Journal Homepage: - www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI: 10.21474/IJAR01/13997
DOI URL: http://dx.doi.org/10.21474/IJAR01/13997

RESEARCH ARTICLE

FAILURE MODE AND EFFECT ANALYSIS FOR THREE DIMENSIONAL RADIOTHERAPY AT AIN SHAMS UNIVERSITY HOSPITAL

Gehad Sobhy Muhammad, Iman Aly Sharawy, Hatem Mohamed Abdalla, Khalid Nagib Abdel Hakim, and Ghada Refaat Meckawy
Department of Clinical Oncology and Nuclear Medicine, Faculty of Medicine, Ain Shams University.

Manuscript Info

Manuscript History
Received: 25 October 2021
Final Accepted: 29 November 2021
Published: December 2021

Keywords:-
Failure Mode, Effect Analysis, Three Dimensional Radiotherapy

Abstract

Introduction: Three-dimensional radiotherapy (3-D) is an important modality in the management of cancer. This complex process is liable to many types of errors. Risk management approaches are mandatory to decrease the risk of these errors. Failure mode & effect analysis (FMEA) is a proactive risk assessment strategy used to identify and anticipate potential errors and to take action before a radiation incident occurs.
Aim: The aim of this study is to apply a proactive risk analysis of the 3-D radiotherapy process, to quantify the most significant sources of failures using FMEA & to recommend risk reduction measures.
Methods: A FMEA was conducted over a 12-months period at Clinical Oncology and Nuclear Medicine Department at Ain-Shams University Hospital. A detailed process map for the 3-D radiotherapy technique was created starting from the decision taken for radiotherapy till the end of radiotherapy sessions. The Delphi method was used in this study to achieve consensus among participants about the level of risk associated with failure modes. Semi-structured interviews were conducted with twenty radiation personnel to identify potential failure modes in each step of the 3-D radiotherapy process. Scoring of the failure modes was identified in round 1, according to Severity, Occurrence, and lack of detectability scores. Round 2 confirmed the results of round 1. In Round 3:Risk mitigation strategies were suggested.
Results: The 3-D radiotherapy process map consisted of 69 process steps of the 10 stages of the 3-D radiotherapy process. One hundred – fifty-two failure modes were identified. Thirty-two top-ranked failure modes were prioritized according to the risk priority number (RPN) and severity scoring. An affinity diagram for these preventive measures was constructed.
Conclusion: FMEA is an effective proactive risk assessment approach in 3-D radiotherapy as elaborated by identification of potential failure modes, focusing on the top-ranked ones and also suggesting risk reduction measures.

Corresponding Author:- Gehad Sobhy Muhammad El-Benbawy
Address:- Department of Clinical Oncology and Nuclear Medicine, Faculty of Medicine, Ain Shams University.

……………………………………………………………………………………………………....

Introduction:-

Radiotherapy is an important treatment modality in the management of cancer. It plays a fundamental role in the treatment of 40% of those patients who are cured of their cancer with other modalities such as surgery and chemotherapy **(Ringborg et al., 2003)**.

The process of radiotherapy requires understanding of the principles of medical physics, radiobiology, radiation safety, quality management, radiotherapy planning, and interaction of radiotherapy with other modalities. The radiotherapy process requires collaboration between radiation oncologists, radiation therapists, medical physicists, and radiation engineers **(IAEA, 2018)**.

Increased complexity of the radiotherapy process caused many types of errors. Accidental errors in radiotherapy may result from human error, operating error, or equipment failures. The risk of failures has increased due to the interaction of many health care personnel working together on highly advanced technologies **(Valentin et al., 2000)**.

FMEA is a structured and logical analysis of a process to identify steps which are associated with the highest risk of failure. It also provides tools as a basis of risk mitigation strategies **(Huq et al., 2016)**.

The FMEA technique offers several advantages as a safety analysis tool. It permits identifying vulnerabilities before failures actually occur. It allows one to consider the severity and detectability of a failure mode in addition to its occurrence frequency. Different delivery errors have been measured by many studies **(Marks et al., 2007).**

The Delphi method was used in this study to gain consensus among radiation personnel about the level of risk associated with identified failure modes.

The aim of this Study is to perform a prospective risk assessment by FMEA of the 3-D radiotherapy process in Clinical Oncology Department at Ain-Shams University Hospital to quantify the most significant sources of risk and to recommend risk mitigation strategies.

Methodology:-

The FMEA was conducted over a 12 -months period from April 2020 to April 2021 at Clinical Oncology and Nuclear Medicine Department at Ain-Shams University Hospital.

