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Original Article

Evaluating radiotherapy treatment delay using Failure Mode and Effects Analysis (FMEA)

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ABSTRACT

Purpose: This study identified and evaluated the factors that are responsible for delay in the clinical workflow of radiation therapy, starting from the CT simulation (CT-Sim) to the first fraction of treatment delivery using the Failure Mode and Effects Analysis (FMEA) methodology.

Materials and methods: A total of 1106 patient cases were retrospectively analyzed using FMEA methodology. For each failure mode (FM), the following factors were rated and discussed by the group: occurrence (O), severity (S), detectability (D), and methods of improvement or mitigation. In addition, two new factors, namely social effect (SE) and economic effect (EE), were introduced to evaluate the impact of FM on the department or hospital. Risk priority number (RPN) and the product of RPN, SE, and EE (i.e. RPN_{SE-EE}) were calculated for each FM.

Results: Average delay caused by identified FM was 8 days while 76% of the FMs resulted in delay of less than 5 days. The RPN of all the FMs ranged from 4 to 60 with an average value of 18. "Tumor volume, prescription and objective" had the highest average RPN of 23. The majority of FMs with high RPN were identified in "CT-Sim" (RPN: 21.5 ± 11.1; RPN_{SE-EE}: 97.0 ± 46.4) and "treatment planning" (RPN: 20.1 ± 8.1, RPN_{SE-EE}: 152.9 ± 76.5) stages.

Conclusion: The FMEA enabled identification of the factors that caused delay in the pre-treatment process of radiation therapy. "CT-Sim" and "treatment planning" stages had more FMs with high RPN values which have higher priority for future improvement. Two new factors, SE and EE, were introduced and appeared to be valuable in evaluating the impact of FMs on radiation oncology department or hospital in general.

The whole process of radiation therapy for cancer treatment is very complex, which is comprised of various advanced technologies such as medical linear accelerator (linac), imaging system, treatment planning system, etc. Additionally, the process of radiation therapy is time-sensitive and contains many discrete coordinated steps that are susceptible to errors and delays that may compel to postpone the start of the treatment.

Although quality and safety are still the main concerns in radiation therapy, studies have reported that long delay in the start of radiation treatment may decrease the tumor control [1–3]. The relation between treatment delay and local recurrence have been reported for breast cancer patients treated with postoperative radiation therapy [4,5]. Long treatment delay such as 4 to 6 weeks tended to increase the risk of local recurrence at 5 years for head and neck cancer patients [6,7]. For patients receiving palliative radiation treatments, delay in gaining relief from symptoms may have critical effect on the quality of life. The development of the local recurrence is associated with an increased risk of distant metastasis, thus delay in initiating radiation treatment may also increase the risk of distant metastasis [1]. In addition, delays in receiving treatment may compound the distress, anxiety and depression experienced by the patients [3,8,9]. However, in most of the cancer cases, a short delay within a couple of weeks may not be very critical in terms of clinical outcome. For the hospital, delay in treatment initiation will affect resource allocation, efficiency of patient throughput, and the hospital's reputation in the community.

The purpose of Failure Mode and Effects Analysis (FMEA) approach is to create an error-free radiotherapy using a quantitative analysis method to identify potential systemic failures and evaluate the effect. FMEA involves identification of process-based failure modes (FM) and evaluation of their associated risks. FMEA assesses the likelihood of failure modes in each step of a process

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and considers the impact on the final process outcome [10]. Nowadays, there are numerous publications on utilizing FMEA for proactive risk analysis for various workflows of different radiation treatment techniques [11–23]. However, there are not many studies focusing on the pre-treatment phase. López-Tarjuelo et al. reported their FMEA study for intraoperative electron therapy from CT simulation (CT-Sim) to dose delivery [19]. Broggi et al. applied FMEA in pre-treatment phases of Tomotherapy for safety improvement [12]. Cantone et al. applied FMEA in treatment planning stage for proton therapy and stated that the most critical process appeared related to the delineation and correction of artifacts in planning CT data [23]. In this study, FMEA was used to quantify the risks for delays in our radiation therapy process starting from patient scanning at the CT-Sim to the first fraction of radiation treatment. In addition, our professional group introduced two new factors, which were social effect (SE) and economic effect (EF), to further evaluate the impact of FM on the department or hospital.

