels (table 4) were used to analyse the results.

Despite the effectiveness of the measures (procedure) used to avoid any "Failure Mode", four criticalities have been identified:

- Wrong match images: RPN 7.6
- Wrong assessment of Set-up protocol: RPN 8.3
- Linac failure: RPN 9.3
- Wrong patient positioning (Set-up), conn. to "Treatment delivery on wrong side": RPN 7.7

A Focus Group has been organized in order to define possible corrective actions, such as a reorganization of the work and some operator training courses.

Second part of the study

The second part of the project focused on the instrument enlargement, considering Failure Mode linked to a specific pathology and to the type of LINAC used. Radiation Oncologists and Medical Physicists were asked to add possible Failure Modes related to their working environment, and RTTs were also involved, asking them to express considerations and add possible Failures, if missing.

In the first part of the study we analysed 86 Failure Modes with a response rate of 88.6% while in the second part we analysed 315 Failure Modes with a response rate of 69.7%

(88% RTTs; 59.4% Radiation Oncologists; 66.6% Medical Physicists).

Operating and analysis procedures were the same of the first part of the study:

1. Definition of the instrument;
2. Delivery and collection of the questionnaire;
3. Data analysis and processing;
4. Focus Group to define Damage Value;
5. Focus Group to define "Actions" [3].

Results and discussion

Data analysis (see ADDENDUM) found 44 critical issues (14% of all Failures studied) that required intervention planning. In the Table 5 the details.

High risk areas	0	Implementation of urgent corrective actions
Medium risk areas	44	Planning corrective actions
Low risk areas	241	Failure Monitoring
Acceptable risk areas	30	No intervention
Total investigated Failure	**315**	

Table 5. Overview table about critical issues

14 Failures [4] (see ADDENDUM and Table 6) were overestimated due to a high damage. The reason that led us to increase the risk level of such Failures is that, when some events can cause catastrophic damage, even considering their "remote" or "low" probability of occurrence, they require enhanced, specific attention and management, that is not necessarily preventive, such as risk insurance transfer.

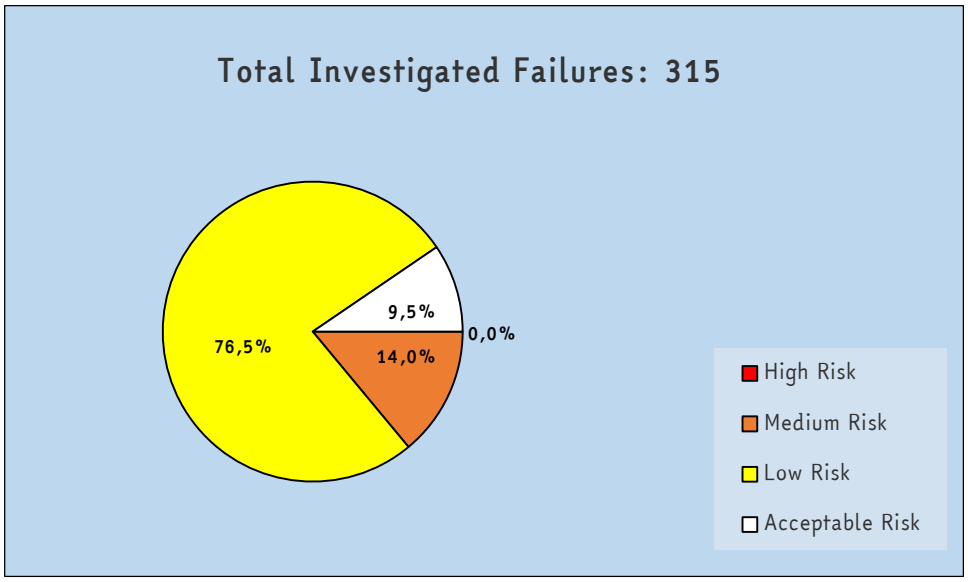

Figure 2. Activity area %

F44 and F97 represent the same Failure, described in two different moments: F44 refers to "Evaluation of the patient during the CT – Set-up" and scored a RPN value of 10.0, whereas F97 scored 10.5 and it is part of the "CT scan".

This differentiation is based on the fact that a possible error, albeit serious, committed during patient evaluation (like an allergy risk not communicated or ascertained) may be detected in a subsequent step, but this would prove impossible during the contrast medium injection (during CT scan).

In addition to the ones already used (Administration of Informed consent - mandatory by law), other corrective actions, not involving an increase of the working time, concern the scheduling of "Inter-Intra divisional trainings" [3], with the aim of sensitizing the professionals on the importance of this failure, on the medical and legal implications related to the Informed consent, and on the ways to deal with a potential negative event, due to a patient's allergic reaction to contrast medium (training course as suggested by the AAPM TG 100 report).

Another preventive action concerns the good practices and working rules that every professional (RTTs, doctors and nurses) must follow. An example is verifying with "Verbal investigation (Verbal communication)" [3,15] that the patient performed all the actions mandatory for the exams, never trusting solely the Informed consent (even if it is a written document with legal value).

The improvement in verbal and non-verbal communication represents an important corrective action: communication, as highlighted by Frewen et al (Journal of Medical Imaging and Radiation, 2018) is connected to "four out of five major Failure modes" and this is confirmed by the AAPM TG 100 report [3,15].

It is necessary to introduce "appropriate Infographics" along corridors and in waiting rooms, explaining to the patients the risks related to a missed communication about allergies. This kind of corrective actions will also affect the failure "Adverse reaction to contrast medium caused by missing pre-medication in case of known allergy (F100)", because the patient will be an active part of the prevention process.

The introduction of "Periodical staff meetings open to everyone" or "Inter- and Intra-Divisional Training Courses" could be useful to increase the attention of the workers on issues like F5, F15, F237 e F238.

The "Methodical review of the medical records" (corrective action for F7, F9, F15, F18, F19, F20, F21) can be useful to avoid inattentions or errors due to previous process, that could cause an Adverse Event, if not spotted.

The introduction of the "Digital medical records" (not yet present in Radiotherapy) is in alignment to the hospital's operative standard, and it will introduce a qualitative improvement with the aim of avoiding failure such as F9, F18, F19, F20, F21, F147, F148, F149 e F150.

An improvement might be represented by the introduction of an "Application with mandatory Sign In" (Restrictive template [5]) as the one in operating rooms: all the fields of the Digital medical records must be filled-in, in order to proceed to the next steps. This process would reduce the number of errors due to missing data.

