REVIEW ARTICLE (PREGLEDNI RAD)

Failure Mode and Effects Analysis Application in External Beam Radiotherapy: a Systematic Review

Vedran Manestar[1,2], **Anita O'Donovan**[1], **Sarah Barrett**[1]

[1]Applied Radiation Therapy Trinity (ARTT), School of Medicine, Trinity College Dublin, Ireland

[2]University Hospital Center Zagreb, Croatia

Corresponding author: Vedran Manestar, email: vedran.manestar@kbc-zagreb.org

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Abstract:

Background: Radiotherapy is a medical procedure with potential high risk to harm patients. In order to reduce that risk and create a workflow safe for patients, prospective analysis tools are used.

Failure modes and effect analysis (FMEA) is one such tool, used to evaluate potential risks.

As FMEA originated from industry, there is a constant effort to adjust FMEA methodology for use in radiotherapy. This has caused a variety of approaches and inhomogeneous practices.

Purpose: To investigate the current practice of FMEA in external beam radiotherapy and to propose a more standardised approach.

Materials and Methods: The search was performed in PubMed, Ovid and Embase databases, resulting in 312 articles retrieved. Using PRISMA methodology the number of unique articles meeting inclusion and exclusion criteria was reduced to a total of 35, containing 38 analyses. The data on FMEA methodology implemented, scope of analysis, expert team composition, number of failure modes (FM) detected, relative priority number (RPN) threshold, number of FM exceeding the threshold, minimum, maximum and mean RPN, RPN calculation method and risk mitigation strategies were selected as important properties of FMEA.

Results: Data retrieved showed large variation in how FMEA is conducted. There is a considerable underreporting of minimum and mean RPN values. Large variations in RPN threshold value selection were also observed. Two different approaches to RPN calculation procedure were reported, and it is unclear what the best practice is. Expert teams were assembled according to the guidelines, but the optimal number of members is unclear. The vast majority of risk mitigation measures were applied directly, without the use of systematic tools.

Conclusion: FMEA is a well-established and widely used tool for prospective risk assessment in radiotherapy. As a result of this analysis, recommendations for more standardized approaches were proposed. Possible additional research goals were proposed in order to provide evidence for best practice in some areas of FMEA.

Keywords: Radiotherapy, FMEA, Risk analysis

Introduction

Failure modes and effect analysis (FMEA) is a prospective tool used to design safe radiation therapy (RT) workflow. Since FMEA is a generic tool initially developed for industry application, there is an ongoing effort to make it more user-friendly and suitable for use in RT. Despite existing FMEA guidelines (1), there are a variety of approaches in implementing FMEA analysis in radiotherapy clinical practice.

Radiotherapy is a medical procedure that uses high doses of radiation to treat tumours. Since these high doses are also harmful to surrounding healthy tissue, the process of radiotherapy is connected with the risk of accidental patient radiation exposure. This can cause additional adverse effects and have negative impact on patient's health. To reduce and prevent that risk, a systematic approach to workflow design is required. The design of hardware (machines) and software that are used to deliver radiotherapy today has reached a high level of safety, and

they routinely incorporate many safety mechanisms that prevent errors (1). But this does not automatically result in departement workflow design unification across different sites. Variability in the design of processes requires a high degree of process customisation, and this is a source of risk and uncertainty. Each workflow design requires the achievement of a safe environment for radiotherapy treatment delivery. To design quality workflow there are prospective and retrospective tools available

Prospective analysis tools (2) are used prior to and during workflow design in order to anticipate and prevent potential errors. Retrospective tools are used on existing workflows in order to improve workflow, based on the errors that have occurred. Since errors in radiotherapy may cause harm to patients, greater emphasis should be put on error prevention, using prospective quality management tools (2). There are three complementary tools used in prospective risk analyses: process mapping, FMEA and fault tree analysis (1,2).

Process mapping is the flow chart of the steps in the process describing in the details the steps that have higher risk of failure.

FMEA is a systematic tool used to score and prioritise the individual failure modes (FM).

Fault tree analysis is the tool used to identify the causes of potential FMs. Based on this, risk mitigation strategies and measures can be proposed and implemented.

FMEA is the central tool in prospective risk management and will be the focus of this research. First, it was developed for use in the aerospace (4) and automobile industries (5).

It is a well-established and recommended tool for prospective risk analysis in RT (6) and is widely adopted across many fields of medicine (3). Prospective analysis should be conducted when a new workflow is introduced, or the current workflow is changed in a way that mean new risks may occur. Prospective analytic tools aim to anticipate, assess, and manage possible risks.

Before conducting an FMEA analysis, a detailed process map should be created. A separate FMEA analysis of each process step should then be performed. The two main pillars on which a good FMEA analysis depends are the multidisciplinary team and the FMEA scoring table. The multidisciplinary team must include representatives from all professions in a certain step of the process. These individuals must be experienced and able to anticipate and assess the potential risk. Their expertise combined with other team members must provide the complete analysis from different points of view. The quality of the individual team members and their professional contribution directly impacts the quality of analysis. The first task that the multidisciplinary team must do is to list all potential risks that can occur in the observed part of the process. Each of these risks must then be assessed using an FMEA scoring table.

An FMEA scoring table is the main component of performing FMEA analysis. For each individual risk, three factors should be determined, occurrence (O), detection (D) and severity (S). Occurrence describes the likelihood that this event will actually happen. Detection represents the likelihood that if the event occurs, it will be detected. Severity represents the estimation of the actual negative effects of a certain event on patients or staff. Of these three factors, occurrence and severity are defined values and detectability is more an estimation. Detectability is heavily influenced by certain situations and staff presence, and therefore does not actually measure the contribution to risk, because its definitions are unclear (7), In the standard FMEA scoring table, all these three properties are assigned with numbers from 1-10 and multiplied. The final result can be any number between 1 and 1000. This result is described as Relative Priority Number (RPN). RPN=OxDxS. The RPN is used to rank listed risks. As the name says this rank list and RPN are defining the order in which risks should be managed. RPN is also a relative value and not the actual risk measurement. Besides the standard 1000 points scale FMEA, there are other numerical scales in the use (8) as well as descriptive, non-numerical scales (9,10).