Methods

We have considered the patients who were eligible for external beam radiation treatment (EBRT) at main campus where 90–100 patients were treated each day. This study was conducted by a professional group consisted of physicists, therapists, dosimetrists, physicians from the radiation oncology department along with relevant administrative personnel. Once the patient was determined for EBRT modality, the course of treatment and corresponding time frame from CT-Sim to initiation of the first fraction of treatment were scheduled based on the department policy (Fig. 1). According to the treatment planning technique, a total of 8–12 working days is assigned for the pre-treatment process starting from CT-Sim to treatment initiation.

During this process, therapists, dosimetrists, physicists and the attending physician who were involved in the treatment would notify the record-keeping dosimetrist whenever there was any delay. Then the dosimetrist would document the details of the delay including the reason, length, and final delayed days in treatment initiation. All the FMs were categorized and rated during the professional group meeting following the American Association of Physicists in Medicine (AAPM) Task Group 100 guidelines [10].

General process: from CT simulation to the first fraction treatment

For a patient receiving EBRT, the general time frame from CT-Sim to the first fraction of treatment is illustrated in Fig. 1. Image fusions (4DCT, PET/CT, or MRI as appropriate were fused to the planning CT) were performed within one day after the CT scan for physicians to contour the targets. Physicians had three days to complete the prescription, dosimetric objectives, contours including the gross target volume (GTV), clinical target volume (CTV), planning target volume (PTV), and adjacent organs at risk (OARs). Required normal structures are generally delineated by the assigned dosimetrist first and then reviewed by the physicians. During the treatment planning process, the time frame varied according to the complexity of the treatment and planning techniques. Scheduled days for 2D, 3D conformal, standard fractionated intensity modulated radiation therapy (IMRT) or volumetric modulated arc therapy (VMAT), and stereotactic body radiation therapy (SBRT) were 1 day, 2 days, 3 days, and 4 days, respectively. It is not uncommon that plans were subjected to modifications due to changes in dose constraints or PTV adjustments. As illustrated in Fig. 1, dose constraint changes were categorized as level 1 modification which allowed one extra day for planning, while PTV change was categorized as level 2 modification which allowed two extra days for planning. Physicians in our department normally started with the constraints that were stricter than those required by national clinical protocols. For some cases, the critical structures were overlapped with target and dosimetrists had to communicate with physicians several times and apply other feasible and clinically acceptable dosimetric constraints for the target and OARs. This cost the dosimetrist longer time to accomplish the plan. When the initial plan was completed, the physician would be notified for the plan review and approval. Once the plan was approved, corresponding physics chart checks and quality assurance (QA) test for the plan should be completed within two days by the physicists. Finally, the first fraction would be started after the plan passed all the checks.

FMEA for treatment delay

Patients treated from October 2014 to December 2015 were retrospectively reviewed. There were 102 out of 1106 patients who had delayed treatment initiation. According to the standard time frame, a preliminary process map was developed by the study group first. Details of each component in the pre-treatment process were discussed and revised during the group meeting. The final process map (Fig. 2) was then presented to all the members for final agreement.

For each occurrence of a delay, the following factors were recorded: failure mode (FM), the probability of occurrence for each possible failure (O), the severity of the effect on the final process outcome resulting from the FM if it is not detected or corrected (S), the probability that the failure will not be detected in time to prevent an event (D), and the method of mitigation [10]. Some failure modes, such as "Re-scan for anatomical changes" or "Biopsy requested before treatment", were related to complex procedures. Higher "D" values were applied to those FMs since they might or might not cause a serious delay and the corresponding delay time was difficult to predict.

The FMEA rating scale proposed by the AAPM TG 100 was applied [10]. The risk priority number (RPN), which is the product of the occurrence, severity, and detectability values, was calculated for each FM (Eq. (1)).

$$\mathrm{RPN} = \mathrm{O} \times \mathrm{S} \times \mathrm{D} \tag{1}$$

Two new evaluation metrics, i.e. the social effects (SE) and economic effects (EE) were introduced and rated based on the feedback from administrative personnel. The SE is the potential degradation of hospital's reputation and the relationship between patients and the radiation oncology department or hospital due to treatment delay caused by specific FM. The EE is the anticipated effect of the delay on department/hospital's revenue. The SE and EE were considered as important factors which potentially govern the allocation of resources to the department as well as long-term sustainability of the department/hospital's mission objectives. Therefore, it is reasonable to incorporate these two factors in the FMEA study for mitigating treatment delay and to have sustainable long-term solutions. Both the SE and EE were rated from 1 to 5 where 1 means negligible or no impact and 5 means severe social or economic impact and they are accounted into the final score of RPN as shown below in Eq. (2).

$$RPN_{SE-EE} = \mathrm{RPN} \times \mathrm{SE} \times \mathrm{EE} \tag{2}$$

All the average RPN values of different processes were expressed in mean ± standard deviation.