The "double check on Contouring" by two different radiation oncologists (the one who took on the patient and the one who designed the treatment plan) is the correction identified for F137. This solution is also useful to prevent another Failure, "Wrong target contouring" (F134).

The introduction of the "Check List (memorandum)" (created for the Linac's operating station), the "Validation of a single treatment plan" and the "Time-out" are corrective actions able to act as protective barriers to a lot of failures (F147, F148, F149, F150, F195, F196 and F234).

The Check List will be useful to verify that: all the radiotherapy documents have been signed and inserted into medical records; and all the technical parameters of the treatment plan have been verified before starting the radiotherapy.

The Validation of a single treatment plan on the operating computers would allow to detect any wrong choice about the plan which must be delivered.

The time-out represents the introduction of a standardized communication form similar to that used in surgery or in aeronautics, where a double check on the actions can limit the errors.

Some failures (F174, F175, F176 and F177) related to "Quality Assurance" deserve special attention: the solution is to perform a dosimetry check on all treatment plans, although this is hard to implement due to the high volume of patients treated daily.

To overcome this, we have to calculate a percentage of patients on whom to perform the item "Verify the dosimetry check on random treatment plans".

The import of the patient's treatment plan on the Vero® is a critical moment because no measure can be implemented to avoid errors; we need to pay more attention to limit F190.

The analysis has also focused on Trilogy® where the RTTs could modify some treatment parameters using a SuperUser password to overcome the tolerance table limits (imposed by the system).

The corrections linked to rotation shifts are an example: we can accept up to 1.9° (rotation degrees) while the system accepts only up to 0.9°. The RTT's passwords do not work over 1° so they have to use a SuperUser's credentials.

Another example is the treatment of metastatic patients: due to their motor impairment, it could be difficult to position them in the same spot of the couch. To solve this problem (changing the treatment parameters), it could be useful:

- "Review the Tolerance Table for some treatment";
- Set-up user passwords with revised restrictions on TRANSLATION and ROTATION shifts, and block treatment parameters (Field and Gantry) modification is not possible with a "normal password".

Wherever possible, we secure the immobilization devices on the couch, to reduce the overriding of the Tolerance Table.

The "Study of Set-up Protocols" (internal IEO protocols defining the frequency and type of set-up verifications, set on the technique and the purpose of the treatment) and the "Reduction of the number of Operative Protocols [6] from four to three" are very important to limit the frequency of occurrence of F239 and F242; knowledge is useful to avoid errors in the assignment of protocols when they are not reported in the clinical records.

This problem only concerns Trilogy®, so we have identified as a corrective action the calculation of the percentage of various protocols: %P1, %P2, %P3 and %P4, and the subsequent evaluation of the possibility of starting from protocol 2 (P2) (three checks for the first three days of treatment and then calculation of the average shifts) so that we can increase the therapy's accuracy.

The analysis of F301 (linked to F305) represents a structural critical issue, and its resolution would involve a complete re-evaluation of the Radiotherapy Division environments.

However, "the identification of additional patients for Primary Nursing [7] and pro-active identification of fragile patients (with subsequent activation of care services such as: psychological and nutritional support)" were the corrective actions to reduce acute symptoms.

The aim of this action is to improve care efficiency and effectiveness, and the analysis permitted to define many corrective actions useful to solve not only the discussed Failures, but also to correct others, at the same time reducing more criticalities.

F. Nr	Failure Mode	F	D	RPN	Corrective Actions
F 5*	**Radiation Oncologist wrong report (e.g. side, disease, etc.)**	1.3	5	6.5	Triple active identification (first medical examination, CT simulation and start of radiotherapy)
F 7	Wrong or missing staging documentation (e.g. wrong indication of side)	1,7	4	6,8	- Double check on medical records by two Radiation oncologists - Training communication courses - Restrictive template: Clinical patient details
F 9*	**Non registration by Radiation oncologist or failure to communicate by patient of concomitant diseases (which could contraindicate or modify therapy)**	1,4	5	7,0	
F 10	Physical examination not carried out	1,7	4	6,8	Good practice rules
F 15	Missing staging documentation	2.3	4	9.2	Staging tests requested and booked by Radiotherapy's secretary
F 18*	**Incorrect compilation of medical records by Radiation Oncologist: wrong side**	1.3	5	6.5	- Double check on medical records by two Radiation oncologists - Restrictive template: 1) clinical patient details 2) treatment type 3) Set-up protocol
F 19*	**Incorrect compilation of medical records by Radiation Oncologist: omission of previous radiotherapy**	1.4	5	7.0	
F 20*	**Incorrect compilation of medical records by Radiation Oncologist: failure to report co-morbidity and allergy**	1.6	5	8.0	
F 21*	**Incorrect compilation of medical records by Radiation Oncologist: omission of reporting the presence of pacemaker**	1.2	5	6.0	
F 40	No delivery of the Exams required by Radiation Oncologist	2,1	3	6,3	Training communication courses (with patient)
F 44*	**Defective preparation of the patient to contrast medium: fasting / creatinine / cortisone pre-medication/suspension of oral drugs and antihyperglycaemic**	2.0	5	10.0	- Informed consent (mandatory by Law!) - Verbal communication other than written - Training about medico-legal importance and implication on Informed consent (Inter- Intra-divisional)
F 97*	**Poor preparation of the patient to contrast medium: fasting / creatinine / cortisone pre-medication / suspension of oral drugs and antihyperglycaemic**	2.1	5	10.5	
F 98*	**Lack of administration of Informed consent for contrast medium**	1.3	5	6.5	None – mandatory by Law
F 100*	**Adverse reaction to contrast medium in case of missed pre-medication (known allergy)**	1.0	5	5.0	- Informed consent - Warning Infographics about contrast medium
F 103	Defective visual monitoring of the patient during CT simulation (e.g. Interruption errors: phone ringing, fast communications, etc.)	1.8	4	7.2	- Work schedule with two RTTs - Good practice rules
F 137*	**Contouring on wrong exam**	1.2	5	6.0	Double check on contouring by two different radiation oncologists (who took on the patient and who designed the treatment plan)