First, a process map was created consisting of a detailed flow chart of the main steps of the 3-D radiotherapy process. This process map formed the foundation of the FMEA and Delphi round questionnaires. A purposive sample of 20 radiation personnel including the Head of department, Oncology staff, assistant lecturers, residents, physicists, technicians, and engineers were invited to participate.

The Delphi method was used in this study to gain consensus among staff members about the level of risk associated with failure modes they have identified in the first round. Semi-structured interviews were done with each radiotherapy personnel. These interviews were conducted after creating six different forms of a questionnaire for every category of radiotherapy involved personnel.

In round 1 (R1), open-ended questions were asked to participants to identify at least one failure mode in each step of the radiotherapy process and a possible cause for each. Participants were asked to give a score to each of the identified failure modes according to three parameters Severity (S), Occurrence (O), and lack of Detectability (D). The four possible severity ratings are Catastrophic (4), Major (3), Moderate (2), and Minor (1). The four probability ratings are Frequent (4), Occasional (3), Uncommon (2), and Remote (1). The four detectability ratings are Very easy (1), easy(2), moderately difficult (3), and impossible to be detected (4). Definitions of each probability, detectability, and severity rating are shown in Tables 1, 2, and 3 respectively **(VHA National Center for Patient Safety (NCPS), 2021).**

After the end of round (1), the Risk Priority Number (RPN) for each identified failure mode was calculated. The RPN is "the product of the numeric ratings for severity, probability of occurrence, and detectability"RPN= S.O.D. Failure modes were ranked according to the RPN and Severity scoring **(Huq et al, 2016).**
Round (2) compromised of confirmation of the results of round (1) regarding potential failure modes, potential causes of these failure modes, and scoring results according to severity, occurrence, and detectability.

After the end of round (2), the average (S), (O), (D), and RPN scoring for each failure mode were calculated. The failure modes were re-prioritized according to the average RPN & (S) scoring to allow focusing on the failure modes with a cut-off value equal to or more than 24 and ⁄or severity score equal to or more than 3.

Round (3) Risk mitigation strategies for potential failure modes with an RPN value equal to or above 24 were discussed with participants. Suggested risk mitigation strategies were finally evaluated by recalculating the RPN for potential failure modes after anticipating the application of these risk reduction strategies.

Table (1):- Healthcare FMEA (HFMEA) Probability Ratings.

HFMEA Probability Ratings
Frequent Event (4) Likely to occur immediately or within a short period (may happen several times in one year)
Occasional Event (3) Probably will occur (may happen several times in 1 to 2 years)
Uncommon Event (2) Possible to occur (may happen sometime in 2 to 5 years)
Remote Event (1) Unlikely to occur (may happen sometime in 5 to 30 years)

This table was used to assign a probability rating when calculating the risk priority number (RPN) of a failure mode.

Table 2:- HFMEA detectability Ratings.

HFMEA detectability ratings
Impossible (4) Impossible to be detected (no QA in place)
Moderately difficult (3) Moderately difficult to be detected
Easy (2) Easy to be detected (could be missed without check)
Very easy (1) Very easy to be detected (QA checks already in place)

This table was used to assign a detectability rating when calculating the risk priority number (RPN) of a failure mode.

Table 3:- HFMEA Severity Ratings.

	Patient Outcome	***Visitor Outcome***	***Staff Outcome***	***Equipment or Facility***
Catastrophic Event (4)	Death, major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery or procedure on the wrong patient or wrong body part	Death; or hospitalization of 3 or more visitors	Death or hospitalization of 3 or more staff	Damage equal to or more than $250,000. Any fire that grows larger than an incipient stage
Major Event (3)	Permanent lessening of bodily function, disfigurement, surgical intervention, increased length of stay or level of care for 3 or more patients	Hospitalization of 1-2 visitors	Hospitalization of 1-2 staff, 3 or more staff with lost time or restricted duty injuries/illnesses	Damage equal to or more than $100,000.
Moderate Event (2)	Increased length of stay or increased level of care for 1 or 2 patients	Evaluation and treatment for 1- 2 visitors (less than hospitalization)	Medical expenses, lost time or restricted duty injuries or illness for 1-2 staff	Damage more than $10,000 but less than $100,000. A fire at an incipient stage or smaller
Minor Event (1)	No injury, nor increased length of stay nor increased level of care	Visitor evaluated (no treatment or treatment refused)	First aid only (no lost time, restricted duty injuries or illnesses)	Damage less than $10,000. Loss of utility system with no adverse outcome.

This table was used to assign a severity rating when calculating the risk priority number (RPN) of a failure mode.