These different FMEA scoring tables are the result of an effort to make the FMEA more suitable for application in healthcare and RT. FMEA was originally developed for industrial use. The scales and risks from industry cannot be directly applied to a healthcare environment. This resulted in developing modified FMEA tools better suited for application in medicine and radiotherapy. In 2002 the Healthcare Failure Mode and Effects Analysis (HFMEA) was developed (11). In the Netherlands, the faster modification of HFMEA was promoted (12). HFMEA was also modified and integrated into Global Risk Analysis, a systematic approach developed in France (13). Besides those FMEA method modifications, different 10 point scales are in use (1,14,15). Although the initial goal of the customisation of FMEA was to make its use more user-friendly, the variety of different versions has made the choice and application more complicated. What is the right choice for a certain user and setup? Those questions can cause unwillingness to start the risk assessment process, exclude some occupational groups and subsequently deteriorate the quality of risk assessment (15).

Radiotherapy techniques and treatment modalities are getting more complex and demanding for radiotherapy professionals. Understanding the potential risks and imposing safety barriers is necessary to provide safe and efficient radiotherapy treatment to patients. The proper application of FMEA and other Quality Management (QM) tools is essential to achieving this goal.

Aims and Objectives

The aim of this research is to investigate the current practice of FMEA analysis in external beam radiotherapy and to propose a more standardised approach.

Objectives:

- To establish the type of FMEA methodology that was used for analysis, and scoring method used for RPN calculation.
- To identify who performed the analysis, was it an individual effort or team work? How was the risk assessed?
- To extract the results of FMEA analysis (number of FMs, minimum, maximum, and mean RPN, RPN threshold, number of FM requiring corrective measures).
- To identify risk mitigation measures implemented.

Materials and methods

This review encompasses FMEA application for risk assessment in external beam radiotherapy (EBRT).

EBRT is the most prevalent type of radiotherapy used for the treatment of cancer patients. There are three major types of EBRT: electrons, photons and particles treatment. Despite being different types of radiation, their mechanics and the workflow are similar and consequent risks are comparable. This fact enables us to observe external beam radiotherapy as a uniform group regarding the potential risks.

Inclusion criteria: all the papers covering FMEA application in external beam radiotherapy published after 2011. This review will encompass English language publications. It includes studies covering all the steps in the radiotherapy process. These papers should provide detailed information on how FMEA analysis was performed, preferably providing the data on FMEA methodology type, the object of analysis, number of failure modes detected, RPN threshold applied, number of FMs requiring action, maximum, minimum, and average RPN, RPN calculation method, staff who performed it and risk mitigation strategies proposed.

Exclusion criteria comprised results such as conference proceedings and poster presentations since insufficient data on FMEA analysis is reported. For the same reason articles referencing FMEA analysis, but without an actual FMEA analysis were excluded. Brachytherapy was excluded, as it is internal radiation therapy. The principles, workflow and connected risks in brachytherapy are also different from those of external beam radiotherapy. These analyses and results cannot be compared directly, therefore brachytherapy was excluded. Animals' external beam radiotherapy has a different standard of care and faces some unique risks and therefore cannot be directly correlated to the standard human EBRT. So, articles covering the application of FMEA in animal radiotherapy will not be included. FMEA is a prospective tool, and articles covering its retrospective application will also be excluded. In addition, non-clinical process analyses were excluded

The literature search was performed using the terms: FMEA, failure mode and effects analysis, radiotherapy and radiation oncology. The scope included articles published between 2011. And 2021. The search was performed in PubMed, Ovid and Embase databases on November 8. 2021. An initial search resulted in 67 relevant publications in PubMed, 83 in Ovid and 162 in Embase. Details of the searches conducted for the respective databases are provided in Appendix 1.

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (16) is a tool used to guide the literature selection. PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. It ensures transparent reporting in systematic reviews and enables the reader to follow and reconstruct the literature selection. Also, it helps the author to track selection and improve reporting. Therefore, further selection was performed using the PRISMA methodology.

A total of 312 references were imported into EndNote, reference management software package. Using the "find duplicates" option in EndNote the number of results was reduced to 251 removing overlapping results. After additional manual overview and removal of the 60 duplicates, the number of unique results was 192 (*Figure 1*)

Title and abstract screening resulted in 144 studies being excluded. 107 results were identified as conference proceedings and posters. These results were removed for the reasons mentioned above. 22 articles covered the application of FMEA in brachytherapy and were removed. Four results covering the field of nuclear medicine were also removed. A further 7 papers were published in non-English languages (French, German, Japanese) and can't, therefore, be analysed. These results were also excluded.