F 147	Lack of communication regarding change of prescription: dose	1.9	4	7.6	- Double radiation oncologists' signature - Check-list (memorandum) - Restrictive template
F 148	Lack of communication regarding change of prescription: number of volumes	2.1	4	8.4	
F 149	Lack of communication regarding change of prescription: number of fractions	2.2	4	8.8	
F 150	Lack of communication regarding prescription: treatment days	2.4	4	9.6	
F 152	No signature on treatment plan: Medical physicists / Radiation oncologists	2,3	3	6,9	Double check performed by radiation oncologist and medical physicist
F 174	Lack of verification of the treatment plans using dosimetric phantoms (Trilogy®)	2.2	4	8.8	- Perform every quality assurance (dose measurements on all treatment plan) – very difficult - Dose measurements on random treatment plans
F 175	Lack of verification of the treatment plans using dosimetric phantoms (Tomotherapy®)	2.2	4	8.8	
F 176	Lack of verification of the treatment plans using dosimetric phantoms (CyberKnife®)	1.9	4	7.6	
F 177	Lack of verification of Dynamic Wave ARC treatment using dosimetric phantoms (Vero®)	1.6	4	6.4	
F 179	Missing delivery of the Exams required by Radiation Oncologist	2,3	3	6,9	Training communication courses (with patient)
F 185	Fail to communicate change in prescription: treatment days	2.4	4	9.6	- Double check performed by radiation oncologists - Warning into Restrictive template
F 190*	**Change of technical parameters in the plan import phase (Vero®)**	1.5	4	6.0	- None – we need to pay more attention (Vero®) - Review the Tolerance Table for some treatment (Trilogy®) - User passwords with revised restriction on translation and rotation shifts, and treatment parameter block (Trilogy®)
F 195	Wrong or missing virtual simulation execution (wrong or missed isocenter)	1.9	4	7.6	- Kv-kv image or cbct (cone beam computed tomography) acquisition - Time-out into treatment room - Scout CT view after virtual simulation to assess new isocenter (comparative assessment with bev - beam eyes view)
F 196*	**No check of treatment plan**	1.4	5	7.0	- Check list (memorandum) - Validation of a single treatment plan
F 229	Patient's anatomical changes (e.g. patient thinner, tumour volume decrease/increase) (H&N) (lung) (pelvis) (breast)	2,4	3	7,2	More presence and involvement of radiation oncologist caseworker
F 230	Patient's wrong set-up due to voluminous breast (breast)	2,1	3	6,3	
F 234	Wrong shift of treatment couch	1,6	4	6,4	- Training communication courses - Double-checking information

F 237	Wrong match images control	1.8	4	7.2	- New residents' training - Real time double check between youth/old residents and RTT - Regular training of staff
F 238	Wrong view and evaluation of anatomical changes (patient or tumour) (H&N)	1.8	4	7.2	
F 239	Wrong Set-up protocol assessment	1.9	4	7.6	- Study and signature of Set-up Protocols - Restrictive template (Set-up protocol voice)
F 242	No communication of further checks due to repeated shifts out of safety margins	2.1	4	8.4	- Study of Set-up Protocols - Reduction of Operative Protocols from 4 to 3 – start with Protocol 2 (P2)
F 252	No patient active identification	1,6	4	6,4	Good practice rules
F 257	No patient visual monitoring during the treatment	1,6	4	6,4	
F 259*	**Linac's collision with patient (Trilogy®) (Vero®) (CyberKnife®)**	1.2	5	6.0	- Delivery of demonstration plan (CyberKnife®) - CQP delivery for dose measurements (CyberKnife®) - Installed proximity sensors on head of Linac (Trilogy®) - Linac manual handling inside bunker in dubious situations (Trilogy®) - Visual monitoring
F 261	Wrong planning (volume treatment number)	2,3	3	6,9	- Double radiation oncologist checks on prescription therapy - Restrictive template
F262	No treatment plan correction due to anat. changes (oedematous breast, thinner patient, tum. volume decrease/increase)	2.0	4	8.0	- Discuss case to case - More presence and involvement of radiation oncologist caseworker
F 263	Lacking communication about patient positioning problems at the first 3/4 fractions	2,1	3	6,3	
F 264	Patient anatomical changes: oedematous breast / breast volume decrease	2,3	3	6,9	
F 265	Patient anatomical changes (pelvis): patient thinner	2,3	3	6,9	
F 271	Lack of medical notes on clinical diary	2,3	3	6,9	- Good practice rules - Training communication courses
F 277	Wrong note about therapy session on radiation diary	2,3	3	6,9	
F 301*	**Limited emergency management for acute patients**	2.0	5	10.0	- Structural critical issue - The identification of additional patients for Primary Nursing - Pro-active identification of fragile patients (activation of care services as: psychological and nutritional support)
F 305	Limited access to hospitalization for supportive care management	2.0	4	8.0	

Table 6: Corrective actions. F (weighted frequency of occurrence), D (Damage), RPN (Risk Priority Number). We overestimated the Failure signed with (*). We have also added F190, because we discussed about this item during the Focus Group and then the debate moved to Trilogy®; we consider it useful to show our results.

ADDENDUM

The analysis was performed by considering the "Risk matrix assessment" (Table 3). Some failures (F5, F9, F18, F19, F20, F21, F44, F97, F98, F100, F137, F196, F259 and F301 – highlighted with the symbol *) were overestimated because of a high damage value. We considered it appropriate to increase the risk level of these Failures since, if an event can cause a catastrophic damage, despite its "slight" or "low" frequency, it needs more specific attentions and a management which is not necessarily preventive, such as risk insurance transfer. F190 was also highlighted, because we discussed about this item during the Focus Group and then the debate moved to Trilogy®. It seemed useful to show the results to the readers.

Combifix®, Posirest®, Posiboard® e Wing Board® are immobillization devices produced by CIVCO Radiotherapy, Orange City, Iowa, USA.

FIRST MEDICAL EXAMINATION / RADIOTHERAPIC CONSULT		Weigthed Freq. of occurrence	Damage	Risk Priority Number
F 1	Omitted scheduling of Radiotherapy first visit (holidays/ physician forgetfulness, etc.)	1,7	3	5,1
F 2	Absence of the patient	1,7	1	1,7
F 3	Wrong or missing prescription from the General Practitioner	1,8	1	1,8
F 4	Wrong indication for Radiotherapy treatment	1,2	4	4,8
F 5*	**Radiation Oncologist wrong report (e.g. side, disease, etc.)**	**1,3**	**5**	**6,5**
F 6	Wrong treatment programme	1,2	4	4,6
F 7	Wrong or missing staging documentation (e.g. wrong indication of side)	1,7	4	6,8
F 8	Lack in delivery of side effects information files	1,8	1	1,8
F 9*	**Non-registration by Radiation oncologist or failure to communicate by patient of concomitant diseases (which could contraindicate or modify therapy)**	**1,4**	**5**	**7,0**
F 10	Physical examination not carried out	1,7	4	6,8
CT SIMULATION PROGRAMMING AND TREATMENT PLANNING		**Weigthed Freq. of occurrence**	**Damage**	**Risk Priority Number**
F 11	Wrong scheduling of patient's programme	2,3	1	2,3
F 12	Wrong communication of appointments schedule to the patient	2,1	1	2,1
F 13	Wrong communication of appointments schedule to the patient: poor coordination with end of chemotherapy (breast)	2,0	1	2,0
F 14	Incorrect contacts with the patients (homonymy)	1,2	2	2,4