Results

The average length of treatment delay caused by identified FMs was 8 days. Among all the FMs, 76% of them resulted in delay of less than 5 days. A total of 25 FMs were identified and the corre-

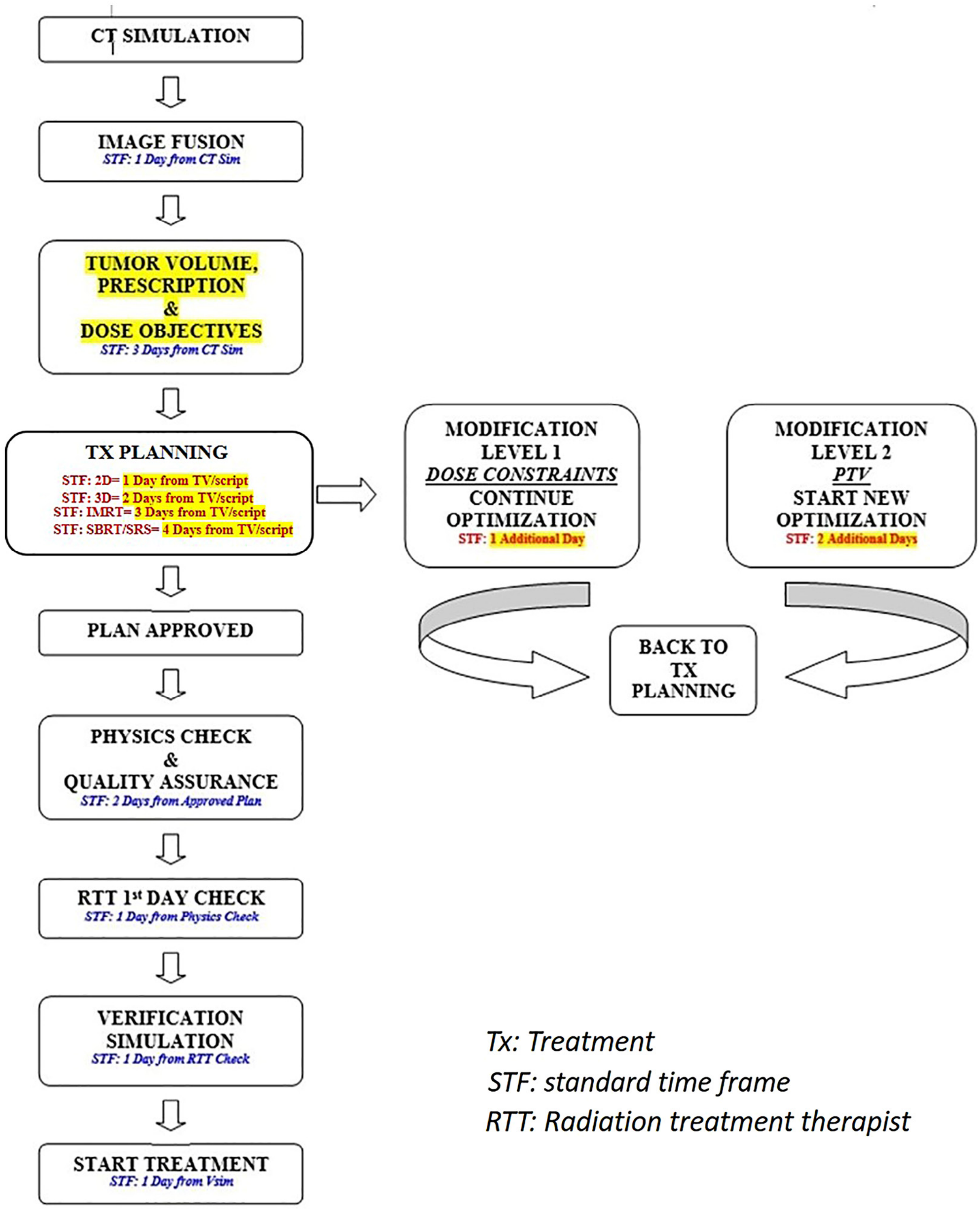

Fig. 1. The treatment planning flowchart in our department. Note that the patient start day failure was recorded in this treatment planning process.