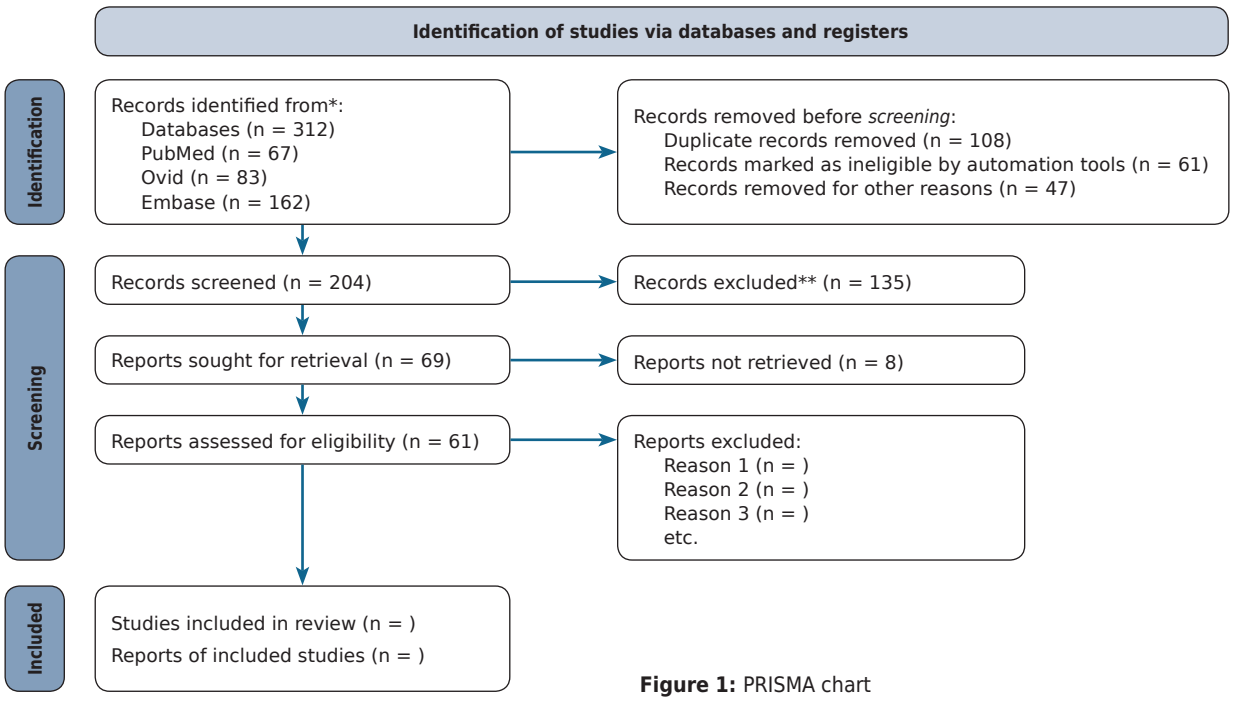

Figure 1: PRISMA chart

The last 4 excluded papers were 2 small animals' radiotherapy, chemotherapy application, and academic comment (*figure 1*).

Of the remaining 47 results, 45 were successfully retrieved for full-text screening and 2 were not in accessible journals.

Full text screening eliminated a further 11 results on the basis of inclusion and exclusion criteria. One additional article was excluded due to inconsistency in reporting. In this article, the number of detected modes, 104, was lower than the number of modes requiring corrective measures,115. The corresponding author was contacted for clarification, but no response was received. So, this study was also removed making the list of 33 articles selected.

A secondary search was performed using the same methodology on March 23. 2022. This search identified two additional articles published meanwhile for the total list of 35 articles. Since three of the selected articles contained two FMEA analyses, the 38 FMEA analyses were the subject of this systematic review.

During the literature selection process, common properties of FMEA analyses were extracted. The data on FMEA methodology type, the object of analysis, number of failure modes detected, RPN threshold applied, number of FM requiring action, maximum, minimum, and average RPN, RPN calculation method, performing staff and risk mitigation strategies proposed were identified as relevant criteria in evaluating FMEA.

The data on the FMEA methodology used in a certain study is basic information we must obtain to be able to compare different studies. This is a basis for any FMEA analysis and all the other extracted data results depend on this foundation. Only results obtained using the same methodology can be correlated. The scoring table applied is an integral and central part of the FMEA methodology. This table provides criteria and values for risk evaluation and determines the outcome RPN value. The standard FMEA table has a value of 1 to 10 for each factor (occurrence, detection, and severity), but the descriptive part of the table where are the information on how to assign a certain number has been adapted over the years (1,14,15).

The object of analysis describes the subject and the scope of inquiry. Is a subject of analysis the whole workflow, or just a certain step in workflow? This information has a direct impact on a number of FM results. The broader scope of analysis usually results in a higher number of FM detected

RPN threshold values describe the value that is the action point in certain analyses. All the RPN results exceeding the threshold are considered significant and are the subject of further analysis and corrective measures. There are no firm guidelines determining the RPN level requiring corrective measures implementation (15). Additionally, a single factor value (usually severity) can be set as an action threshold requiring action. The number of FM exceeding the RPN threshold represents the scope of the corrective measures that should be undertaken.

Minimum and maximum RPN represents a range of results in analysis. Together with the mean RPN value, they can serve as a safety indicator of the analysed process. These data can be very useful for additional analysis. If a secondary FMEA analysis is performed after risk mitigation strategies have been applied, then we can measure the improvement by comparing the RPN results from pre and post corrective measures analyses.

RPN calculation describes how the expert team produced RPN numbers. There are two ways this can be achieved. First, in a team meeting reaching a consensus. Each FM detected is discussed where agreement on its evaluation must be achieved. Secondly, each FM detected by the expert team is individually assessed by every team member. The final result is a product of mean values from all individual evaluations.

Performing staff provide the data on persons that performed the analysis, their number and role. These persons represent the expert team. This team should represent all professions included in a specific part of the work process. Each individual should provide contributions from his field of expertise in order to critically examine potential errors and properly evaluate them. The composition of this team has a direct impact on the quality of the analysis.

Risk mitigation measures are actions taken after the FMEA analysis in order to reduce the identified risks. These measures can include training, checklists, protocols and procedures, technologies, changes in the workflow etc. A single corrective measure can sometimes diminish multiple risks.

The data from selected articles were extracted to a prepared Excel worksheet. This enables structured data collection and a clear overview. In this phase, gaps in reporting were filled in, if enough data for reconstruction was available. For instance, the Mean RPN can be calculated when all RPN results are provided.

Results

Distribution of selected papers

The distribution of selected articles over the years is presented in figure 2. As the results for 2022 are incomplete since the year is not over yet, the distribution will be observed through an 11 year period, from 2011 to 2021. In that period 34 studies were published.

This makes an average of 3.09 conducted studies per year.