F 15	Missing staging documentation	2,3	4	9,2
F 16	Incorrect communication of a change in the therapeutic programme between Radiation oncologists and RTT (treatment erased, stand-by, etc.)	2,2	1	2,2
F 17	Delayed or omitted compilation of the medical records for treatment scheduling.	2,0	3	6,0
F 18*	**Incorrect compilation of medical records by Radiation Oncologist: wrong side**	**1,3**	**5**	**6,5**
F 19*	**Incorrect compilation of medical records by Radiation Oncologist: omission of previous radiotherapy**	**1,4**	**5**	**7,0**
F 20*	**Incorrect compilation of medical records by Radiation Oncologist: failure to report co-morbidity and allergy**	**1,6**	**5**	**8,0**
F 21*	**Incorrect compilation of medical records by Radiation Oncologist: omission of reporting the presence of pacemaker**	**1,2**	**5**	**6,0**
F 22	Omission in reporting that the patient is Oxygen-depending	1,3	3	3,9
F 23	Omission in reporting the necessity of posing metal landmarks on scares (H&N – breast – mesothelioma)	1,6	2	3,2
F 24	Failure to observe the scheduled times	2,0	2	4,0
F 25	Lack of coordination with concomitant chemotherapeutic treatments and with surgery: wrong start of Radiotherapy	1,6	3	4,8
F 26	Difficulty in contacting the patient (wrong phone number, no e-mail addr., laryngectomized pat. with phonation problems)	2,0	1	2,0
F 27	Failure to observe appropriate therapy starting times (≤6-8 weeks in post-surgery according to guidelines NCCN)(H&N)	1,5	3	4,5
F 28	Wrong technique and LINAC scheduling: 3D vs IMRT / Trilogy® vs Tomotherapy® vs Vero® vs CyberKnife®	2,0	2	4,0
F 29	Wrong scheduling of therapeutic scheme: patient with bi-frac-tionated treatment	1,1	2	2,2
F 30	Missing/wrong information to the patient about the procedures for the CT – preparation	2,0	2	4,0
F 31	Poor understanding by the patient (i.e. inadequate preparation)(pelvis)(prostate)	2,9	2	5,8
F 32	Lacking information about the necessity (or not) of carrying out a CT (contrast medium administration)	2,0	2	4,0
F 33	Lacking information about the necessity or not of carrying out a P.E.T.	1,8	2	3,6

RADIOTHERAPY CT SIMULATION		Weigthed Freq. of occurrence	Damage	Risk Priority Number
Evaluation of the patient during the CT – Set Up				
F 34	Missing active patient's identification	1,4	4	5,6
F 35	Lack of administration of the informed consent to the patient	1,5	1	1,5
F 36	Lack of administration of the information sheets to the patient	1,7	1	1,7
F 37	No return of the information sheets signed by the patient	1,8	1	1,8
F 38	No information interview with the patient	1,3	3	3,9
F 39	Defective collection of medical documentation by the Radiation oncologist	1,7	3	5,1
F 40	No delivery of the Exams required by Radiation Oncologist	2,1	3	6,3
F 41	Failure to replace the tracheostomic metallic cannula with a plastic one (H&N)	1,3	2	2,6
F 42	Clinical examination of the patient absent	1,5	3	4,5
F 43	Lack of clinical records	1,5	2	3,0
F 44*	**Defective preparation of the patient to contrast medium: fasting/creatinine/cortisone pre-medication/suspension of oral drugs and antihyperglycaemic**	**2,0**	**5**	**10,0**
F 45	Only partial inflation of the expansion (breast)	1,8	2	3,6
F 46	Defective report of side effects related to post-surgery which can delay the beginning of Radiotherapy (breast) (prostate): haematoma / seroma / liponecrosis / infections / wound dehiscence / lymphocele	2,0	2	4,0
F 47	Missing indication to the patient of pre-medication during the treatment (Vero®) (CyberKnife®) (Trilogy®)	2,0	1	2,0
F 48	Defective report of the patient's physical problems due to the overhead arms positioning (breast) (lung)	2,2	2	4,4
F 49	Lack of Primary Nursing	1,5	2	3,0
Patient's Set-Up				
F 50	Lack of active patient's identification	1,4	4	5,6
F 51	Lack of patient's identification photo	1,8	1	1,8
F 52	Lack of insertion of patient's photo into the Clinical File	1,8	1	1,8
F 53	Wrong patient's photo insertion in the Clinical File: another patient's picture	1,0	1	1,0
F 54	Wrong identification of the side to be treated	1,1	3	3,3

F 55	Lack of acquisition of the identification photo of the breast to be treated (breast)	1,5	1	1,5
F 56	Lack of documental photos for complex Set-up	1,5	2	3,0
F 57	Wrong immobilization device: use of Combifix® vs cylinder under the knees (metastatic patient)	1,7	2	3,4
F 58	Wrong immobilization device: use of Wing Board® vs Posirest® vs Posiboard® (patients with thoracic neoplasia)	1,7	2	3,4
F 59	Wrong immobilization device (CyberKnife®): cushions with chin-lock Vs H&N thermoplastic mask (from D4 – D6 till C3)	1,5	2	3,0
F 60	Wrong patient's positioning due to the shape/dimension of the breast: use of Posiboard® vs "Prone Breast-Board"	1,4	2	2,8
F 61	Patient's inability to remain in supine position due to breathing troubles: inadequate slope of Posiboard® / lack of adequate devices under the head (to rise up the head)	1,7	3	5,1
F 62	Wrong choice of the headrest (H&N)	1,7	2	3,4
F 63	Wrong choice of the thermoplastic mask (H&N)	1,3	2	2,6
F 64	Lack of the adequate material necessary for a right patient positioning and set – up (H&N)	1,9	2	3,8
F 65	Bad-shaped mask (H&N) (CyberKnife® Skull)	1,8	2	3,6
F 66	Wrong patient's alignment	1,9	2	3,8
F 67	Lack of tongue stand (H&N)	1,5	2	3,0
F 68	Lack of dental bite (H&N)	1,4	2	2,8
F 69	Not removed dental prosthesis (H&N) (CyberKnife®)	1,4	2	2,8
F 70	Wrong or lack of Bolus positioning	1,5	2	3,0
F 71	Wrong identification of repere points	1,5	2	3,0
F 72	Metallic repere not positioned on the scare (H&N) (mesothelioma)	1,4	2	2,8
F 73	Not adequate Fiducial Markers positioning (CyberKnife®)	1,3	2	2,6
F 74	Adequate Fiducial Markers positioning but wrong patient set – up (CyberKnife®)	1,3	2	2,6
F 75	Metallic repere not positioned on the re-irradiated scare (breast)	1,4	2	2,8
F 76	Wrong isocenter identification	1,5	2	3,0
F 77	Wrong fill-in of the Set-up form	1,8	2	3,6
F 78	Wrong fill-in of the Set-up form: operators ID	1,9	2	3,8
F 79	Defective information, the patient can't keep the arms in an overhead position. (breast) (lung)	1,8	2	3,6