sponding RPN, SE, EE, and $RPN_{SE\text{-}EE}$ values are listed in Table 1. Fig. 3 illustrates treatment initiation delay in days caused by identified FMs.

In this study, RPN of all the FMs ranged from 4 to 60 with an average value of 18. The RPN values of all the FMs was relatively low since the maximum RPN could be up to 1000. The average RPN values for "CT-Sim", "image fusion", "tumor volume and prescription", "treatment planning", and "treatment start" stages were 22, 20, 23, 20, and 12, respectively. The majority of FMs with high RPN were identified in "CT-Sim" (RPN: 21.5 ± 11.1; $RPN_{SE\text{-}EE}$: 97.0 ± 46.4) and "treatment planning" stages (RPN: 20.1 ± 8.1, $RPN_{SE\text{-}EE}$: 152.9 ± 76.5). FMs of high RPN in "CT-sim" stage were mainly caused by re-scanning and those in "treatment planning" stage were due to delay in receiving target volumes or physicians changed their decisions on previous contours because of changes in patient's condition, availability of additional diagnostic information, modification of intended treatment, etc. The FMs with the highest RPN were "re-scan the patient with Active Breathing Coordinator™ (ABC) device (Elekta, Crawley, UK)" (RPN: 40) and "serious delay in providing contours for planning" (RPN: 60). The FMs with high $RPN_{SE\text{-}EE}$ (i.e. $RPN_{SE\text{-}EE}$ larger than 150 in this study) were "re-scan with ABC" ($RPN_{SE\text{-}EE}$: 160), "delay in contouring" ($RPN_{SE\text{-}EE}$: 150–600), "volumes and script dose changed multiple times" ($RPN_{SE\text{-}EE}$: 300), "re-plan for multiple treatment sites" ($RPN_{SE\text{-}EE}$: 180), "re-plan due to new treatment area discovered" ($RPN_{SE\text{-}EE}$: 160), "re-plan with treating volume change and coverage improvement" ($RPN_{SE\text{-}EE}$: 180), "re-plan with ABC device" ($RPN_{SE\text{-}EE}$: 180), and "insurance changes" ($RPN_{SE\text{-}EE}$: 153).