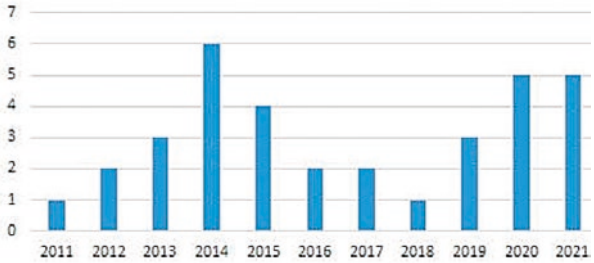

Figure 2. Distribution of the selected articles thru years

The type of FMEA methodology used in this study

The 35 included studies contained a total of 38 FMEA analyses. 24 analyses (63.16%) were conducted using the methodology proposed by TG-100 report (1). A further 6 (15.78%) analyses used the methodology described by

Ford et al. in 2009 (15). The m-HFMEA methodology was the basis for 2 analyses (5,26%) (6,7). The remaining 5 analyses, each representing 2.63% of the results, used different sources as their basis for methodology, IRCP 86 (17), P-FMECA (10), Scorsetti et al., 2009 (8), Perks et al, 2012 (18) and Ford et al., 2014 (14). The one remaining study (2.63%) (19) didn't specify the specific source of its methodology, and an indirect conclusion could not be drawn from the data available. The distribution of methodology applied is presented in *figure 3*.

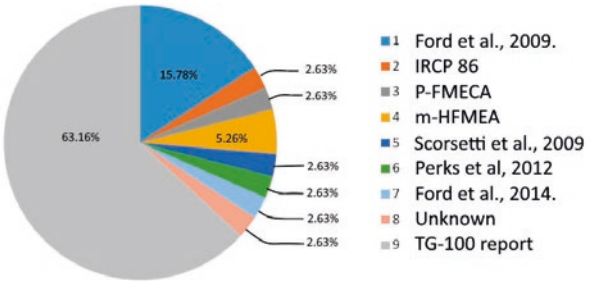

Figure 3. The distribution of different fmea methodologies

The 35 studies (92.05%) used FMEA methodologies based on a 1000 points scale. One (2.63%) used a methodology based on 80 points scale. The remaining two used an m-HFMEA methodology that uses a descriptive scale (very low to very high) rather than numerical values.

The scope of FMEA analysis

Of the 35 papers included in this study, 5 (14,29%) described the FMEA analysis of a single workflow step. A further 9 (25.71%) articles were encompassing FMEA analysis of multiple workflow steps. The majority of 21 (60%) papers elaborated on FMEA analysis of the complete workflow *(figure 4).*

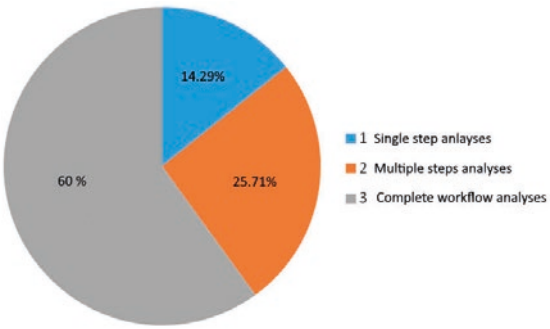

Figure 4. Scope of fmea in included studies

The number of failure modes identified

Of the 38 FMEA analyses inspected, 36 reported the total number of FM detected. The range of the FM per study was 10 to 409. The average number of FM detected per study is 86.02.

Risk priority number threshold

The majority of the studies, 21 (55.26%), used fixed numerical threshold values.

In 6 studies (15.79%) the top-ranking results were selected, the top 5 results in one study, the top 10 results in 3 studies and top 20 in 2 studies.

The top 20% of the results were the threshold criteria in 4 studies (10.52%). In 3 studies (7.89%) the threshold was not described. Two studies (5.26%) used descriptive, "high risk", values. The last two studies (5.26%) didn't use any form of threshold aiming just at the highest-ranking RPN value FM.

Additionally, in 12 studies (31.58%) the severity number threshold was determined as an extra threshold value. FM exceeding this threshold were also an additional object of risk mitigation strategies regardless of their eventual low overall low RPN number. The range of severity threshold was from 4 to 9 on a 10 point scale.

The number of failure modes exceeding the risk priority number threshold

A total of 33 studies (86,84%) reported the number of FMs exceeding the threshold. The number of FM requiring risk mitigation measures ranged from 3 to 106 across different studies with an average of 18.33 FMs per study. The remaining 5 (13.16%) studies have not reported the data on FMs exceeding a threshold,

Minimum risk priority number value

The minimum RPN is reported in only 18 studies (47.34%). In 2 studies (2.63%) these criteria were not applicable, since the FMEA methodology applied uses descriptive rating (very low) instead of numerical value. In the remaining 18 studies (47.34%) the data on minimum RPN was not reported,

Maximum risk priority number value

The maximum RPN was reported in all 38 studies. In 35 studies (92,1%) it was a numerical value in the range of 74 to 648 with an average value of 287.97. In one study (2.63%) the maximum value was 10, but it was the study using an 80 point scale. The remaining 2 studies (5.26%) used descriptive values "very high" and "high-risk class III" to describe the maximum RPN value.

Mean risk priority number value

The mean RPN value was reported in 11 studies (28.95%). In four additional studies (10.54%), the mean RPN value was not reported but it was possible to calculate it from data in the paper or supplemental materials available online. In the total of 15 studies, the mean RPN ranged from 14 to 174. In 2 studies (5.26%) using descriptive RPN values, the mean value can't be calculated. The remaining 21 studies (55.26%) didn't report a mean RPN value.

Risk priority number calculation method

As previously explained, there are two ways that RPN can be determined, by consensual agreement or as a calcu-

lated average. Out of 38 performed FMEA analyses, in16 cases (42.08%) the RPN was the calculated average of individual scoring. In 13 (34.19%) analyses, the RPN was obtained through team members' consensus. In 9 studies (23,67%) it was not possible to unambiguously determine the way the RPN was calculated.

Personnel Involved in FMEA Process and Assignment of risk priority number Values

There were a total of 36 multidisciplinary teams conducting the 38 studies reported in 35 selected articles. The structure of 33 teams (91.66%) was described, and for 3 (8,33%) teams no specific data was reported. The multidisciplinary team in selected studies consisted of 2 to 8 different professions with an average of 3.91. All the teams described had a radiation oncologist and medical physicist as their members. Radiation therapy tehnologists were present in most of the teams described. Some of the teams had dosimetrist and nurse members. Additionally, administrator, dosimetry manager, quality improvement manager, medical student, scheduler, DICOM expert, mid level provider, researcher, engineer, clerk, quality director, IT specialist and director were rarely present as a members. The size of the team was from 3 to even 69 members, with an average of 9.42.