F 80	Wrong choice of the tracking system (Position Array Vs Optoelectronics Markers) (Vero®)	1,5	2	3,0
F 81	Optoelectronics Markers not positioned (Vero®)	1,3	2	2,6
F 82	Wrong positioning of Optoelectronics Markers (Vero®)	1,6	2	3,2
F 83	Patient not well informed about the importance of keeping the repere patches (Vero®) (CyberKnife®) sticking	1,6	2	3,2
F 84	Lack of the documentation photo of the Optoelectronics Markers (Vero®)	1,5	2	3,0
F 85	Wrong Set-up; lesion very lateral (hard to reproduce the set – up during the treatment) (Vero®)	1,7	2	3,4
F 86	Patient Set-up "Prone" or "Feet First" (Vero®)	1,2	2	2,4
F 87	Patient Set-up not adequate because the lesion has too cranial (arms) or too caudal (legs) location (couch sterical limits) (Vero®)	1,5	2	3,0
F 88	Lack of devices to help the patient to keep the Set-up position	1,6	2	3,2
CT Scan				
F 89	Lacking patient preparation to the Set-up CT (H&N): removing of the tracheostomic metallic tube / prosthesis (acoustic and dental) / metallic objects	1,6	2	3,2
F 90	Wrong patient submitted to the CT scan	1,1	4	4,4
F 91	Fail in preparing the patient to the Set-up CT (pelvis): empty bladder / too full bladder / not adequate rectal preparation	2,6	2	5,2
F 92	Wrong choice of CT radiological parameters: kV / mAs / slice thickness	1,5	2	3,0
F 93	Wrong CT scan for treatment planning: wrong choice of anatomical volumes	1,6	2	3,2
F 94	Wrong CT scan for treatment planning (Vero®): Optoelectronic markers not completely included into the scan	1,5	2	3,0
F 95	Wrong CT scan for treatment planning (CyberKnife®): scan volume not compliant to the specifics requirements of the TPS	1,4	2	2,8
F 96	Wrong CT scan for treatment planning: fiducial markers not implanted	1,4	2	2,8
F 97*	**Poor preparation of the patient to contrast medium: fasting/creatinine/cortisone pre-medication/suspension of oral drugs and antihyperglycaemic**	**2,1**	**5**	**10,5**
F 98*	**Lack of administration of Informed consent for contrast medium**	**1,3**	**5**	**6,5**
F 99	No contrast medium administration	1,3	2	2,6

F 100*	**Adverse reactions to contrast medium in case of missed pre-medication (known allergy)**	**1,0**	**5**	**5,0**
F 101	Wrong venous access (H&N): wrong choice of the vein / difficult choice of venous access / extravasation / vein breakage during Contrast medium injection	1,4	3	4,2
F 102	Wrong administration time of Contrast medium (flow rate, scan delay)	1,6	3	4,8
F 103	Defective visual monitoring of the patient during CT simulation (e.g. Interruption errors: phone ringing, fast communications, etc.)	1,8	4	7,2
F 104	Poor patient's cooperation	2,8	2	5,6
F 105	Patient's inability to keep the supine position due to pain (lack or insufficient pre-medication)	2,4	2	4,8
F 106	Failure to record claustrophobic patient (T/C) on simulation form	2,0	2	4,0
F 107	Failure to place temporary patches while waiting for final isocenter setting	1,2	2	2,4
F 108	Immobilization device distortion in the period between acquisit. and treatm. beginning (tight or large mask) (H&N)	1,9	2	3,8
F 109	Patient weight loss before treatment beginning (H&N) (pelvis)	1,8	2	3,6
F 110	Patient leaves after injection of Contrast medium	1,4	2	2,8
F 111	No preliminary check of CT scan images	1,8	2	3,6
F 112	CT scan images not sent to servers for treatment planning	1,8	1	1,8
F 113	Failed CT scan images uploading to server for treatment planning	1,6	1	1,6
F 114	CT scan images linked to the wrong patient	1,1	4	4,4
F 115	Fail in saving CT scan data	1,1	2	2,2
F 116	Failure to complete the simulation form	1,8	1	1,8
F 117	Fail verifying the correct therapeutic program	1,6	2	3,2
F 118	Lack of reconstruction of 4D CT scan images (Vero®) (CyberKnife®)	1,5	2	3,0
F 119	Reconstruction of 4D CT scan images into wrong phases (CyberKnife®)	1,4	2	2,8
F 120	LOT: wrong exposure parameters (CyberKnife®)	1,4	1	1,4
F 121	LOT: wrong positioning with X sight® spine tracking system (CyberKnife®)	1,4	2	2,8
F 122	LOT: wrong lung node identification and ROI assignment (CyberKnife®)	1,3	2	2,6

