



Utilizing Failure Modes and Effects Analysis to Promote Medical Quality and Patient Safety by Improving the Planning Process in Radiotherapy

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1- 【Purpose】

The purpose of this study is to use the failure mode and effects analysis (FMEA) to identify high-risk failure modes of the treatment planning process and to promote the medical quality and patient safety by improving the planning compliance rate in radiotherapy.

2- 【Methods】

Retrospective analysis was applied to treatment plans in 2020-2022. A process map (Figure 1) of the treatment planning including a major process tree and subprocess steps was generated based on the guidelines in TG-100 report published by the AAPM. 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 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. Based on the FMEA results, changes were made to the treatment planning workflow to reduce associated risk. Some Interventions were given to improve the planning compliance. 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. The threshold of the compliance rate is set to 90% to check if the interventions were effective. The PDCA (Plan-Do-Check-Act) method was used to review the improving process and to evaluate the strategies.

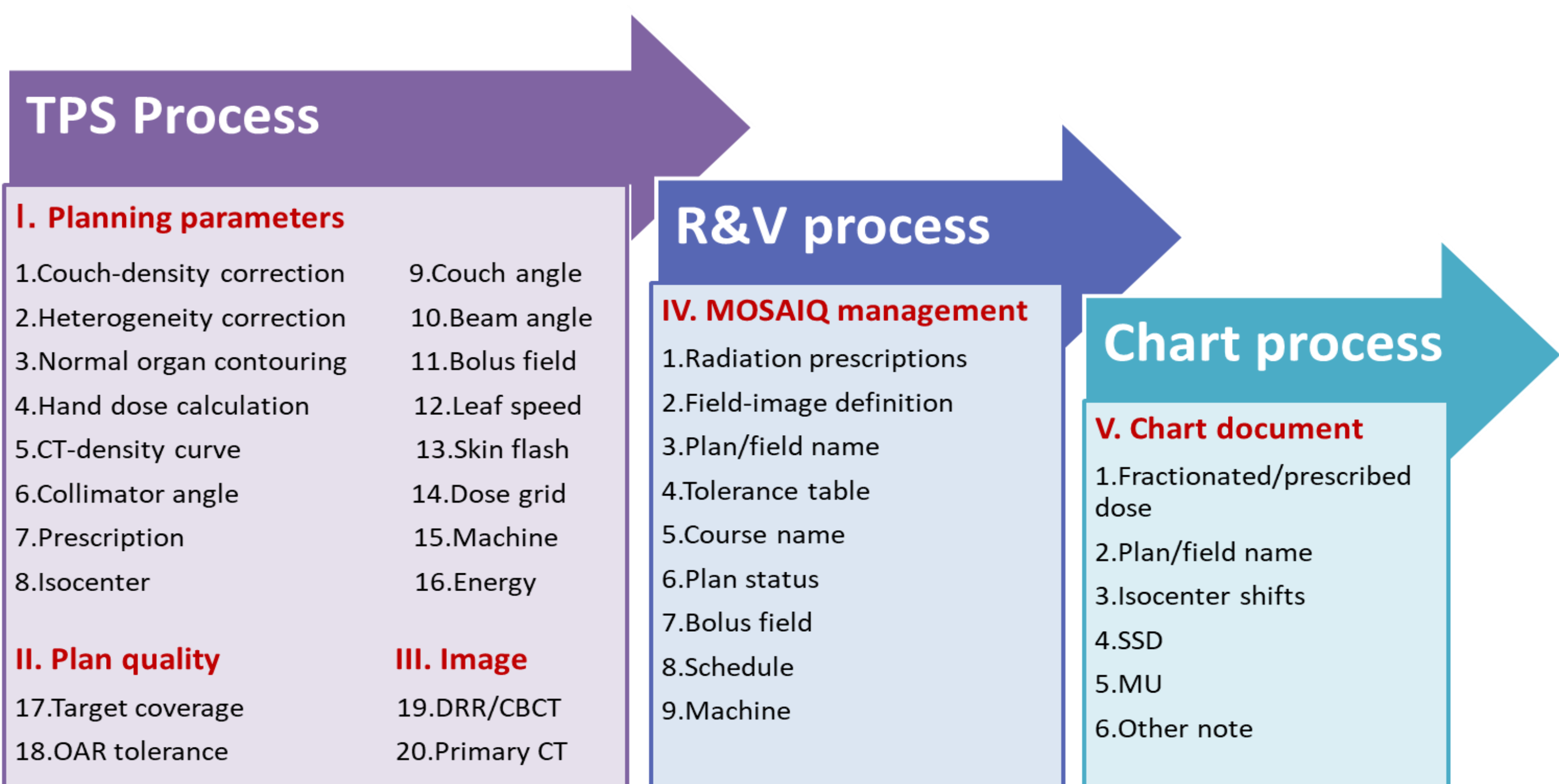


Figure 1. A process map of the treatment planning. TPS, treatment planning system; R&V, record and verify; CT, computed tomography; OAR, organ at risk; MU, monitor unit; DRR, digitally reconstructed radiograph; CBCT, cone-beam computed tomography; SSD, source-to-surface distance.

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		<0.2	Limited toxicity or tumor underdose	Incorrect dose, dose distribution, location, or volume	Moderately difficult to detect	2
6	Often	<0.5				5
7		<1	Recordable event, potentially serious toxicity or tumor underdose		10	