Risk Mitigation Measures Implemented as a Result of FMEA Process

In 26 studies (68.42%), only the list or description of implemented changes was reported. No systematic approach was undertaken and measures were implemented as a direct response to the high risk FMs detected Fault tree analysis was used in 4 studies (10.52%) to analyze the detected risk and propose risk mitigation measures. In one study (2.63%) root cause analysis was used to analyze risk and propose a proper solution. In 7 studies (18.42%), no risk mitigation strategies were reported.

Discussion

All the results presented show a variety of approaches to implementing the FMEA analysis in external beam radiotherapy. Some of these differences are determined by local circumstances and specific demands. The scope varies from a single phase to a complete workflow. Despite all these differences, there is enough space to conclude how to optimise FMEA application in EBRT further.

Distribution of selected papers through time

The time distribution of selected papers suggests that there is a constant drive toward tailoring the FMEA methodology to better suit its application in EBRT and apply it to new technologies and techniques. The constant publishing of the new articles suggests that there is a continuous development of improved FMEA application and its implementation on the new treatment techniques. The shortfalls of FMEA application in EBRT have been detected in early works describing FMEA analysis in radiotherapy (12). Two main objections were that FMEA requires experienced staff and a significant amount of time available. The early development resulted in the publishing of the AAPM TG-100 guidelines in 2016 (1). These guidelines are widely accepted (*fig 2*). But this didn't stop the efforts to further optimize the FMEA methodology for EBRT application. The main objective is the development of a more suitable FMEA methodology in EBRT to make it less time consuming and more user friendly. However, these new approaches do not automatically bring benefits to experienced FMEA users since they do not provide more reliable results. New FMEA methodologies aimed at inexperienced, first-time FMEA users with limited resources in order to spread the FMEA methodology in wider practice. The more experienced users often continue to use the familiar FMEA methodology. The time and effort required to make the transition to the more "advanced" FMEA methodology is often not justified by expected gains. This can be observed through the comparation of columns 1 and 2 in *appendix 2* where the distribution of the FMEA methodology through time can be seen. The expert team can choose any familiar FMEA methodology that suits the purpose. This selection is at the discretion of the expert team, based on experience and professional judgement.

The scope of FMEA analysis

As described, FMEA methodology is useful for the analysis of the whole EBRT workflow. As the results show, in the majority of cases, the whole workflow was the object of analysis. This may have two causes. First, when the whole FMEA analysis process is initiated, it is beneficial to evaluate all the possible risks. Second, even a small change in single workflow step has the potential to cause cumulative risks in all subsequent workflow steps. However, if implemented changes do not influence the whole workflow, then only single or a couple of the workflow steps can be the object of FMEA analysis. Selecting the optimal scope of the analysis can have a positive influence on reducing the workload, time required, staff involvement and overall cost of the performed analysis. Selecting the appropriate analysis scope is the first task that impacts the expert team composition workload and time required.

The number of failure modes identified

There is a large variety of range in the number of FMs identified in selected studies, ranging from 10 to 409. This can be influenced by two main factors. First, the larger scope of FMEA analysis potentially offers the higher number of FMs possible. Second, if there are already safety measures implemented in the workflow, this reduces the number of possible FMs. Also, the subjective approach of the scorer can influence whether some of the FM will be included in the analysis or not. The number of FMs identified has a major impact on the FMEA workload and time required. Each of the FMs identified as a potential risk should be properly evaluated and scored.

Risk priority number threshold

The RPN threshold is the value applied as selection criteria in order to select FM requiring further mitigation. The standard RPN threshold for RPN originated from the industry is 125 (20) for the 1000 points scale FMEA methods. But other authors suggest different RPN threshold values (15) implemented in healthcare to achieve a manageable number of results requiring corrective measures implemented. Since FMEA is a semi quantitative method (1) the

final results may be biased by the subjective approach of the scorer. Some authors used different approaches to set up the thresholds such as top percentage or top numbers of the results. Authors using different scoring methods than 1000 points, defined the threshold according to their methodology. This variety of approaches doesn't have a negative impact on the FMEA analysis outcomes. The main goal of FMEA analysis is the correct RPN priority ranking and relative risk assessment rather than the exact risk score. Additional severity thresholds applied can be used to better define the failure modes requiring corrective measures. The threshold should be selected in a way that resulting number of FMs is manageable. Therefore, sometimes the top percentage or number of results is used as a threshold value.

Minimum risk priority number value

Minimum RPN is poorly reported in studies describing FMEA application in EBRT. This is also the case with most of the results below the RPN threshold value. The main focus of the studies are the higher risk values that require action. Since FMEA analysis is a systematic approach, the lower value RPN results need to be properly reported. If the space and number of results do not allow this in the main body of the article, then these results should be provided as supplemental material. The implementation of the risk mitigation strategies in order to reduce the high RPN FMs can sometimes indirectly reduce the RPN score of the FM with lower RPN. The absence of these results makes the mean RPN value calculation impossible. The reduction of mean RPN value is the main indicator of a systematic risk reduction if a process is re-evaluated using FMEA to measure the risk reduction achieved through implemented risk mitigation strategies. If minimum and low RPN FMs are underreported, such an evaluation is not possible.

Maximum risk priority number value

On the other hand, maximum RPN value is reported in all studies. This is understandable because this is the main focus of the FMEA study and the value that we want to manage in order to reduce the highest potential risks. The high value of the maximum RPN is usually a sign of poor workflow design and lack of safety barriers. Usually, it is accompanied by a relatively high number of FMs exceeding the threshold (22). Such a situation requires risk reduction and re-evaluation. These values can be recalculated after applying risk mitigation measures to evaluate the single risk reduction of this relatively high-value FMs (8,19,21.). After re-evaluation remaining risk can be acceptable or further corrective measures should be undertaken.