Results:-

First, a high-level flow chart for the major steps of the 3-D radiotherapy process at Ain -Shams University hospital was created. Then, a detailed process map was constructed. This process map formed the foundation of the FMEA and Delphi round questionnaires. The detailed process map was formed of 69 process steps of the 10 stages of the three-dimensional radiotherapy process.

Delphi method was used which is " an established method of structuring a group communication process. It involves multi-round questionnaires to achieve consensus of opinion among a group of experts in the field under investigation. The anonymous questionnaire style of the Delphi method is less prone to participant peer pressure and bias from experts with dominant personalities" **(Skulmoski et al, 2007).**

Round 1
Radiotherapy personnel identified 152 failure modes in the 10 stages of the radiotherapy process. Each personnel was asked to give a score for severity, occurrence, and lack of detectability. Failure modes were ranked according to the RPN and Severity scoring.

Round 2
Confirmation of the results of round (1) was done. After the end of round (2), the average (S), (O), (D), and RPN scoring for each failure mode were calculated. The failure modes were re-ranked according to the average RPN & (S) scoring.

Fifty-eight failure causes for the highest-ranked 32 failure modes were identified. All suggested failure causes fall into nine main categories including Human factors, documentation error, communication error, inadequate procedure ⁄policy, medical devices failure, lack of financial resources, workload, and lack of standardized institutional guidelines. Human factors, documentation errors, and communication errors were the most commonly cited causes of the highest risk failures. Ten causes of failures resulted in failure modes with the highest RPN score (31.5), three of them were related to a communication error including lack of standardized interdisciplinary communication method and inaccurate case presentation by a junior resident. Six of the identified failure causes had an RPN equal to 27, two of them attributed to the inadequate number of radiotherapy personnel including lack of enough qualified technicians and unavailability of a qualified radiotherapy nurse at CT simulator and treatment machine. Five of the failure modes with an RPN score equal to 26.2 were caused by errors related to medical devices failure and Lack of regular preventive maintenance. Twenty-one causes of failure had an RPN equals 24, six of them were due to documentation error including incorrect manual entry of patient ID data, incomplete documentation of the aim of treatment, incomplete documentation of patient name on accessories, multiple verbal plan modifications, and incomplete documentation of treatment parameters at radiotherapy sheet.

The top-ranked failure modes with an RPN equal to or more than 24 and ⁄or severity score equal to or more than 3 were discussed with participants at round 3.

Round 3
Twenty-six top-ranked failure modes with RPN values equal to or more than 24 were discussed with radiotherapy personnel to suggest at least one preventive measure for each failure mode. Six more failure modes with severity scores equal to or more than 3 were also considered. The six failure modes with high severity scores and an RPN less than 24 were identified at five steps of the radiotherapy process (treatment decision, patient reassessment, CT simulation, delineation, and treatment delivery).

Sixty-three preventive measures and checkpoints were suggested by participants. These included accurate documentation (accurate, complete & timely), appropriate communication (including interdisciplinary, intra-disciplinary, horizontal & vertical communication), adequate task allocation (adequate job description for each member involved in radiation therapy), financial support (for new accessories, facilities & techniques), regular training & workshops for radiotherapy personnel (at least twice ⁄year), adequate number of qualified radiotherapy personnel, adequate procedure ⁄policy, regular preventive maintenance (not only on demand) and standardized institutional guidelines (updated yearly).

Table (4) illustrates the major processes of 3-D Radiotherapy, potential causes of failure, severity scoring, Risk priority number (RPN), and suggested preventive measures for each failure mode. Failure modes at the same step of the radiotherapy process were written at different fields at table (4) if they had different RPN scores.

Risk analysis was done after anticipating the application of these risk reduction strategies according to participants' views. According to participants, the RPN scores will decrease if these risk mitigation strategies are applied mostly due to the decrease of occurrence and detectability scores.

Table 4:- Illustrates major processes of 3-D Radiotherapy, potential causes of failure, severity scoring, Risk priority number (RPN), and the suggested preventive measures for each failure mode.

Major process	Potential Failure Modes	Potential Causes of Failure	(S)	RPN	Preventive measures
1. Decision of treatment	-Incomplete documentation of aim of treatment.	-documentation by junior resident.	4	24	-Complete documentation (accurate, timely, signed) of Decision of radiotherapy at radiotherapy sheet or Electronic Medical Record EMR (radiotherapy items) by assistant lecturer or senior