8	Usually	<2	Very difficult to detect		15	
9		<5		Reportable event, possible very serious toxicity or tumor underdose	20	
10		Always	>5	Catastrophic	Impossible to detect	>20

3- 【Results】

Ten key high-risk failure modes with RPN scores >100 were found from the FMEA results as shown in Table 2 and were modified with some interventions. The compliance rate (shown in Figure 2) of treatment planning are increased from 2020 to 2022.

Table 2. The FMEA results of radiotherapy planning process.

Process	Failure mode	O	S	D	RPN
Planning parameters					
	#Couch-density correction	8.0	6.8	2.8	152.3
	#Heterogeneity correction	6.0	5.2	3.6	112.3
	Isocenter	6.0	3.2	2.4	46.1
	Beam angle	6.0	3.2	2.8	53.8
	Energy	6.0	3.6	2.4	51.8
	#Skin flash	6.0	5.0	3.6	108.0
	#Prescription	5.0	9.6	2.8	134.4
	#Bolus field	5.0	7.6	3.2	121.6
	Dose grid	5.0	4.0	2.8	56.0
	#CT-density curve	4.0	8.0	3.2	102.4
	Machine	4.0	2.0	2.4	19.2
	Collimator angle	4.0	4.4	2.8	49.3
	Leaf speed	4.0	3.6	2.8	40.3
	Couch angle	4.0	3.2	4.0	51.2
	Normal organ countoring	4.0	5.6	4.4	98.6
	#Hand dose caculation	4.0	10.0	2.8	112.0
MOSAIQ management					
	Field-image definition	8.0	2.2	2.4	42.2
	Schedule	6.0	2.0	2.4	28.8
	Machine	4.0	2.4	2.8	26.9
	Plan status	6.0	2.0	3.2	38.4
	Plan/field name	7.0	2.0	2.8	39.2
	Radiation prescriptions	6.0	4.2	3.2	80.6
	Bolus field	6.0	4.4	2.8	73.9
	Course name	4.0	2.0	2.4	19.2
	Tolerance table	4.0	2.8	4.0	44.8
Chart document					
	#Isocenter shifts	9.0	7.6	2.0	136.8
	MU	8.0	2.0	2.8	44.8
	SSD	7.0	2.8	2.0	39.2
	Fractionated dose	7.0	2.4	2.4	40.32
	Plan/field name	6.0	2.0	3.6	43.2
	Other note	6.0	2.0	2.4	28.8
Plan quality					
	Target coverage	6.0	5.4	2.4	77.8
	OAR tolerance	4.0	7.0	2.4	67.2
Image					
	#DRR/CBCT image	6.0	3.0	8.0	144.0
	#Primary image	4.0	10.0	3.2	128.0

Abbreviations: O = occurrence; S = severity; D = detectability; RPN = risk priority number (S × O × D);
#Failure mode with RPN >100