Mean risk priority number value

As it is closely correlated to the minimum RPN reported, mean RPN value is equally underreported. The mean RPN value can be used for two main purposes.

The mean RPN value can be used as an indicator when two different FMEA methodologies are being compared. In a study (6) comparing a visual rating scale based upon a TG-100 report and an ordinal rating scale developed locally, the mean RPN values were 62.3 and 67.5 ($p=0.7$) which was not significantly different. So, the RPN calculation results were comparable in terms of quality, suggesting that other factors could be used as the methodology selection criteria. But further research should be conducted to evaluate these results.

Another application of mean RPN is to evaluate the risk reduction after implementing risk mitigation measures and thus the improvement in workflow design. This was presented in study (8). This measures the overall risk reduction over the whole observed scope of workflow.

Risk priority number calculation method

There are no clear recommendations in the guidelines (1) on how to actually calculate the RPN number inside the multidisciplinary team. The two approaches have their advantages and disadvantage. The calculated average method is less time-consuming in terms of the time required for meetings. On the other hand, it diminishes the influence of expert opinion on the final result, giving the same weight to all team members. Obtaining the RPN through team members' consensus is a time-consuming process The individual risks are determined by team members' agreement during dedicated meetings. The team member that actually performs a certain activity can estimate a certain risk more accurately and his opinion has more weight. This method has the potential to provide more accurate RPN values, but the final results may be biased if there are strong personalities among team members. This potential should be further investigated, and the research could be easily performed as a part of an ongoing FMEA analysis without much additional effort.

A combined approach was implemented in the single study (17). The team members scored the risk individually and the agreement is reached using the Delphi method. The Delphi method is an established method of structuring a group communication process using a multi-round survey technique. This removes the strong personality bias. Still, it is unclear how time-consuming and how much work for data processing is required. The further inquiry resulted in 2 additional studies using FMEA and Delphi combined. One from the industry (23) and other from medical laboratory (24). The later study reported that FMEA and Delphi combination brings ease of administration, the lack of disruption to the normal working environment, and the honesty in answers. Still, it is unclear why this approach is not widely adopted in RT.

Personnel Involved in FMEA Process and Assignment of risk priority number values

Assembling the optimal team composition and size can greatly improve the FMEA analysis efficiency. FMEA methodology and the guidelines (1) define that all professional groups involved in a certain step of the workflow must be represented by an experienced representative. A higher number of experienced professionals provides a deeper insight into potential risks and give a higher chance of detecting potential errors. On the other hand, a bigger expert team is harder to manage in terms of organizing meetings and constructive discussions. Of the 33 studies describing the team 30 (90.91%) had team sizes of up to 11 members. Two teams (6.06%) had 18 and 20 members. One team had 69 members (17), but they used the Delphi method instead of regular team meetings.

When an average number of persons included in the team is compared to the number of professions repre-

sented, there is an average of 2.41 persons per profession represented. This is suboptimal in terms of cost and effectiveness. The number shouldn't be above 2 persons per profession in team, but ideally bellow 1.5.

Risk Mitigation Measures Implemented as a Result of FMEA Process

Despite the guidelines recommending a structured approach to the risk mitigation strategies, only a small number of selected studies have accepted this approach. Instead, the vast majority of studies, 68.42%, use a direct approach and propose direct corrective measures. It is unclear from the available literature what the limitations of such an approach are, and the potential pitfalls. On the other hand, a structured approach is time-consuming and therefore less attractive to the users. Is there a benefit if an additional effort is undertaken? Further research should be conducted to establish the evidence-based practice in proposing the risk mitigation strategies.

The FMEA analysis is a well described, documented and defined procedure. However, there are variations in its reporting and practical implementation. Standardised reporting of adverse effects in oncology is a constant aspiration (25). The goal of standardized reporting is to make subjective scoring methods more objective This is the main prerequisite in order to be able to compare the results of different studies and put them in the right context. The same principle can be applied to studies in other areas including the reporting of FMEA. The FMEA properties extracted and described in this article present solid ground for establishing a standard of FMEA reporting. Additionally, authors of the study (26) suggest reporting the equipment and systems used to deliver the service. If a results section is too broad, these data should be provided as supplemental material. Since a large number of FMs can be listed and scored low, further study should be conducted to establish minimum RPN value threshold for reporting. This will result in the lowering the total number of FM detected and reduce the analysis and reporting workload.

Except for one study (17) and a small line in guidelines (1), there is no wider usage of the international Incident Learning System (ILS) such as ROSIES and SAFRON in addition to FMEA analysis reported. Every team expert is limited by his experience when anticipating potential risks. ILS can be a powerful tool to provide information on previously unaware potential error modalities. Raising awareness of possible potential FMs that occurred elsewhere among team members can improve the FM detection and proper evaluation.

The limitation of this review is that is focused solely on FMEA application in EBRT. Ideas and experiences from FMEA application in other medical and non-medical environments could be transferred into its EBRT application, and a broader review could identify potential synergies.

A potential benefit could arise from eventual FMEA process digitalization. Digitalization in the RT department reduces the staff workload (27). Use of a standalone application or web service could reduce the time required for analyses, standardise the approach, improve data calculation and processing provide process mapping templates, and offer a connection to ILS. This could make the FMEA more user friendly and expand its usage. These services are already available, but their use in medical environment hasn't yet been explored. Additionally, more advanced risk calculation algorithms and methods could be developed resulting in more objective results.