TREATMENT PLANNING		Weigthed Freq. of occurrence	Damage	Risk Priority Number
F 123	Problems with images match and fusion	1,7	3	5,1
F 124	No medical records	1,8	2	3,6
F 125	No staging exams	1,9	1	1,9
F 126	No signed informed consent in the medical records	1,6	2	3,2
F 127	Missing prescribed clinical examinations	2,2	2	4,4
F 128	Wrong exam registration number	1,4	2	2,8
F 129	Wrong medical record number	1,4	1	1,4
F 130	Error in the CT exam import	1,3	4	5,2
F 131	Missing report of the required exams for fusion and target volume detection	1,7	2	3,4
F 132	No display of the fusion exams	1,4	4	5,6
F 133	Lack of treatment prescription	2,0	2	4,0
F 134	Wrong target contouring	1,1	4	4,4
F 135	Wrong rating of risk of tumour and incorrect target identification	1,2	4	4,8
F 136	Imperfect OAR (Organs at Risk) contouring	1,4	4	5,6
F 137*	**Contouring on wrong exam**	**1,2**	**5**	**6,0**
F 138	Bad timing in contouring	2,4	2	4,8
F 139	Bad communication between professionals	2,4	2	4,8
F 140	Inverse Planning errors: dose description / number of fractions / planning aims	1,4	4	5,6
F 141	Direct planning errors: dose description / number of fractions / accessories / geometric factors	1,4	2	2,8
F 142	Lack of critical issues recognition in CT images (breast): cardiac toxicity, breath holding need?	1,4	4	5,6
F 143	Wrong isocenter selection by medical physicists	1,6	2	3,2
F 144	I.T. error in plan shipping	1,3	4	5,2
F 145	Mismatch between TPS and effective plan usability	1,3	4	5,2
F 146	Lack of Treatment plan for RT start	1,8	2	3,6
F 147	Lack of communication regarding change of prescription: dose	1,9	4	7,6
F 148	Lack of communication regarding change of prescription: number of volumes	2,1	4	8,4

F 149	Lack of communication regarding change of prescription: number of fractions	2,2	4	8,8
F 150	Lack of communication regarding prescription: treatment days	2,4	4	9,6
F 151	Lack of information to patient about change of prescription	2,2	1	2,2
F 152	No signature on treatment plan: Medical physicists / Radiation oncologists	2,3	3	6,9
F 153	Wrong Spine grid positioning for Spine treatm. (CyberKnife®)	1,2	2	2,4
F 154	Wrong Spine grid positioning for "LOT" (CyberKnife®)	1,3	2	2,6
F 155	Wrong prescription	1,3	4	5,2
F 156	Fail in the reconstruction of the old treatment plan in case of re-irradiation	1,2	4	4,8
F 157	Non-optimal reconstruction of the old treatment plan in case of re-irradiation	1,4	3	4,2
F 158	Inability to reconstruct the old treatment plan in case of re-irradiation (absence of information about previous treatments)	1,4	3	4,2
F 159	Wrong Pitch (Tomotherapy®)	1,4	2	2,8
F 160	Wrong Modulation Factor (Tomotherapy®)	1,3	2	2,6
F 161	Wrong field size	1,4	3	4,2
F 162	Treatment plan not included in the medical records	1,3	2	2,6

QUALITY ASSURANCE (Q.A.)		Weigthed Freq. of occurrence	Damage	Risk Priority Number
F 163	Lack of execution of daily quality measures	1,0	4	4,0
F 164	Lack of execution of daily AQA check: wrong films position into the phantom (CyberKnife®)	1,0	2	2,0
F 165	Lack of execution of daily AQA check: incorrect phantom positioning (CyberKnife®)	1,0	2	2,0
F 166	Lack of daily execution of the absolute dose measurements: wrong ionization chamber or electrometer selection	1,2	2	2,4
F 167	Lack of execution of the E2E test (CyberKnife®)	1,1	3	3,3
F 168	Lack of verification of the imaging system alignment (CyberKnife®)	1,1	3	3,3
F 169	Lack of verification of the robotic couch position (CyberKnife®)	1,1	1	1,1
F 170	Lack of verification of the beam parameters (CyberKnife®)	1,1	3	3,3

F 171	Lack of execution of pre-treatment checks on patient's plan (CyberKnife®)	1,3	4	5,2
F 172	Lack of execution of weekly/monthly/annual quality checks	1,4	4	5,6
F 173	Lack of evaluation of weekly/monthly/annual quality checks	1,5	2	3,0
F 174	Lack of verification of the treatment plans using dosimetric phantoms (Trilogy®)	2,2	4	8,8
F 175	Lack of verification of the treatment plans using dosimetric phantoms (Tomotherapy®)	2,2	4	8,8
F 176	Lack of verification of the treatment plans using dosimetric phantoms (CyberKnife®)	1,9	4	7,6
F 177	Lack of verification of Dynamic Wave ARC treatment using dosimetric phantoms (Vero®)	1,6	4	6,4

RADIOTHERAPY TREATMENT		Weigthed Freq. of occurrence	Damage	Risk Priority Number
First treatment day				
F 178	No pre-treatment medical examination	1,9	3	5,7
F 179	Missing delivery of the Exams required by Rad. Oncologist	2,3	3	6,9
F 180	Patient's exams are not given back or are lost	1,6	1	1,6
F 181	Lack of active patient identification	1,4	4	5,6
F 182	Missed patient's photo	1,9	2	3,8
F 183	No verification of the right side of the treatment	1,6	3	4,8
F 184	Communication issues	2,5	2	5,0
F 185	Fail to communicate a change in prescription: treatment days	2,4	4	9,6
F 186	No notification of treat. suspension (postponed treat. start)	2,2	2	4,4
F 187	Fail in importing treatment plans on RV CLIENT (Vero®)	2,0	2	4,0
F 188	Lack of Fail in importing treatment plans on ExacTrac® (BrainLab AG, Feldkirchen, Germany) (Vero®)	1,9	2	3,8
F 189	Missing patient's personal data and treatment data in the plan import phase (Vero®)	1,4	4	5,6
F 190*	**Change of technical parameters in the plan import phase (Vero®)**	**1,5**	**4**	**6,0**
F 191	No photo of the optoelectronic markers position into clinical reports (Vero®)	1,6	2	3,2
F 192	Loss of Patient's positioning patches	2,3	2	4,6