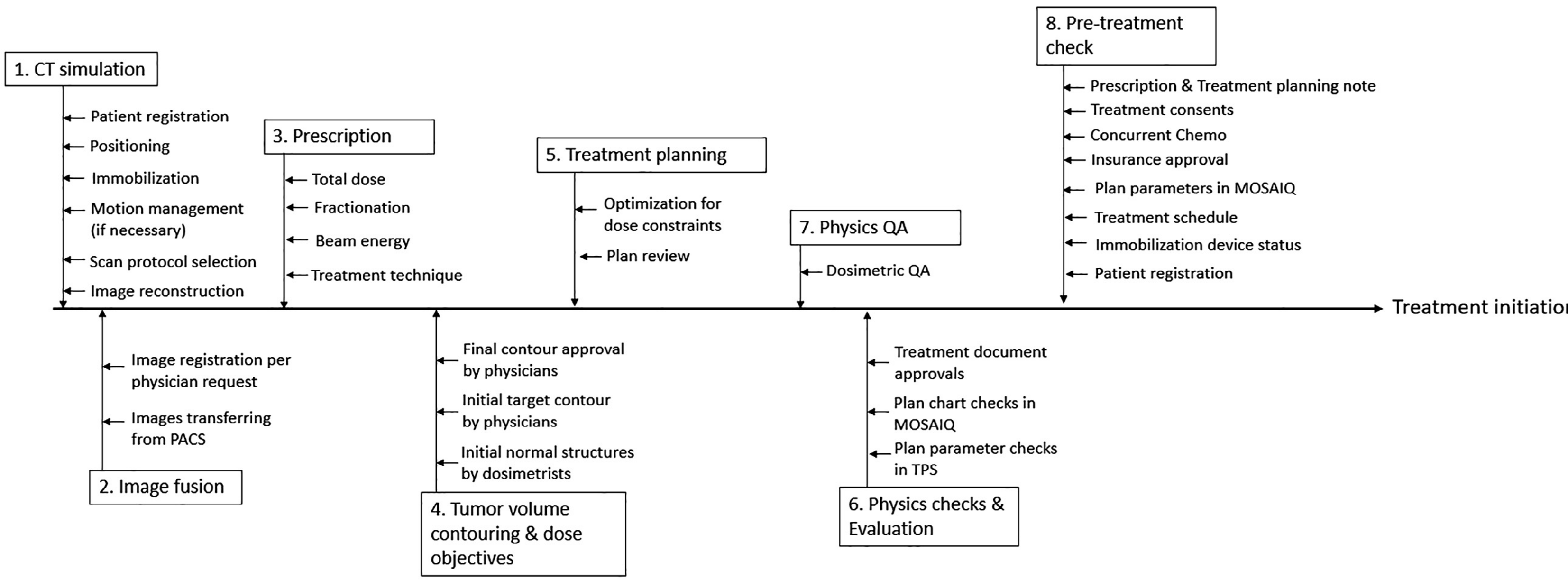

Fig. 2. Process map for pre-treatment phase from CT simulation to first treatment fraction initiation.

Table 1
Summary of failure modes for FMEA analysis.

Potential Failure Modes	O	S	D	RPN	SE	EE	RPN_{SE-EE}
CT scan							
Re-scan for eFOV	4.0	1.5	3.0	18	2.0	3.0	108
Rescan for anatomical changes	4.0	1.5	3.0	18	2.5	2.0	90
Re-scan with ABC	4.0	5.0	2.0	40	2.0	2.0	160
Patient did not show up or cancelation	4.0	2.5	1.0	10	1.5	2.0	30
Image Fusion							
Delay in dose composite for dosimetric evaluation	4.0	2.5	2.0	20	2.5	2.0	100
Tumor Volume, Prescription & Objectives							
Delay in contouring	5.0	2.5–8.0	1.0–1.5	12.5–60*	4.0	2.5	125–600
Waiting for further imaging study	4.0	2.0	1.0	8	2.0	2.0	32
Treatment Planning							
New dose objectives	5.0	1.5	1.0	7.5	2.0	2.5	37.5
Physician needed changes to the final plan	5.0	2.5	1.5	18.8	2.0	2.5	94
Volumes and script dose changed multiple times	5.0	2.5	2.0	25	4.0	3.0	300
Re-plan for multiple treatment sites	5.0	3.0	2.0	30	2.0	3.0	180
Re-plan due to the new treatment area was discovered	5.0	2.0	2.0	20	2.0	4.0	160
Re-plan with TV change and coverage improvement	5.0	3.0	2.0	30	2.0	3.0	180
Re-plan with ABC device	5.0	2.0	1.5	15	4.0	3.0	180
Treatment Start							
Switched to a different Linac	4.0	2.5	2.0	20	2.0	2.5	100
Machine was down	4.0	1.0	1.0	4	2.0	2.0	16
Multiple treatments at different hospitals	4.0	2.5	1.0	10	4.0	3.0	120
Treatment method was changed	5.0	3.0	1.5	22.5	2.0	3.0	135
Biopsy requested before treatment	4.0	1.5	3.0	18	3.0	2.5	135
Patient did not show up or cancelation	3.0	2.0	1.0	6	2.0	3.0	36
Patient went to hospice	4.0	2.0	1.0	8	1.0	5.0	40
Insurance changes	5.0	3.5	1.0	17.5	3.5	2.5	153
Patient was having surgery	4.0	2.0	1.5	12	1.0	2.0	24
Physician decided to put the patient on a break	4.0	2.0	1.0	8	1.0	2.0	16
Concurrent Chemotherapy scheduled for later start date	4.0	1.5	3.0	18	2.0	2.0	72

* RPN value varied with delay days.