Conclusion

FMEA has been recognized and recommended as a reliable tool for prospective risk assessment. It has been widely accepted and used in EBRT in order to reduce potential risk and design the quality workflow. Although there are clear guidelines developed, there are a variety of practical FMEA applications across different sites as presented in this study. But based on this review some recommendations could be given:

- For the routine use choose FMEA methodology that is accepted and recommended in your professional environment.
- Properly select the scope of analysis based on potential risks to optimize the workload.
- Expert team composition should be determined based on the process analysed. All the professions should be represented, but the total number of members should be as low as possible.
- Use all professional experience available and resources (ILS) to identify possible FMs.
- Setup the RPN threshold value in a way to comprehend all the high-risk FM but to keep the number on a manageable level.
- Systematically implement risk mitigation strategies.
- Evaluate risk reduction strategies on high risk FMs and the whole analysis scope,
- Standardize reporting. Report on: FMEA methodology implemented, scope of analysis, expert team composition, number of FMs detected, RPN threshold, number of FMs exceeding the threshold, minimum, maximum and mean RPNs, RPN calculation method and risk mitigation strategies. Available equipment and systems should also be reported to provide an insight into the system analysed.
- Perform FMEA accordingly to current best practice standards.

Suggested additional research could potentially better define best practice in some areas of FMEA. This could further standardize the methodology and improve guidelines. The guidelines will steer the whole process more precisely reducing the variability and human factor bias. In the future FMEA will probably be in the form of structured questionaires. The whole scoring process and risk prioritization will be performed automatically in the back based on the staff answers. The system will propose risk mitigation measures as an end product.

List of abbreviations

EBRT- External beam radiation therapy
FM- Failure mode
FMEA- Failure modes and effect analysis
HFMEA- Healthcare failure modes and effect analysis
ILS- Incident Learning System
RPN- Relative Priority Number
RT- radiation therapy

Appendices

Appendix 1: Search strategies:

Pub Med (67)
(FMEA) AND (Radiotherapy)
EMBASE [162]
'failure mode and effects analysis'/exp
('fmea' OR 'failure mode and effects analysis'
OR 'failure modes and effects analysis'):ti,ab
#1 OR #2
'radiotherapy'/exp OR 'radiation oncology'/exp
('Radiation Therapy' OR radiotherapy
OR 'radiation oncology'):ti,ab
#4 AND #5
#3 AND #6

Medline [83]
(fmea OR "failure mode and effects analysis" OR
"failure modes and effects analysis").ti,ab.
exp Radiotherapy/ OR exp Radiation Oncology/
(Radiation Therapy OR radiotherapy
OR radiation oncology).ti,ab.
or/2-3

Appendix 2: Data extracted from selected articles

Author and year	FMEA Scale applied	Scope of analysis	RPN calculation method	Expert team composition	Risk mitigation measures implemented
Perks, J.R. 2011	Ford et al., 2009.	entire workflow	not reported	3 MP, 2 RO, 1 Dos, 1 RTT, 2 QIM, 5/9	Change in procedure, staffing composition change
Ciocca, M. 2012	Ford et al., 2009.	Multiple workflow steps	Calculated average	not reported	Clear role definition, Monitor units double check In vivo dosimetry
Santanam, L. 2012	TG-100	Multiple workflow steps	Calculated average	4 MP, RTT, 1 Dos, 3/6	not reported
Noel, C.E. 2013	TG-100	Single workflow step	consensus	3 MP, Dos, Engineer, DICOM expert 4/7	Quality assurance with Plan Veto implementation
Broggi, S. 2013	Ford et al., 2009.	Multiple workflow steps	consensus	5MP, 2 RO 2/7	Information sheet, double check, vendor modification
Cantone, M.C. 2013	Ford et al., 2009	Single workflow step	consensus	1 RO, 4 MP, 5 Dos, 1 IT (4/11)	Documentation list, Plan verification
Denny, D.S. 2014	Ford et al., 2009	entire workflow	not reported	QD, RO, RTT, MP, Dos, Director, RM 7/7	Weekly chart review Electronic record Staff training
Ford, E.C. 2014 (14)	TG-100	entire workflow	consensus	7 people	Changes in policy, Improved forms, Automated process
Lopez-Tarjuleo, 2014	TG-100	entire workflow	not reported	2 MP, 2 RO (4/4)	Double check, Automation, In vivo dosimetry
Masini, L. 2014	TG-100	entire workflow	consensus	8 RO, 2 residents, 3 MP, 4 RT, nurse (5/18)	Bar code verification Peer review
Noel, C.E. 2014	TG-100	entire workflow	consensus	2 MP, 1 RO, 1 CE (3/5)	Protocols, checklist, training, additional software
Younge, K.C. 2014	TG-100	entire workflow	Calculated average	2 MP, 3 RTT, 2 dos, 2 RO, 2 Admin (5/11)	secondary check

Author and year	FMEA Scale applied	Scope of analysis	RPN calculation method	Expert team composition	Risk mitigation measures implemented
Yang, F. 2015	Ford et al., 2009	Single workflow step	Calculated average	1 RO, 4 MP, 5 Dos, 1 IT (4/11)	not reported
Veronese, I. 2015	Perks et al, 2012	entire workflow	not reported	MP, RO, RTT (3/3)	Dedicated training, systematic double check
Manger, R.P. 2015	TG-100	entire workflow	not reported	1 RO, 4 MP, 2 RTT, 1 dosimetrist (4/8)	fault tree analysis (FTA) reviewing images,using structure templates
Jones, R T. 2015	TG-100	entire workflow	consensus	2 RO, 5 MP, Dos, 2 RTT, medical student (5/11)	Checklist, improved imaging, QA modification Additional time available
Rah, J.E. 2016	TG-100	entire workflow	not reported	1 RO, 4 MP, 1 Dos, 2 RTT (4/8)	not reported
	m-HFMEA				
Zheng, Y. 2016	TG-100	Single workflow step	consensus	MP, RO, dosimetry manager 3/3	root cause analysis (education, peer review, and automatic check tools)
Xu, A.J. 2017	TG-100	entire workflow	Calculated average	RO, MP, NS, RSO, Nurs, Sched (6/6)	added morning QA procedure, additional check, additional imaging
Schuller, B.W. 2017	TG-100	entire workflow	consensus	Dos, RTT, nurse, RO, MP, admin,, res, mid-level provider (8/8)	QA procedure change, setup imaging, immobilization,
Frewen, H. 2018	IRCP 86	entire workflow	consensus	RO 9, RTT 60 (2/69)	changes in policy, new equipment, staff training
Kisling, K. 2019	TG-100	Single workflow step	consensus	3 MP, 1 RO (2/4)	3 types of qa
Liu, S. 2019	TG-100	Single workflow step	Calculated average	RO, MP, Dos, RTT (4/4)	modification in check list parameters
Shen, J. 2019	not specified 10point	entire workflow	Calculated average	4 RO, 5 MP, 9 RTT, 2 Nurse (4/20)	couch test change, additional scanning, immobilization, sedation
Viscariello, N. 2020	TG-100	entire workflow	not reported	RO, MP, RTT, Nurse (4/4)	screening of patients, regular cleaning, requiring masks.
Baehr, A. 2020	TG-100	Multiple workflow steps	Calculated average	2 MP, 3 RO, 1 RTT (3/6)	not reported
	m-HFMEA		Calculated average		not reported
Mancosu, P. 2020	Scorsetti et al., 2009	entire workflow	Calculated average	3 RO, 2 MP, 1 RTT, 1 clerk, 1 nurse (5/8)	improve communication, education, training, peer review
Rassiah, P. 2020	TG-100	Multiple workflow steps	Calculated average	MP, Dos, RTT (3/3)	checklist modification, standardization, automation
Rusu, I. 2020	TG-100	entire workflow	Calculated average	2 RO, 3 MP, 2 Dos, 2 RTT (4/9)	fault tree analysis (FTA) secondary verification, improved delineation,
Ahmed, S. 2021	TG-100	entire workflow	Calculated average	3 MPs, 2 ROs, 2 RTs (3/7)	Patient motion monitoring, Table double check Secondary timer