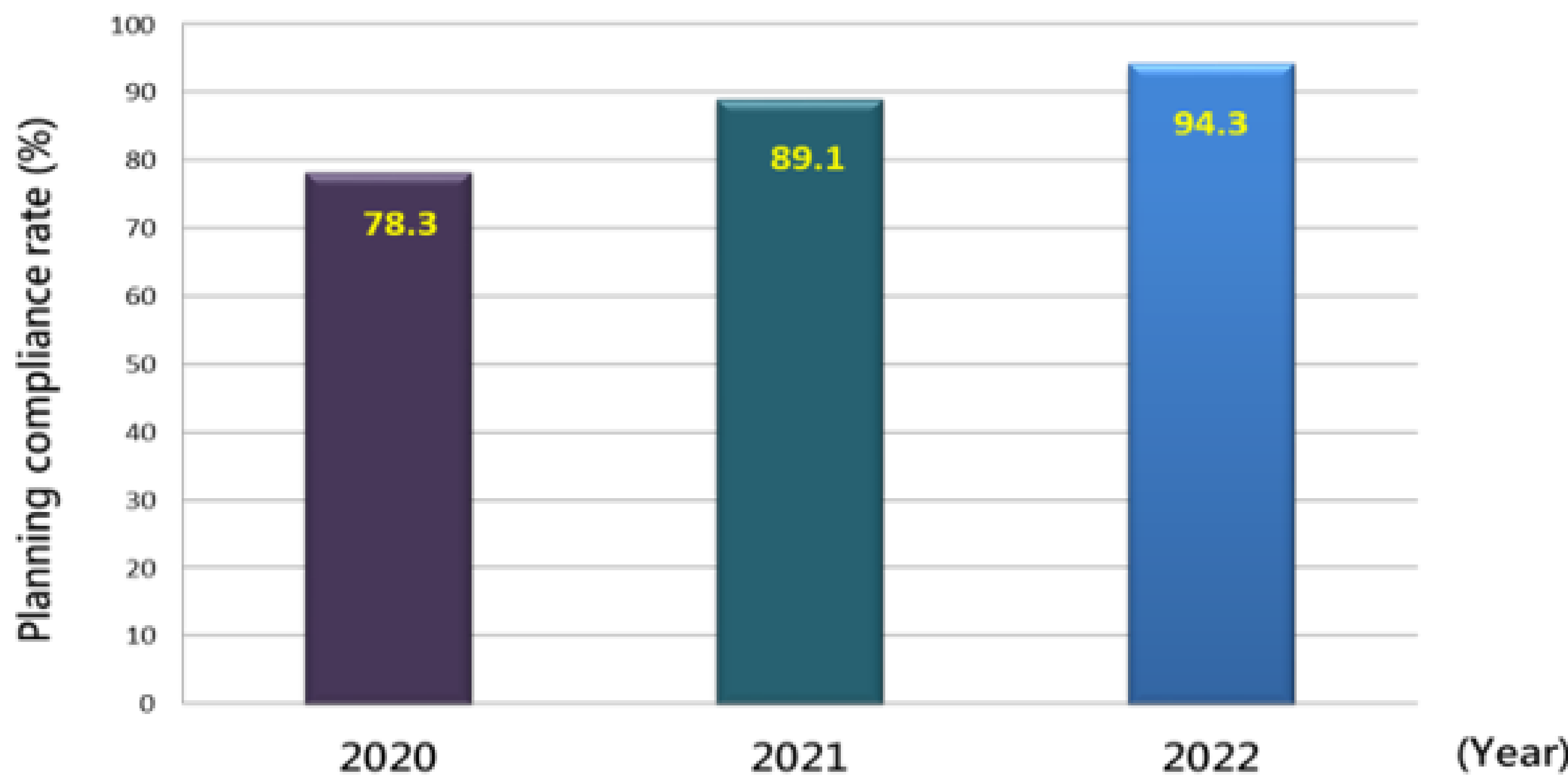


Figure 2. The planning compliance rate before (2020) and after (2021-2022) the improvement of the planning process.

4- 【Conclusions】

The FMEA provided a useful method for evaluating high-risk failure modes in treatment planning process. The FMEA results and the planning compliance rate could help us to improve the quality of treatment planning and to ensure the patient safety in radiotherapy.

【Acknowledgments】

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