					resident**(1(,(3)**
1. Decision of treatment	-Delayed Concurrent chemo-radiotherapy (CCRTH) patient assessment	-Workup needed before chemotherapy is delayed (e.g. full lab, audiometry) -Untimely chemotherapy referral -Lack of coordination between clinics	3	18	-Accurate documentation of CCRTH decision by assistant lecturer or senior resident. **(1),(3)** -Referring oncology clinic should instruct workup needed before CCRTH. **(4)** -Co-ordination between clinics to schedule CCRTH cases for chemotherapy at the beginning of the week (e.g. Electronic CCRTH list).(**4**) -Better design of patient CCRTH record**. (1)**
2. Patient re-identification	-Incorrect patient identification	- Patient identification by only one method. -Incorrect manual entry of patient ID data.	4	24	-Patient identification by 3 methods (Full name as documented in the ID card, ID number, Birthdate)**. (1)** -Qualified nurse secretary for entry of patient's full data to EMR and Rth sheet**. (3)**
3. Patient re-assessment	-Inaccurate patient assessment -Inadequate interpretation of target or normal tissue	-Inadequate design of radiotherapy sheet and radiotherapy items at the electronic medical record (EMR) -Case presentation by a junior resident -Lack of appropriate interdisciplinary communication method	3.5	31.5	-Organized Workshops and training schedules for junior residents. **(5)** -Case presentation under the supervision of assistant lecturers or senior residents. **(3)** -Case presentation by a Multi- Disciplinary Team (MDT) in presence of pathologists, surgeons, and radio- diagnosticians. **(2)** -Complete documentation (accurate, timely & signed) of the plan of treatment by a senior resident or assistant lecturer**. (1),(3)** -Standardized interdisciplinary communication methods (Horizontal &vertical) with the staff of pathologyand radiology departments (e.g. available schedule of daily shifters and their telephone number)**. (2)** -Available nutrition & psychiatry clinics at the department. **(2)** **-**Radiotherapy checklist including body weight. (1)

3. Patient re-assessment	-Delayed patient assessment -Missed interventions needed before starting radiotherapy (e,g Dental exam, Feeding tube or D-J insertion)	-workload -lack of knowledge. -Long waiting list at interventional radiology, surgery, or dentistry clinic. -Lack of communication with other departments -Delay of Ministry of Health financial approval report.	3.5	21	-Assistant lecturer supervision. **(3)** -Extracurricular training and educational schedule for residents. **(5)** -Standardized interdisciplinary communication methods(Horizontal &vertical). **(2)** -Available non-governmental organizational (NGO)funding if MOHR is delayed. **(4)**
4. CT/simulation and image transfer	- Mislabeled Immobilization devices -Immobilization devices damaged	-Workload -Documentation error by radiotherapy technician	4	24	-labeling of devices by patient barcodes. **(1)**
4. CT/simulation and image transfer	-Application of inappropriate immobilization technique -Inaccurate marking of isocenter set up point	-Inadequate training of technicians. -Miscommunication between technician and physician -Lack of technician experience	3	12	-Regular training and workshops for technicians.**(5)** -patient fixation should be done under the supervision of an assistant lecturer. **(3)**
5. Delineation	-Inconsistent PTV construction with department procedure	-No institutional standards for PTV construction	3	27	-Measurement of setup errors at our department. **(9)**
5. Delineation	-Inaccurate delineation of GTV ⁄CTV.	-Lack of standardized guidelines -Inaccurate image fusion -Limited imaging modalities in contouring -Different patient setup at radio-diagnosis -Lack of time -Delineation units: not enough	3.5	21	-Standardized Atlas ⁄Guidelines for delineation. **(9)** -Revision by senior staff. **(3)** -Extracurricular delineation workshops for residents and assistant lecturers. **(5)** -Co-ordination with radiology department to provide rotations for oncology residents for more practice on CT Anatomy. **(5)** -Communication with radiology department to access patient imaging on the same treatment position. **(2)** -Accurate formal requests to the radio-diagnosis department (treatment position should be mentioned). **(1)** -Increase the number of delineation units. **(4)**
5. Delineation	-Wrong images selected -Wrong site (especially if paired organs)	-Inadequate training -Incomplete documentation of critical information (e.g.preparation) -workload	4	16	-Available connection between the electronic record system and planning system. **(2)** -Complete documentation (accurate, timely&signed) of patient data at radiotherapy