Author and year	FMEA Scale applied	Scope of analysis	RPN calculation method	Expert team composition	Risk mitigation measures implemented
	TG-100	entire workflow	Calculated average	2 MPs, 2 ROs, 2 RTs (3/6)	Morning QA modification Compensators check
Lis, M. 2021	TG-100	Multiple workflow steps	consensus	consensus group of experts,	fault tree analysis (FTA) : permanent corrective actions
Lee,S. 2021	Ford et al., 2009.	Multiple workflow steps	Calculated average	2 RTT, Dosimetrist, 4 MP, 2 RO (4/9)	fault tree analysis (FTA) Training, imaging potocol
Klüter,S. 2021	P-FMECA	entire workflow	Not reported	2 MP, 2 RO, 2 RTT (3/6)	standard operation procedures, specific checklists,
Gilmore. MDF 2021	TG-100	entire workflow	consensus	2 RO, 2 MP, 3 RTT (3/7)	Not reported
Bright, M. 2022	TG-100	Multiple workflow steps	Calculated average	1 RO, 3 RTT, 2 MP (3/6)	add barriers and computerization, establish protocols, check-off forms,

Appendix 3: FMEA results from selected articles

Author and year	Number of FM identified	RPN Threshold	Number of FM above threshold	Minimum RPN value	Maximum RPN value	Mean RPN value
Perks, J.R. 2011	29	20	10	not reported	80	not reported
Ciocca, M. 2012	10	125	3	42	216	110
Santanam, L. 2012	not reported	not reported	not reported	not reported	448	not reported
Noel, C.E. 2013	55	200	6	not reported	324	not reported
Broggi, S. 2013	74	125 (S=8)	4 (7)	not reported	196	not reported
Cantone, M.C. 2013	44	125	5	18	196	not reported
Denny, D.S. 2014	108	not reported	not reported	1	500	not reported
Ford, E.C. 2014 (14)	52	150	4	not reported	400	not reported
Lopez-Tarjuleo, 2014	57	not reported	not reported	3	324	84.27
Masini, L. 2014	116	125 (S>7)	4	1	180	14
Noel, C.E. 2014	127	200	48	11	441	174
Younge, K.C. 2014	99	150	5	not reported	228	not reported
Yang, F. 2015	63	150 (S>8)	8	5	336	69.7

Author and year	Number of FM identified	RPN Threshold	Number of FM above threshold	Minimum RPN value	Maximum RPN value	Mean RPN value
Veronese, I. 2015	not reported	80 (S>9)	19	not reported	160	not reported
Manger, R.P. 2015	167	100	25	not reported	288	not reported
Jones, R T. 2015	72	125	22	not reported	576	not reported
Rah, J.E. 2016	167	125 (top 20)	20	not reported	288	not reported
	167	High risk	14	not reported	Very high	Not applicable
Zheng, Y. 2016	36	100	10	16	336	98.86 calculated
Xu, A.J. 2017	86	Top 5	48	5,27	122	27,59 (calculated)
Schuller, B.W. 2017	409	100, (S>9)	106	not reported	648	not reported
Frewen, H. 2018	83	99 (top 20%,S >9)	17+3	15	230	not reported
Kisling, K. 2019	68	200, (S>9)	15	not reported	504	91
Liu, S. 2019	59	Highest ranking, (S>7)	not reported	40	330	129.2
Shen, J. 2019	122	Top 20%	25	3	264.3	42
Viscariello, N. 2020	33	no	not reported	18	448	145 (calculated)
Baehr, A. 2020	29	Top 20%	6	10.8	246.7	62.3
	29	Top 20%	5	9.3	284.6	67.5
Mancosu, P. 2020	+7	Top 10	10	not reported	24	not reported
Rassiah, P. 2020	50	20, (S>4)	18	not reported	74	not reported
Rusu, I. 2020	102	Top 10, (S>8)	14	9	105	not reported
Ahmed, S. 2021	87	Top 20	20	not reported	104.9	not reported
	87	Top 20	20	not reported	74.9	not reported
Lis, M. 2021	58	125, (S>5)	9	1	294	not reported
Lee,S. 2021	73	200	3	8	293	68.78 (calculated
Klüter,S. 2021	89	High-risk class III	59	not applicable	not applicable	not applicable
Gilmore. MDF 2021	36	Top 10	10	not reported	400	not reported
Bright, M. 2022	57	92, (S>7)	7	not reported	115	68

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