FMEA prospective analysis before AlignRT clinical implementation

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AIMS

Before implementing a new device or a new treatment technique, a multidisciplinary working group is set up to carry out a self-assessment of the risks associated. This self-assessment allows to draw up a risk map and to prioritize the actions to implement in order to improve the safety of treatments. Recently, the "surface-guided radiotherapy solution AlignRT" (VISION RT, London, UK) was installed in our radiotherapy department. The aim of this poster is to present the risk analysis and the specific actions that were taken to mitigate the identified risks.

TEAM

The choice of the members of the working group is essential: it must be composed of experienced members and experts in the area analyzed. The group must be multidisciplinary: doctor, physicist, RTT in order to have different points of view or expertise. They must also have decision-making power within the service to initiate the development of corrective measures.
Our team was lead by the RTT quality manager and made up of a doctor, a physicist (who followed the training courses given by VisionRT), the head of RTTs and the RTT TrueBeam referent (who followed the training courses given by VisionRT).

METHODS

The dedicated Failure Mode and Effect Analysis [1] approach is a predictive analysis of the reliability of a system: it identifies the modes of potential failures before they occur. It consists of three steps: 1-identification of the involved subprocesses; 2-identification and ranking of the potential failure modes, together with their causes and effects, using the risk probability number (RPN) scoring system; and 3-identification of additional safety measures to be proposed for process quality and safety improvement. The multidisciplinary working group met regularly and discussed each failure mode until the members afreed on the levels of severity based on their personal experience, taking into account the specific processes in our department.

SCALES

Severity scale

Level	Organisation impact (patient or department management)	Material or environnement or financial impact	Impact on patients safety	Index
Minor	*Negligible effect on the achievement of the mission*			1
	No impact. No waste of time. Immediate alternative solution available.	Minimal	None	
Significant	*Impact on mission performance (partially completed, delayed)*			2
	Mission carried out with degraded solution. Delay in mission> 1 hour	Light	None	
Major	*Impact on mission performance (mission failure)*			3
	Mission partially accomplished. Mission delay <1 day	Important	Possible physical / psychological damage	
Critical	*REVERSIBLE Impact*			4
	Mission not carried out. Mission delay> 1 day	Very important	Reversible physical / psychological damage	
Disastrous	*IRREVERSIBLE impact*			5
	/	Major	Ireversible physical / psychological damage	

The severity, frequency and detectability scales must be defined by the working group before starting the analysis. They have to be adapted to the practices of the department.

Detection scale

Level	Criterion	Index
Impossible	Impossible to detect	5
Very difficult	2/10 detected	2
Difficult	4/10 detected	3
Easy	7/10 detected	2
Very easy	9/10 detected	1

Frequency scale

Level	Criterion	Index
Highly unlikely	Less as one time per year	1
Very unlikely	≥ one time per year	2
Unlikely	≥ one time per month	3
Likely	≥ one time per week	4
Very likely	≥ one time time per day	5

RESULTS

A total of 33 failure modes were identified: 13 in the stage of preparation of the region of interest (ROI) used by AlignRT for tracking the movements of the patients, 11 in the stage of the daily treatment and the rest in stages of quality controls, users training and computing. RPN upper threshold for little concern of risk was set at 9. This threshold was exceeded in 8 cases: 2 in the stage of preparation of the region of interest, 5 in the stage of the daily treatment and 1 about users training. The most critical failures appeared to be related to the creation of the region of interest. Based on these findings, additional solutions have been proposed for completing the safety strategies already adopted in the clinical practice for limiting the risk of these failures, and increasing patient safety.

ANALYSIS TABLE OF FAILURE MODES

Here are four examples from the final failure mode analysis table. They come from four different stages in the process of using the AlignRT system. [a]

N°	Step	Failure mode	Possibles causes	Potential effects	Existing means of detection	S	F	D	FxD	Criticaly index	Risk reduction actions to implement
4	Entire processing chain	Shock to the cameras (technical service or manufacturer intervention, cleaning staff, etc.)	Human factor. Failure to follow instructions.	Perturbation of camera calibration	Daily quality control of cameras	2	1	1	1	2	If in doubt (intervention at the ceiling), repeat the daily QA
8	Surface creation	Wrong anatomical site selection (unsuitable tolerances).	Lack of information. Incorrect data entry. Inattentive operator.	Inadequate treatment.	Manufacturer's booklet.	2	2	3	6	12	Complete the file control and AlignRT procedures.
25	Treatment	Patient goes out of tolerance during treatment.	Patient moved. Different breathing.	Impossible to deliver the treatment.	AlignRT system prevents treatment.	2	3	1	3	6	Define strategy: since the reference surface always follows a Cone-Beam CT, how to act if the patient is out of tolerance during beam-on?
30	Training	Lack of training for professionals.	Lack of time for training. Lack of skills management.	Poor command of software and hardware.	Skills matrix (head of RTTs). Collaboration with Truebeam referent RTT.	3	3	2	6	18	Internal and external trainings.

CONCLUSION

The FMEA is a prospective systematic method for identifying vulnerabilities before the implementation of a new device such AlignRT. The success of this self-assessment depends in particular on the participation of members of the entire radiotherapy multidisciplinary team. In particular, this FMEA identified 33 failures modes mainly in the stage of preparation of the region of interest. Proposals have been made to preventing these problems and enhancing safety in the clinical use of AlignRT.

REFERENCE

[1] Guide de l'ASN n°4: Guide d'auto-évaluation des risques encourus par les patients en radiothérapie externe. 2009. 2008-186

FURTHER INFORMATION

[a] Complete table (in French) is available upon request to the principal author.

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