F 193	Missing information about concomitant therapies: chemotherapy / supportive therapies	2,0	3	6,0
F 194	Absent information about patient status: discharged / hospitalized / outpatient / bi-fractionated treatment	2,0	2	4,0
F 195	Wrong or missing virtual simulation execution (wrong or missed isocenter)	1,9	4	7,6
F 196*	**No check of treatment plan**	**1,4**	**5**	**7.0**
F 197	No check of Monitor Unit	1,4	3	4,2
F 198	No definition of the Set-up verification protocol	2,5	2	5,0
F 199	Wrong synchronisation between Radiotherapy and chemotherapy beginning	1,7	2	3,4
F 200	No Primary Nursing	1,5	2	3,0
F 201	Lost or deteriorated mask (H&N)	1,5	2	3,0
F 202	Wrong positioning of the bite or tongue depressor (H&N)	1,5	2	3,0
F 203	Wrong or lack of Bolus positioning	1,6	3	4,8
F 204	Fail to remove dental prostheses (H&N)	1,5	2	3,0
F 205	Fail to remove metal cannula (H&N)	1,3	2	2,6
F 206	Fail to remove hearing aid	1,4	2	2,8
F 207	Fiducial Markers in correct position but wrong set-up (this can compromise the plan feasibility (CyberKnife®)	1,3	2	2,6
F 208	No plan transmission (CyberKnife®)	1,6	1	1,6
F 209	Tracking failure due to: target zone / cast positioning / exposure parameters / wrong set-up choice (CyberKnife®)	1,6	2	3,2
F 210	No check of treatment field of view: breast is not completely included in the treatment field (3D treatment)	1,4	3	4,2
F 211	No check of treatment field of view: contralateral breast within treatment field (3D treatment)	1,4	3	4,2
F 212	Supraclavicular region not included in treatment field (breast)	1,5	3	4,5
F 213	No S.S.D. (Skin Source Distance) assessment with Linac Gantry positioned to 0° (breast)	1,4	3	4,2
F 214	Wrong shifting of treatment couch	1,5	4	6,0
F 215	No S.S.D. (Skin Source Distance) assessment with Linac Gantry on treatment position (breast)	1,5	3	4,5
F 216	No check of treatment field of view (3D lung treatments) (palliative treatments)	1,8	2	3,6
F 217	Unknown GAP between chest wall and supraclavicular region (double isocenter treatments) (breast treatment on Trilogy®)	1,8	3	5,4
F 218	Lack of GAP verification between chest wall and supraclavicular region (double isocenter treatments)	1,5	3	4,5

Patient's Set-up (must be used for the start and for the daily treatments)				
F 219	Use of Posirest® inst. of Posiboard®, and vice versa (breast)	1,7	3	5,1
F 220	Wrong immobilization device: use of a different headrest	1,6	3	4,8
F 221	Wrong immobiliz. device: use of a different thermopl. mask	1,1	3	3,3
F 222	Wrong arms posit. on Wing Board®, Posirest®, Posiboard®	1,7	3	5,1
F 223	No use of patient's aids, described on set-up report, as towels	1,7	3	5,1
F 224	Working alone instead of working in pairs	2,8	1	2,8
F 225	Wrong virtual simulation (pre-rt)	1,9	1	1,9
F 226	Non-compliant patient	3,0	2	6,0
F 227	Lack of premedication to claustrophobic patient (H&N)	2,1	2	4,2
F 228	Thermoplastic mask deformation (H&N)	1,8	3	5,4
F 229	Patient's anatomical changes (e.g. patient thinner, tumour volume decrease/increase) (H&N) (lung) (pelvis) (breast)	2,4	3	7,2
F 230	Patient's wrong Set-up due to voluminous breast (breast)	2,1	3	6,3
F 231	No check of treatment field of view: breast is not completely included in the treatment field (3D treatment)	1,6	3	4,8
F 232	No check of treatment field of view: contralateral breast within treatment field (3D treatment)	1,6	3	4,8
F 233	No S.S.D. (Skin Source Distance) assessment with Linac Gantry positioned to 0° (breast)	1,5	3	4,5
F 234	Wrong shifting of treatment couch	1,6	4	6,4
F 235	No S.S.D. (Skin Source Distance) assessment with Linac Gantry on treatment position (breast)	1,6	3	4,8
F 236	Use of Posirest® instead of Posiboard®, and vice versa (breast)	1,5	3	4,5
Image review				
F 237	Wrong match images control	1,8	4	7,2
F 238	Wrong view and eval. of anat. changes (pat. or tum.) (H&N)	1,8	4	7,2
F 239	Wrong Set-up protocol assessment	1,9	4	7,6
F 240	Low quality of the images: wrong choice of acquisition parameters / wrong modalities of images acquisition: CBCT (cone beam CT) vs Radiographs.	2,1	2	4,2
F 241	Missing notes of correction shifts on daily/weekly Set-up sheet (Trilogy®)	1,7	3	5,1
F 242	No communication of further checks due to repeated shifts out of safety margins	2,1	4	8,4
F 243	Wrong choice of acquisition and reconstruction parameters: slice thickness / interval of reconstruction / registration / reconstruction quality / which translation and rotation shifts must be applied (Tomotherapy®)	1,6	2	3,2

Daily Treatment				
F 244	Wrong or missed patient scheduling on time planner	2,1	2	4,2
F 245	Wrong or lacking compilation of radiation treatment diary	2,4	2	4,8
F 246	Missing communication about patient status: discharged / hospitalized / outpatient / bi-fractionated treatment	2,1	2	4,2
F 247	Lack of communication between patient and RTTs or Radiation Oncologists (patient doesn't show up)	1,9	2	3,8
F 248	Linac Failure: incomplete dose delivery	1,9	1	1,9
F 249	Linac Failure: fail to perform daily / weekly / monthly / annual Q.A.	1,5	4	6,0
F 250	Linac breakdown	2,2	2	4,4
F 251	Delayed or absent communication to patient about Linac breakdown	1,7	2	3,4
F 252	No patient active identification	1,6	4	6,4
F 253	Mistaken patient identity	1,0	4	4,0
F 254	Wrong patient positioning (Set-up)	See the Set-up patient's Failure mode		
F 255	Wrong recording of average shifts (new isocenter compared to the old isocenter)	1,8	3	5,4
F 256	Tracking problems caused by (CyberKnife®): treatment area / patient positioning into the cast / wrong exposure parameters / wrong Set-up	1,6	2	3,2
F 257	No patient visual monitoring during the treatment	1,6	4	6,4
F 258	Treatment delivered on wrong side	1,0	4	4,0
F 259*	**Linac's collision with patient (Trilogy®) (Vero®) (CyberKnife®)**	**1,2**	**5**	**6,0**
F 260	Delay in treatment delivering	2,9	1	2,9
F 261	Wrong planning (volume treatment number)	2,3	3	6,9
F 262	No treatment plan correction due to anatomical changes (e.g. oedematous breast, thinner patient, tumour volume decrease/increase)	2,0	4	8,0
F 263	Lacking communication about patient positioning problems at the first 3-4 fractions	2,1	3	6,3
F 264	Patient anatomical changes: oedematous breast / breast volume decrease	2,3	3	6,9
F 265	Patient anatomical changes (pelvis): patient thinner	2,3	3	6,9
Dosimetry In Vivo				
F 266	Lack of dosimetry control	2,2	2	4,4
F 267	Lack of feedback by physicists about dose delivery	2,1	2	4,2
F 268	No detection of natural background radiation pre-dosimetry	2,4	1	2,4