Discussion

Failure modes which resulted in delays in treatment initiation that are longer than two weeks may require more attention since the most frequently reported cutoff point for the postoperative radiation therapy after lumpectomy for breast cancer is 8 weeks and the cutoff point for head and neck cancer is 6 weeks [1]. Among all the identified FMs, "volumes and script dose changes", "re-plan with target volume changes and target dose coverage improvement", "insurance change", "patient had surgery", and "break requested by the physician" resulted in delay longer than 10 days (Fig. 3) where surgery and treatment breaks were the delays for patients' benefits based on their medical conditions. The FMs like "break requested by the physician", "patient had surgery", or "patient went to hospice", are not actually real failures of the system but clinical decisions that caused changes in treatment time frame. In the US, due to the exorbitant cost of radiation therapy, patients highly rely on the medical insurance companies. Based on the specific insurance approval, treatment modality for the patient will be financially covered by the insurance company. Sometimes, it will take a long time to have the insurance coverage approved. The "insurance change" resulted in the longest delay (35 days) due to the denial of proposed treatment technique by the insurance company. Therefore, the attending physician had to switch to an alternative treating technique (e.g. switching from an IMRT plan to a three-dimensional conformal plan) and maintain comparable dosimetric results.

The FMs with higher RPN scores are of higher importance to mitigate first. This allowed for the identification of areas in which process improvements were needed with higher priority at the local site level. At CT-Sim stage, "re-scan with ABC device" has both high RPN and RPN_{SE-EE}. The main reason for this FM is free breathing CT scan was initially ordered during CT-Sim, the target position was then substantially affected by the breathing motion and physician decided to apply ABC device. Therefore, the corrective action is to have the concerned physician present when the patient is having CT scan as long as tumor motion evaluation immediately after the scan. In addition, most modern linac systems are equipped with kilovoltage (kV) on board imaging system which enables fluoroscopic study. For patients with lower lobe lung tumors or gastrointestinal tumors that are located around the diaphragm, some physicians would use a fluoroscopic study for diaphragm motion evaluation.

Another FM with high RPN is "delay in providing contours for treatment planning". Our current policy still requires the dosimetrists to send a "patient contours" request to the attending physicians once the CT-Sim is completed. It is to be noted that our physicians normally focus more on the targets (i.e. GTV, CTV and PTV) and some critical structures. The other OARs are firstly contoured by the dosimetrists and then reviewed by physicians. The RPN and SE of this FM tend to increase as the delay time increases. As a result, RPN_{SE-EE} could be as high as 600 when the treatment plan was delayed by 8 weekdays while the patient had little idea about the details of the progress. The corrective actions for this FM can be (1) dosimetrists should send contour requests to the physicians right after CT-Sim with the clear deadline and the whole team including dosimetrists and physicists should keep track of the progress; (2) there should be efficient communication between the dosimetrists and physicians for any update on patient's anatomical or clinical report changes, especially those may postpone the deadline of providing contours; (3) the radiation oncology team should have better communication with the patient on the treatment progress whenever there is any delay; and (4) the supervisors or administrators, such as the department chair, clinical director, or the hospital QA committee, should make clear to the physicians that it is important to maintain a timely workflow.

The treatment planning stage has the most FMs identified with high RPN and RPN_{SE-EE}. "Re-plan for multiple treatment sites" and "Re-plan due to target volume change or further improvement" have higher RPN compared to other FMs in this process while "Volumes and script dose changed multiple times" has the highest