					sheet and EMR prior to CT simulation by a senior resident or under supervision of assistant lecturer. **(1),(3)**
5. Delineation	Movement not considered in movable organs.	-Lack of four Dimensional computed tomography (4D CT).	4	24	Application of Image-Guided Radiotherapy (IGRT). **(7)**
6. Treatment planning	-Selection of remote isocenter (away from the region of interest)	-Inadequate training of technicians -Lack of communication between assistant lecturer ⁄resident and technician -Inadequate training of junior physicists. -Miscommunication between oncology assistant lecturer⁄residents and technicians	3	27	-Training courses and regular workshops for technicians, physicists, and also periodic assessments should be done. **(5)** -Complete documentation (accurate, complete & signed) of simulation and planning requirements at radiotherapy file (by an assistant lecturer or a senior resident). **(1,3)**
6.Treatment planning	Patient and delivery system collision	-Failure of treatment planning system (TPS) to recognize the effect of patient immobilization and/or fixation devices on collision-free zone. -Lack of communication between radiation oncologist and physicist resulting in poor knowledge of physicist about patient location and positioning on table.	4	24	-For large patients : Check gantry rotation in all angles while patient is on treatment position on D1 treatment in presence of assistant lecturer, physicist, and technician. **(2,3)** -Communication between radiation oncologist, physicist, and engineer prior to treatment delivery**. (2)** -Accurate documentation of patient location and position. **(1)**
7. Plan approval	-Delayed plan approval	-Number of planning units is not consistent with the needs of the department	3	24	-To provide more delineation and planning units. (**4**) -Head of each clinic should follow up the radiotherapy list every week and investigate any delay. (**3**) -Difficult cases to be presented at radiotherapy committee. **(3)**
8. Plan preparation after approval	Wrong total dose, fractionation	- Multiple verbal modifications -Inadequate training of junior physicists on the treatment planning system	4	24	-Completion of formal prescription should be done under the supervision of senior physicists. (**3**) -Regular Training and workshops for physicists. (**5**) -All required modifications should be documented in the patient radiotherapy file and clearly instructed to a senior physicist. **(1,2)**

8. Plan preparation after approval	Unaccepted plan sent to treatment machine	-Unaccepted plans not deleted on time	4	24	-Accurate documentation (complete ,timely &signed) &unaccepted plans should be deleted on time. (**1,7**)
9.Treatment delivery	Incorrect patient in the room	- Poor communication between technician and patient - Poorly trained technician	4	24	-Patient identification by 3 methods (Full name as documented in ID card, ID number, Birthdate). **(1)**
9. Treatment delivery	-Daily QM not done	-Inadequate number of radiotherapy technician -Workload	3	27	-Increase the number of radiotherapy technicians or decrease the number of patients according to machine specifications**. (6)**
9.Treatment delivery	Interrupted radiotherapy treatment course	-Frequent Linear Accelerator (LINAC) hardware failures -Delayed hardware maintenance -Unavailability of spare parts - Frequent electrical shut down -Load on machine -Lack of regular server maintenance	3.5	26.2	-Regular preventive maintenance. **(8)** - Funds should be allocated for the purchase of an adequate supply of spare parts to be maintained on-site. **(5)** -Decrease the number of patients on treatment machine according to machine specifications. **(6)** -Enhancement of electricity system according to machine requirements. (**8**) -Regular server maintenance by qualified maintenance engineers and IT specialists**. (8)**
9.Treatment delivery	- Lack of appropriate safety measures for public protection, emergency preparedness and response, and investigating accidental medical exposures	-Lack of financial resources -No available responsible committee formed of qualified personnel -Radiotherapy personnel do not know all the local emergency procedures and the location of all emergency switches	4	24	-Responsible committee for emergency preparedness & investigating accidental medical exposure. **(7)** -Public protection measures. **(7)** -Measures to reduce the possibility of accidents (e,g. warning signals). **(4)**
9. Treatment delivery	-Missed weekly clinical evaluation	-No available qualified nurse -Miscommunication between resident and patient	4	24	-Responsible resident should be available to follow up patients. **(3)** -Qualified nurse should be available on treatment machine. **(3)**
9.Treatment delivery	-Inaccurate patient Position	-Lack of technician experience and training -Incomplete documentation of patient position and immobilization devices used	3	16	-Regular training and evaluation of technicians. (**5**) -Accurate documentation (complete ,timely & signed)of patient position and

					immobilization devices by technician at radiotherapy sheet and electronic System. (**1**)
9.Treatment delivery	-EPID not done on time	-Workload -Lack of time -Hardware failure	3	26.2	-Weekly revision of radiotherapy sheet should be done by a resident. **(3)** -Responsible resident should be available to follow up patients. **(3)**
9.Treatment delivery	-Inaccurate positional verification	-Unavailability of Cone beam CT (CBCT).	3	31.5	**-**Available CBCT. **(4)**
10. Post treatment completion	missed or delayed patient visit to clinic after finishing radiotherapy	-Miscommunication between resident and patient	3	27	-Resident should clearly inform the patient about follow up plan and imaging required after finishing treatment. **(3)**
10.Post treatment completion	-Inaccurate final check of radiotherapy sheet by a junior resident or Physicist (e.g. missed 2nd phase of treatment)	-Workload -Poor design of radiotherapy file -incomplete documentation of treatment parameters	4	24	-Better design of radiotherapy sheet. (1) -Complete documentation of treatment parameters by a senior resident or assistant lecturer before treatment Planning. (1,3) -Whole treatment plan should be approved by oncology staff before the start of treatmen.t (3) -Whole treatment plan should be explained to patient before starting radiotherapy by an assistant lecturer or resident. (3)

