



Failure Mode and Effects Analysis for Improving the Risk and the Planning Quality in External Beam Radiotherapy

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【Introduction】

Failure Mode and Effects Analysis (FMEA) described in the TG (task group)-100 report in AAPM (American Association of Physicists in Medicine) is a systematic analysis method applied to improve the workflow, which can be used to detect factors affecting safety and to quantify the risk. Therefore, **the purpose of this study is to assess the risk of the treatment planning process and to identify high-risk failure modes with the FMEA to ensure the planning quality and the patient safety by improving the planning process.**

【Methods】

Retrospective analysis was applied to treatment plans in 2019-2021. A process map of the treatment planning workflow at our department was generated based on the guidelines in TG-100 report. Errors detected during or after the pretreatment physics plan and chart review were identified to failure modes (FMs) in each process step. A risk priority number (RPN=O×S×D) was assigned to each FM by the five physicists based on the tabulated scoring system (**Table1**) for the frequency of occurrence (O), the severity (S), and the detectability (D) of errors, each on a scale of 1 to 10. High RPN scores indicate more critical defect in process. The planning compliance rate (= (the number of plans without errors /the total number of plans) × 100%) was calculated to evaluate the quality of the treatment planning. Some Interventions given to improve the planning compliance rate. The PDCA (Plan-Do-Check-Act) method was used to review the improving process and to evaluate the strategies. After modified process, FMs of high RPN scores (>100) were re-scored.

【Results】

Figure 1 shows the process map of the workflow of treatment planning at our department. **Table 2** and **Figure 2** presents the FMEA results with ten key high-risk failure modes of RPN values more than 100 in the original process and decreased values after the modified process. The compliance rate of treatment planning was raised to 89.1% in 2021 from 78.3% in 2020 after our interventions.

【Conclusion】

The FMEA provided a useful method to assess the risk in the treatment planning process. We could improve the medical quality and enhance the patient safety in radiotherapy by the FMEA results and the planning compliance rate.

【Acknowledgments】

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【References】

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Table1. Descriptions of the ranking system for FMEA.

Rank	Occurrence (O)		Severity (S)		Detectability (D)	
	Qualitative	Frequency (%)	Qualitative	Categorization	Qualitative	Estimated probability of failure going undetected (%)
1	Never	0.01	No effect	No effect	Never undetected	0.01
2	Seldom	0.02	Inconvenience	Inconvenience	Very easy to detect	0.2
3	Sometimes	0.05			Easy to detect	0.5
4		0.1	Minor dosimetric error	Suboptimal plan/delay in treatment		1
5		Often	<0.2	Limited toxicity or tumor underdose	Incorrect dose, dose distribution, location, or volume	Moderately difficult to detect
6	<0.5		5			
7	<1		Recordable event, potentially serious toxicity or tumor underdose	10		
8	<2		Reportable event, possible very serious toxicity or tumor underdose	Extreme error in dose, dose distribution, location, or volume		Very difficult to detect
9	Usually	<5			20	
10	Always	>5	Catastrophic		Impossible to detect	>20