Medical examination in treatment				
F 269	Lack of notice about scheduled visit	2,5	2	5,0
F 270	Wrong patient identification	1,2	3	3,6
F 271	Lack of medical notes on clinical diary	2,3	3	6,9
F 272	Lack of notes on nursing diary	1,8	3	5,4
F 273	Lack of delivery of medical prescription to patient	1,8	2	3,6
F 274	Wrong drug prescriptions	1,2	3	3,6
F 275	Wrong drugs administration	1,1	4	4,4
F 276	Wrong patient medication	1,1	3	3,3
F 277	Wrong note about therapy session on radiation diary	2,3	3	6,9
F 278	Scarce formal access to supportive cares: speech therapy / nutrition support / psycho-oncology	1,9	2	3,8
F 279	Supply limitation for medical devices (H&N): creams / solutions	1,4	2	2,8
F 280	Limited access to infirmary for supportive care management	2,0	2	4,0
Potential patient suspension due to clinical reasons				
F 281	Incomplete dose delivery	1,4	1	1,4
F 282	Late or lack of CT re-evaluation of patient to assess any anatomical changes	1,9	3	5,7
F 283	Lack of verification of treatment plan	1,5	3	4,5
F 284	Late or lack of CT simulation for a new treatment plan	1,8	2	3,6
F 285	Lack of portal image check when patient restarts treatment (Trilogy®)	1,3	3	3,9
Medical examination on ending treatment				
F 286	Wrong patient identification	1,1	3	3,3
F 287	Lack of medical notes on clinical diary	1,6	2	3,2
F 288	Lack of notes on nursing diary	1,5	2	3,0
F 289	Wrong drug prescriptions	1,1	3	3,3
F 290	Wrong patient medication	1,1	2	2,2
F 291	No communication about next check-ups	1,3	3	3,9
F 292	Lack of delivery of patient's clinical documentation	1,5	2	3,0
F 293	Lack of delivery of discharge papers	1,1	2	2,2
F 294	Lack of delivery of nursing discharge papers	1,2	2	2,4

RT treatment ending				
F 295	Lack of print of RT treatment report	1,6	1	1,6
F 296	Lack of insertion of schedule Set-up controls into medical records	1,5	2	3,0
F 297	Wrong archiving of treatment plan (Vero®)	1,5	2	3,0
F 298	Lack of archiving of treatment plan (Vero®)	1,6	2	3,2
Toxicity management – H&N				
F 299	Lack of follow-up scheduling to assess post-treatment toxicity	1,4	2	2,8
F 300	Lack of medication and lack of supportive care for patients presenting with post-treatment toxicity	1,2	4	4,8
F 301*	**Limited emergency management for acute patients**	**2,0**	**5**	**10**
F 302	Limited access to infirmary for supportive care management	2,0	2	4,0
F 303	Patient not compliant with scheduled appointments	1,9	2	3,8
F 304	Limited formal access to supportive cares: speech therapy / nutrition support / psycho-oncology	1,8	2	3,6
F 305	Limited access to hospitalization for supportive care management	2,0	4	8,0
F 306	Supply limitation for medical devices after end of treatment: creams / solutions	1,9	2	3,8

FOLLOW-UP		Weigthed Freq. of occurrence	Damage	Risk Priority Number
F 307	Patient doesn't show up at the medical check-up: patient forgetfulness / wrong follow-up booking	1,9	1	1,9
F 308	Wrong planning of visits (Radiation Oncologist absent)	1,3	2	2,6
F 309	Radiation Oncologist Lateness	1,9	2	3,8
F 310	Lack of delivery of the requested documentation on the part of the patient	1,8	2	3,6
F 311	Impossibility to visit the patient due to fibroscopy (H&N)	1,4	2	2,8
F 312	Lack of previous clinical reports (failure of information systems)	1,5	2	3,0
F 313	Mistaken clinical evaluation	1,2	3	3,6
F 314	Incorrect use of templates for follow-up	1,3	2	2,6
F 315	Wrong synchronization of radiotherapy visits with other medical visits into the Institute	1,5	2	3,0

Conclusions

After analyzing all the items regarding Failure Modes, we can say that the Radiotherapy Division of the European Institute of Oncology (IEO) of Milan (Italy) has an acceptable safety level in relation to the treatments performed (volume of activity and type). We have defined a dynamic and flexible analysis instrument with the aim of making it adaptable to every context and situation; this would make it possible to replicate the study in other Radiotherapy Centers, to evaluate and compare the results [12].

We have monitored and investigated with a more detailed study Failures that previously required an intervention. The expanded, revised and corrected analysis instrument found forty-four criticalities (14% of all the failures). The corrective actions have been identified, discussed and implemented with a low impact in terms of completion times. We will carry out an additional Fmea study after one year from the first, to assess whether the corrective actions have led to an improvement; the purpose will be to correct and enlarge the 2017's study, with the aim to analyse a greater number of Failure Modes.

NOTE

(1) Accident or Event: Failure can or could cause a damage to patient's health (voluntarily or involuntarily) [4]

(2) Near miss: situation resulting from a failure that would have compromised the patient's health but it has been detected or it doesn't have any effect [4]

(3) Weighted average: it's a type of average in which each of data set point contribute more than other in relation with importance given. We calculate the weighted average of all frequency of occurrence studied

(4) 10 out of 44 medium risk Failure (F5, F9, F18, F19, F20, F44, F97, F98, F196 e F301), 4 out of 241 low risk Failure (F21, F100, F137 e F259)

(5) Restrictive template: I.T. form useful to make treatment information; any voice's form must be filled to go on the next form

(6) Protocol 1 (P1): one radiological check on the first treatment day and no more verified if we have shifts into safe margins.
Protocol 2 (P2): three radiological checks for the first three treatment days and calculate the average shifts; and then verify the corrected target position on fourth day with averages applied.
Protocol 3 (P3): three radiological checks for the first three treatment days and calculate the average shifts; and then verify the corrected target position on fourth day with averages applied; and then radiological checks one or two times a week (depending on disease).
Protocol 4 (P4): Image Guided Radiotherapy (IGRT), radiological checks every day.

(7) Primary Nursing: it's a method in which all nursing care for one or more patients is managed by one nurse called Primary, from acceptance to discharge. The Primary Nurse schedules all tests and procedures, plans activities and identifies any problem about patient's health [20].

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