Key for numbers mentioned at the preventive measures column as mentioned at the affinity diagram for the suggested preventive measures:

(1) Accurate documentation(Accurate, complete, timely)
(2) Appropriate communication (Interdisciplinary, Intradisciplinary, Horizontal & vertical)
(3) Adequate task allocation (according to job description)
(4) Financial support (for accessories, new techniques, machines & spare parts)
(5) Regular training, workshops & assessment (at least twice/year)
(6) Adequate number of radiotherapy personnel relative to the number of patients
(7) Adequate procedure or policy
(8) Regular maintenance (not only on demand)
(9) Standardized institutional guidelines (updated yearly).

Discussion:-

Risk management refers to all the different organizational structures and processes that are designed to improve safety and prevent or reduce risks, or that decrease the consequences of risks (i.e., all risk preventive measures). Risk management is part of the overall quality management program. As such, appropriate education and training of staff are required and are closely related to important quality assurance tools, such as quality control and audits. **(Malicki et al.,2015).**

Although three-dimensional radiotherapy is the main method of radiation therapy for most tumors used in low, middle, and high-income countries, no available published FMEA to assess risks in 3-D radiotherapy. FMEA is an effective proactive tool of risk management. The validity of FMEA in the identification of risk in the radiation oncology process has been proven by many studies. Radiotherapy process mapping and FMEA will have more important roles in the optimization of clinical processes to achieve maximum safety and quality of patient care. For these reasons, we chose FMEA to be applied in three-dimensional radiotherapy at our department and consequently recommended risk management strategies ***(Ford et al., 2009)(Wexler et al., 2017).***

Three Delphi rounds were held in the form of semi-structured interviews with participants using 6 forms of questionnaires specific for each group of radiotherapy involved personnel. It was clear to participants that we were not analyzing previous radiotherapy incidents but their anticipation of potential failure modes that may occur at our department in order to proactively recommend risk reduction measures. This encouraged participants to identify potential failure modes at different steps of the radiotherapy process according to their experience.

This started by creating a high-level flow chart for the 3-D radiotherapy process then a detailed process map. After that, a total of 20 qualified radiotherapy personnel were chosen for structured interviews and participated in 3 Delphi rounds. Failure modes were ranked according to the RPNs to allow prioritization of the failure modes and to focus on the failure modes with RPN values equal to or more than 24. Failure modes with severity scores equal to or more than 3 were also considered.

The failure modes with the highest RPN (31.5) were attributed to inadequate interpretation of the target & normal tissue, Inaccurate patient assessment, and Inaccurate positional verification. These failure modes can have catastrophic effects on the patient. The most probable causes of these failure modes were suggested as incomplete documentation, lack of appropriate interdisciplinary communication, human error, lack of financial support, and inadequate procedure used.

Fifty-eight failure causes were suggested for the 32 top failure modes. Twenty-nine (50 %) of failure causes were due to communication, documentation, or human errors. This is consistent with other studies of patient safety in Intensity-Modulated Radiation Therapy (IMRT). Task Group 100 has chosen IMRT for applying risk analysis methods including FMEA and application of risk mitigation strategies to identify more effective and efficient ways to make IMRT safer and more efficient. The task group found that human factors were the most commonly cited causes of the highest risk failures. The highest-ranked failure mode according to TG 100 was " Incorrect interpretation of tumor or normal tissue", in our study, this failure mode is one of the first 10 highest ranked failure modes with an RPN score of 31.5 ***(Huq et al., 2016).***

In one study, FMEA was applied in a paperless radiotherapy department to proactively assess the risks in the radiotherapy electronic treatment processes and suggest preventive measures for the most significant risks. According to that study, seven of the top twenty failure modes had causes related to communication errors. Documentation errors were also found to be the major source of error. In our study, 10 causes of the top 32 failure modes were attributed to lack of appropriate communication, and another 10 causes were related to documentation errors ***(Frewen et al., 2018).***

Although the Electronic Healthcare Record system has recently been applied at our department, still paper documentation is used. A suggested preventive measure was to adequately design an electronic concurrent radiotherapy waiting list to facilitate coordination between oncology and chemotherapy clinics at our department. In the previous study of FMEA applied in a paperless radiotherapy department, Electronic checklists facilitated interdisciplinary communication ***(Frewen et al., 2018).***