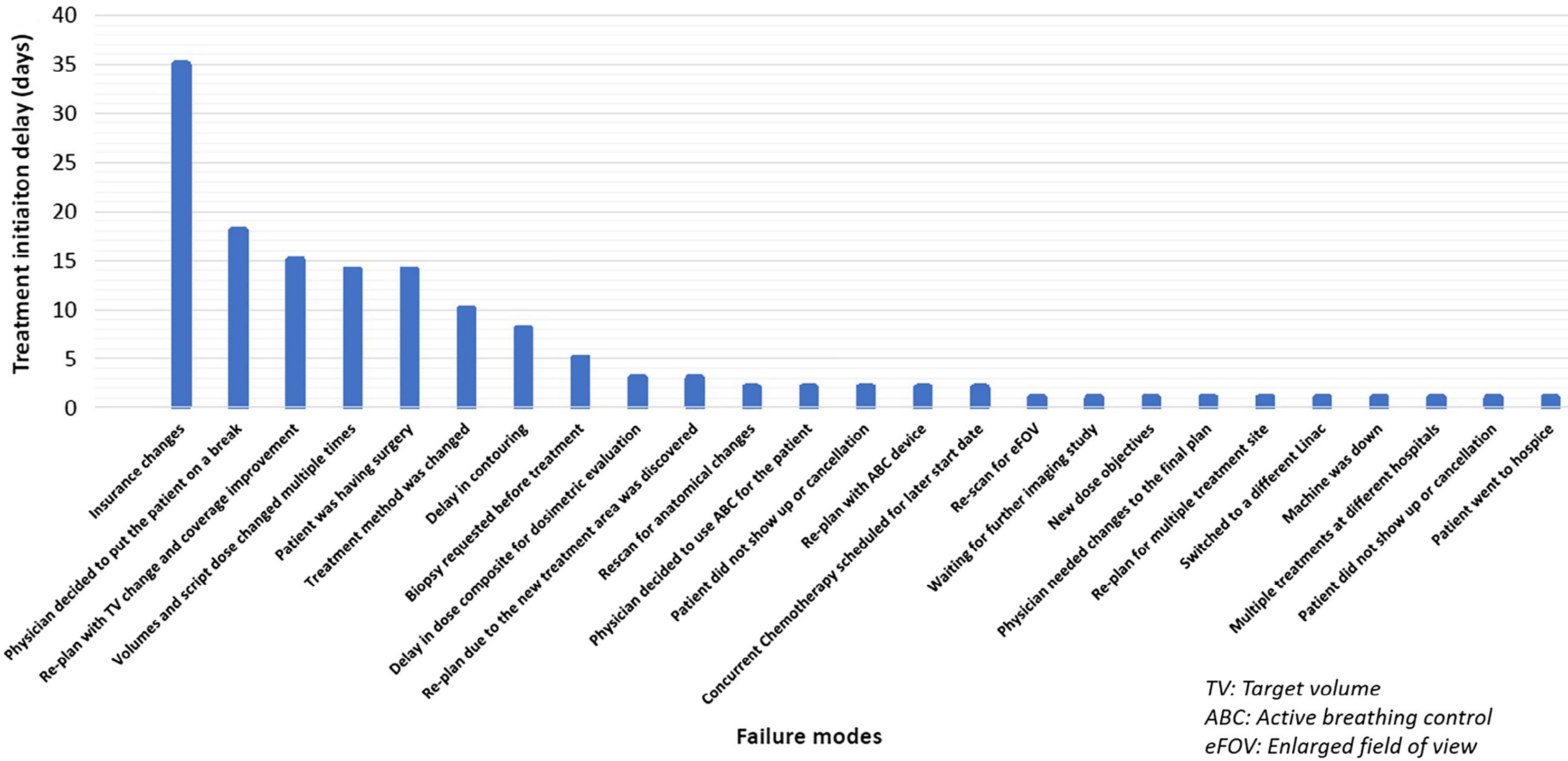

Fig. 3. Treatment initiation delay in days caused by identified failure modes. The insurance change/approval delay was an outlier (around 35 days).

RPN_{SE-EE}. Those FMs are mostly caused by tumor development or target changes based on physicians' clinical concerns on treatment results. This finding agrees with the results from Broggi et al. and Cantone et al. where failures related to contouring and treatment dose prescription had higher RPN scores [12,23]. However, contouring and dose prescription related FMs in their studies mainly affected dose delivery instead of treatment initiation delay since their workflows extended to the delivery process. Suggested actions that are being implemented for mitigating such FMs are: (1) the workflow can be appropriately adjusted by allocating extra planning days for specific modification as illustrated in Fig. 1 (modification level 1 and 2), (2) timely communication between the dosimetrists, physicists and attending physician on the plan including changes in targets, dose objectives, and physics consultations, and (3) the department should have tabulated dosimetric standards for normal tissues and target for different disease sites and clinical protocols. Previously, our physicians would start with very strict dose constraints. If it was impossible to meet all the constraints, they would modify some of the constraints accordingly. Currently, the department has implemented the third action by tabulating dose constraints for different disease sites and clinical protocols in the treatment planning system and adherence to the published or protocol guidelines during planning.