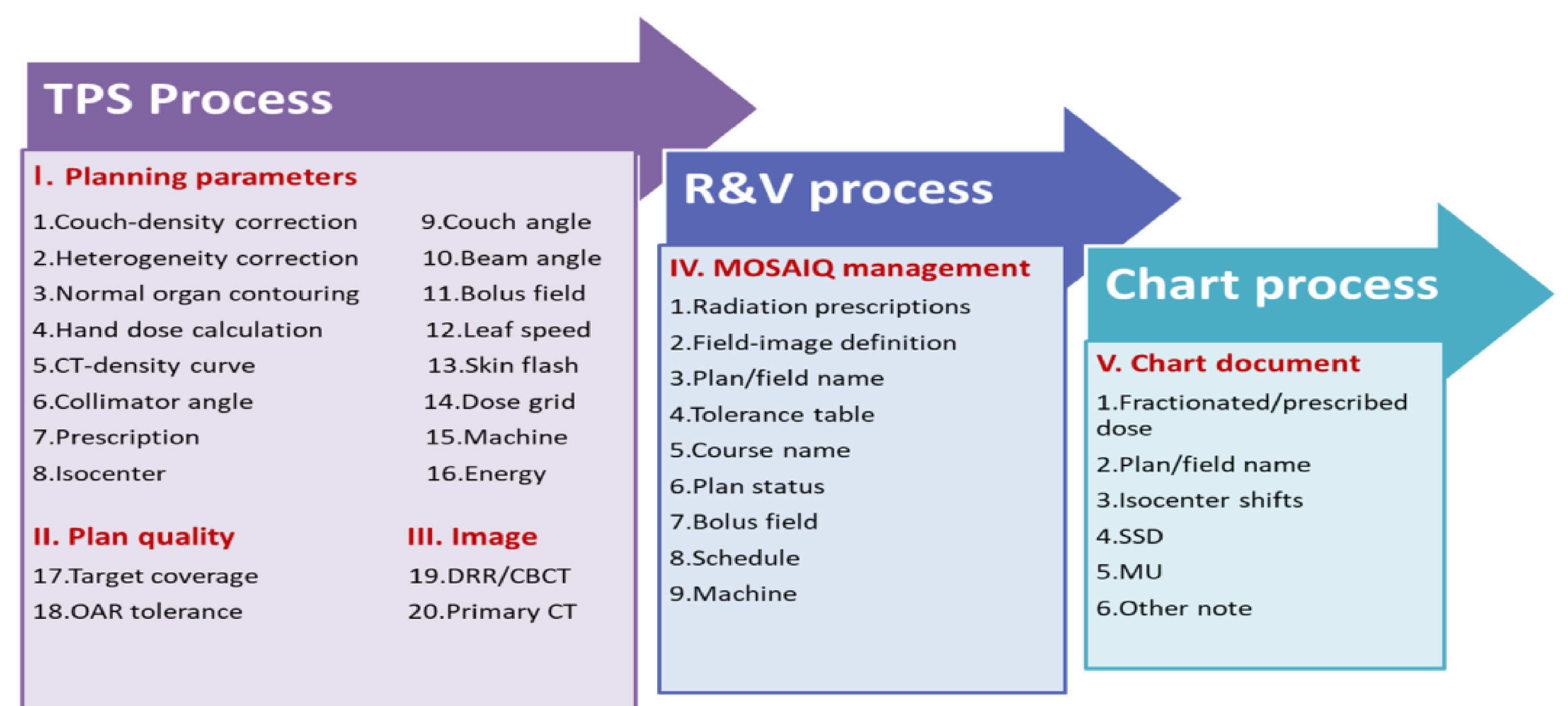


Figure 1. A process map of the treatment planning. TPS, treatment planning system; R&V, record and verify; CT, computed tomography; OAR, organ at risk; MU, monitor unit; DRR, digitally reconstructed radiograph; CBCT, cone-beam computed tomography; SSD, source-to-surface distance.

Table 2. FMEA results for failure modes in original (with RPN >100) and modified process.

Process step	Failure mode	O	O'	S	S'	D	D'	RPN	RPN'	Criticality	Criticality'
Chart document	Isocenter shifts	9.0	1.0	7.6	7.6	2.0	2.0	136.8	15.2	68.4	7.6
	Primary image	4.0	2.0	10.0	9.0	3.2	4.3	128.0	76.5	40.0	18.0
Image	DRR/CBCT image	6.0	2.0	2.4	2.4	8.0	8.0	115.2	38.4	14.4	4.8
	Skin flash	6.0	2.8	7.2	4.8	3.6	3.5	155.5	45.7	43.2	13.1
	Couch-density correction	8.0	2.0	6.8	4.0	2.8	2.8	152.3	22.4	54.4	8.0
	Prescription	5.0	2.8	9.6	8.5	2.8	2.5	134.4	58.4	48.0	23.4
Planning parameters	Bolus field	5.0	3.3	7.6	6.5	3.2	2.8	121.6	58.1	38.0	21.1
	Heterogeneity correction	6.0	3.3	5.2	4.3	3.6	3.3	112.3	44.9	31.2	13.8
	Hand dose calculation	4.0	2.3	10.0	8.3	2.8	2.5	112.0	46.4	40.0	18.6
	CT-density curve	4.0	2.3	8.0	5.8	3.2	2.8	102.4	35.6	32.0	12.9

Abbreviations: FM = failure mode; O = occurrence; S = severity; D = detectability; RPN = risk priority number (S × O × D); Criticality = S × O;

O', S', D', RPN' and Criticality' are values of modified process

DRR = digitally reconstructed radiograph; CBCT = cone-beam computed tomography; CT = computed tomography.