Sixty-three preventive measures and checkpoints were suggested by participants. These risk reduction strategies included 9 key core measures. These components include accurate documentation, appropriate communication (including interdisciplinary, intradisciplinary, horizontal & vertical communication), adequate task allocation, financial support (for new accessories, facilities & techniques), regular training & workshops for radiotherapy personnel(at least twice /year), adequate number of qualified radiotherapy personnel, adequate procedure /policy, regular preventive maintenance (not only on demand) and standardized institutional guidelines (should be updated yearly). These measures are consistent with the previous studies conducted in IMRT by TG 100 and in a paperless radiotherapy department ***(Huq et al., 2016),(Frewen et al., 2018).***

Workload and lack of enough qualified radiotherapy personnel (relative to the number of patients) were major sources of the highest-ranked suggested failure modes. In our department, the number of radiation personnel surpasses personnel requirements for clinical radiation therapy except for radiotherapy qualified nurses. This large number of radiation personnel is essential as the department contracted to get a new linear accelerator which according to the international guidelines will require the availability of two more radiation technologists for every 25 patients treated daily. Our department is not only specialized in radiation oncology but also medical oncology which facilitates the process of decision making and following-up patients in the same setting.

Nurses at our department are involved in both medical and radiation oncology but we do not have specialized nurses in radiation oncology. We recommend the availability of two radiotherapy specialized nurses. Regular training, workshops, and assessment should be done for nurses and technicians.

Appropriate task allocation for assistant lecturers, residents, technicians, and nurses(according to job description) is recommended to make the best benefit of the large number of radiation personnel. Personnel requirements For Clinical Radiation Therapy were shown in **table (5) (IAEA, 2008).**

Table (5):- Personnel Requirements For Clinical Radiation Therapy (IAEA, 2008).

Category	Staffing
Radiation oncologist-in-chief	One per programme
Staff radiation oncologist	One additional for each 200–250 patients treated annually. No more than 25–30 patients under treatment by a single physician at any one time. Higher numbers of predominantly palliative patients can be managed
Radiation physicist	One per centre for up to 400 patients annually. Additional in ratio of 1 per 400 patients treated annually.
Treatment planning staff: ▪ physics Assistant	One per 300 patients treated annually
Radiation therapy technologist: (RTT) ▪ Supervisor ▪ RTT ▪ RTT-Sim ▪ RTT-Br	One per centre Two per megavoltage unit up to 25 patients treated daily; four per megavoltage unit up to 50 patients treated daily Two for every 500 patients simulated annually As needed
Nurse	One per centre for up to 300 patients treated annually and an additional one per 300 patients treated annually
Social worker	As needed to provide service
Dietician	As needed to provide service
Physiotherapist	As needed to provide service
Maintenance engineer or electronics technician	One per two megavoltage units or one megavoltage unit and a simulator if equipment serviced 'in-house

Risk analysis was done again after anticipating the application of these risk reduction strategies. According to participants, RPN scores will decrease if these risk mitigation strategies are applied mostly due to the decrease of occurrence and detectability scores. In order to accurately test the effectiveness of these risk mitigation strategies, FMEA should be repeated after the application of these preventive measures. Risk reduction three years after implementing mitigation strategies was reported ***(Kapur et al. 2013).***

An affinity diagram for the suggested risk reduction strategies in relation to failure modes to be mitigated was constructed. Finally, the suggested process map was created.

Conclusion:-

Application of FMEA in 3-D radiotherapy was proved to be an effective proactive approach for risk assessment. This was elaborated by the identification of potential failure modes, focusing on the top-ranked ones and also suggesting risk reduction measures.

Future directions:

Implementation of the suggested risk mitigation strategies at our department and to repeat FMEA after application of these preventive measures

Limitations of this study:

FMEA was done only to recommend risk mitigation strategies. Implementation of these strategies followed by FMEA was not done.

Funding:

This study was self-funded.

Conflict of interest:
Authors declared no conflict of interest.

Authors contribution:
All authors contributed to the study.