At the treatment start stage, "linac switching" (RPN: 20) and "treatment method change" (RPN: 22.5) have high RPN. Linac malfunction is not uncommon for treatment delay or cancelation. Switching to another functional linac is one of the options. As for "linac switching", this FM is a minor issue for treatment delay after three Elekta linacs at our institution had 6MV, 15MV photon beams and all electron beams matched [24]. Beam matching can not only improve the flexibility of daily treatment scheduling but also mitigate the effect of machine downtime which is another FM identified in treatment start stage. When using RPN_{SE-EE}, the difference between "linac switching" (RPN_{SE-EE}: 100) and "treatment method change" (RPN_{SE-EE}: 138) is larger due to their difference in economic impact. When switching from Tomotherapy to linac, it requires extra time for plan modification or creating a new plan and dosimetric QA. Similar situation exists when switching patients among linacs that are not beam-matched. Again, this highlights the benefits of having beam-matched linacs which enables significant improvement on mitigating the overall effect of those FMs.

The social and economic effects have been incorporated in RPN_{SE-EE} as a new formulation and they are important supplements for evaluating the potential impact of FMs with low RPN. Although the severity of all identified FMs are less than 4 which belong to either "inconvenience" or "suboptimal plan or treatment" categories according to the AAPM TG100 report, some FMs may have further social effect on patients or economic effect on the department/hospital. The FMs such as "re-plan with ABC" (RPN: 15, RPN_{SE-EE}: 180) and "multiple treatments at different hospital" (RPN: 10, RPN_{SE-EE}: 120) have high RPN_{SE-EE} although their RPN are below the overall average (RPN_{ave}: 18). Therefore, such FMs of low severity may still have significant impact on the relationship between the department or hospital and patients as well as financial issues of the hospital, which in turn will potentially affect the resource allocation for the resolution of the failures. "Delay in contouring", "Re-plan with ABC device", "Volumes and script dose changed multiple times", and "Multiple treatments at different hospitals" have relatively high social impact (SE = 4) since they either caused long delay or had patients repeatedly undergo complicated procedures. "Multiple treatments at different hospitals" are mainly due to limited treatment technique options at the satellite hospitals where patients were admitted. Therefore, patients had to be transferred to the main hospital to continue with their treatments. The communication between satellite hospitals and main hospital is not always efficient due to staff shortage or technical problems in networks, servers, or softwares. Without appropriate communication with the patients, treatment initiation delay caused by this FM may have significant impact on hospital's reputation. Our department and hospital are currently taking great effort to improve technical compatibility among hospitals and have more well-trained staff. Then, "Re-plan due to new treatment area was discovered" and "patient went to hospice" have high economic impact on the hospital (EE = 4–5) since the radiation therapy team either had to start the workflow from scratch or had spent significant amount of time on imaging and planning while the treatment could not be initiated.

The potential FMs, together with their causes and effects, can be identified by the professional working group and rated through the FMEA system. For typical FMEA applied in radiation oncology, RPN of specific FM is derived from the ratings provided by the experts from related fields. The study group rates the FMs based on the process map along with their experience in the operating conditions following guidelines from the AAPM TG 100. One major weakness of such methodology is that the assessment of potential risks is mainly based on the work group experts' judgment and knowledge [25]. Although FMEA is capable of producing information on the potential vulnerabilities within the process, and consequently provide appropriate guidance to reduce risk factors in the system, the processes of the FM identification validation are difficult, which may result in failure in predicting actual FM. The incident learning system (ILS) refers to an entire feedback loop of reporting an incident and then analyzing it for salient details and developing interventions to prevent it from happening again [26]. Yang et al. stated that, by integrating FMEA output with retrospective data retrieved from ILS, the institution will have a more complete and less-biased risk overview of risks within the process [27]. Another weakness of this study that may be improved is having more experts from the hospital administration who may provide more accurate and detailed information in analyzing the two new factors (SE and EE).

By applying the FMEA methodology, we are able to identify and evaluate the failure modes in our clinical workflow that caused treatment initiation delay. We have presented a new concept by introducing two new factors, Social Effect (SE) and Economic Effect (SE), in RPN rating for failure modes evaluation. The concurrent consideration of RPN following the AAPM TG 100 guidelines and our proposed new concept of RPN_{SE-EE} may be more effective for FMEA in radiation therapy or healthcare in general.

Disclosure of conflicts of interest

There are no conflicts of interest to declare.

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