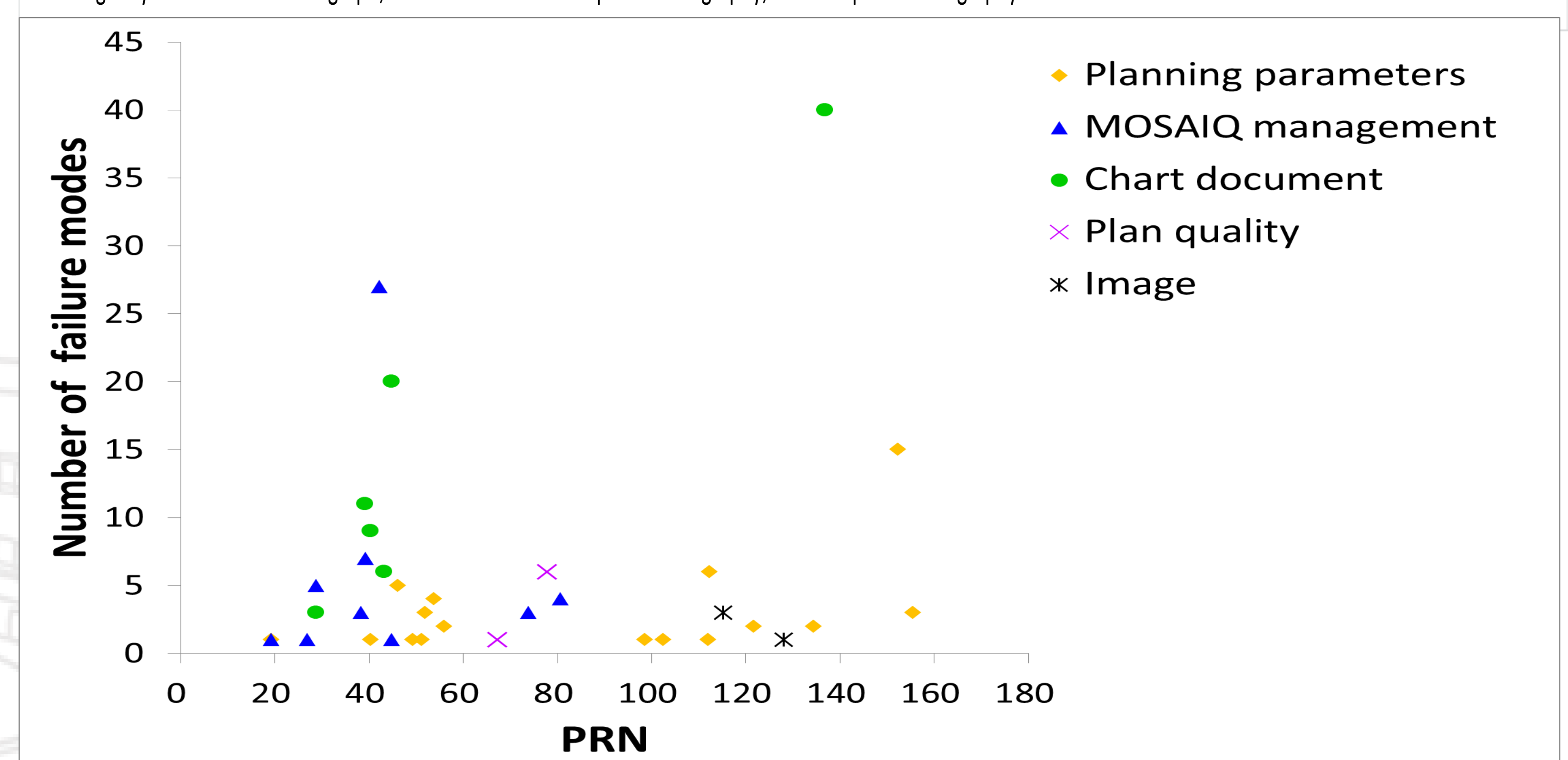


Figure 2. The RPN scores of FMEA results for evaluating the treatment planning process.