Ethical considerations:
The study started after approval was obtained from the Research Ethics Committee at the Faculty of Medicine at Ain-Shams University (FWA 000017858)

Abbreviations
The following abbreviations have been used in the text and are collected here for easy reference:

3-D	Three-dimensional radiotherapy
D	lack of detectability
DRR	Digitally reconstructed radiograph.
DVH:	Dose Volume Histogram
EPID	Electronic Portal Imaging Device
FMEA	Failure Modes and Effects Analysis
HFMEA	Healthcare Failure Modes and Effects Analysis
O	Occurrence
RPN	Risk Priority Number
RT	Radiation Technician.
RTT	Radiation therapy technologist
S	severity
TG100	Task group 100
TPS	Treatment Planning System

References:-

1. ASQ 2021,*Process flow diagrams and maps*,>https://asq.org/quality-resources/flowchart<.
2. Ford, E.C., Gaudette, R., Myers, L., Vanderver, B., Engineer, L., Zellars, R., Song, D.Y., Wong, J. and DeWeese, T.L., 2009. Evaluation of safety in a radiation oncology setting using failure mode and effects analysis.International Journal of Radiation Oncology* Biology* Physics, 74(3), pp.852-858.
3. Frewen, H., Brown, E., Jenkins, M. and O'Donovan, A., 2018.Failure mode and effects analysis in a paperless radiotherapy department. *Journal of medical imaging and radiation oncology*, *62*(5), pp.707-715.
4. Huq MS, Fraass BA, Dunscombe PB et al. The report of Task Group 100 of the AAPM: application of risk analysis methods to radiation therapy quality management. Med Phys 2016; 43: 4209–62.
5. Huq, M.S., Fraass, B.A., Dunscombe, P.B., Gibbons Jr, J.P., Ibbott, G.S., Mundt, A.J., Mutic, S., Palta, J.R., Rath, F., Thomadsen, B.R. and Williamson, J.F., 2016. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. *Medical physics*, *43*(7), pp.4209-4262.
6. Huq, M.S., Fraass, B.A., Dunscombe, P.B., Gibbons Jr, J.P., Ibbott, G.S., Mundt, A.J., Mutic, S., Palta, J.R., Rath, F., Thomadsen, B.R. and Williamson, J.F., 2016. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Medical physics, 43(7), pp.4209-4262.
7. International Atomic Energy Agency, 2008. Setting up a radiotherapy programme: clinical, medical physics, radiation protection and safety aspects. Internat.Atomic Energy Agency.
8. International Atomic Energy Agency, IAEA Specific Safety Guide (No. SSG-46): Radiation Protection and Safety in Medical
9. Uses of Ionizing Radiation, IAEA, Vienna (2018).
10. Kapur, A., Zuvic, P., Goode, G., Riehl, C., Joseph, S., Adair, N.,...& Potters, L. (2013). Incident learning and failure-mode-and-effects-analysis guided safety initiatives in radiation medicine. Frontiers in oncology, 3, 305.
11. Malicki, J., Przybylska, K., Jahnen, A., Godet, J.L., Valero, M. and Bulot, M., 2015. Radiation Protection nº181: General guidelines on risk management in external beam radiotherapy. European Commission, Luxembourg.
12. Marks, L.B., Light, K.L., Hubbs, J.L., Georgas, D.L., Jones, E.L., Wright, M.C., Willett, C.G. and Yin, F.F., 2007.The impact of advanced technologies on treatment deviations in radiation treatment delivery. *International Journal of Radiation Oncology* Biology* Physics*, *69*(5), pp.1579-1586.

13. Ringborg, U., Bergqvist, D., Brorsson, B., Cavallin-Ståhl, E., Ceberg, J., Einhorn, N., Frödin, J.E., Järhult, J., Lamnevik, G., Lindholm, C. and Littbrand, B., 2003. The Swedish Council on Technology Assessment in Health Care (SBU) systematic overview of radiotherapy for cancer including a prospective survey of radiotherapy practice in Sweden 2001--summary and conclusions. ActaOncologica, 42(5-6), pp.357-365
14. Skulmoski, G.J., Hartman, F.T. and Krahn, J., 2007. The Delphi method for graduate research. Journal of Information Technology Education: Research, 6(1), pp.1-21.
15. Valentin, J., López, P.O., Andreo, P., Cosset, J.M., Dutreix, A., Landberg, T., Pinillos, L.V., Yin, W., Harding, L.K., Nakamura, H. and Liniecki, J., 2000.Prevention of accidental exposures to patients undergoing radiation therapy.Annals of the ICRP, 30(3).
16. VHA National Center for Patient Safety (NCPS) (2021) 'Healthcare Failure Modes and Affects Analysis (HFMEA) Guidebook', (January). Available at: https://www.patientsafety.va.gov/docs/joe/HFMEA-Guidebook-January2021.pdf.
17. Wexler, A., Gu, B., Goddu, S., Mutic, M., Yaddanapudi, S., Olsen, L., Harry, T., Noel, C., Pawlicki, T., Mutic, S. and Cai, B., 2017. FMEA of manual and automated methods for commissioning a radiotherapy treatment planning system. Medical physics, 44(9), pp.4415-4425.