Towards quality assurance for first AI-driven online adaptive radiotherapy based on Failure Mode and Effect analysis

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INTRODUCTION

Varian Ethos is the first AI-driven CBCT-based radiotherapy system. The system is highly automated and includes novel components;

- software for treatment directives and automated treatment planning;
- ring gantry linear accelerator with AI-driven contouring on iterative CBCT, deformable image registration, automatic creation of plan of the day and software based patient-specific QA; and
- offline treatment monitoring software for tracking volumetric and dosimetric changes during a course of treatment.

AIM

To conduct failure mode and effect analysis (FMEA) of first AI-driven linear accelerator to inform quality assurance measures ensuring safe delivery of AI-driven online adaptive radiotherapy.

METHOD

- Potential failures and their affect were determined at one Institution for a specific workflow and then two other Institutions supplemented.
- Noted whether cause was related to human error, AI/automation or system limitations.
- Each Institution scored failure modes for severity, likelihood and detectability
- A benchmarking table of descriptors from TG100 [1] assisted with consistency of risk scoring.
- The three clinics represented three continents to explore regional differences in safety, staffing and processes.

RESULTS

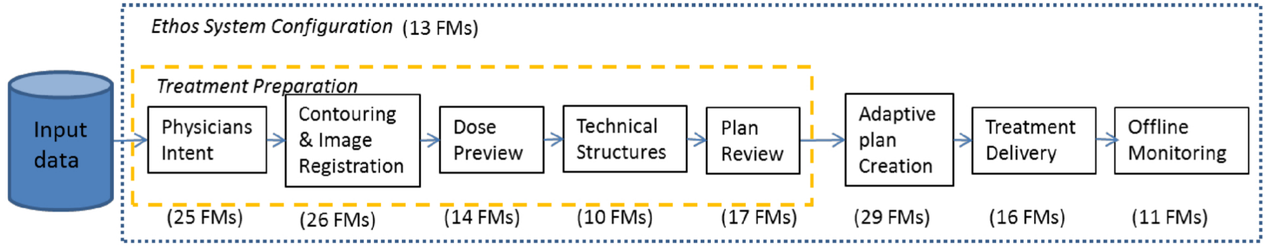

Figure 1. *Workflow for Ethos online adaptive treatment used in this failure Mode and Effect Analysis. Input of patient demographics, planning images, and optional contours and/or deformable image registrations, typically from ARIA or Varian suite (blue can). The number of Failure Modes (FM) identified at each process step is shown in brackets.*

Summary of failure modes at each process step

A total of 161 Failure Modes were identified;

- 13 from System Configuration,
- 89 during treatment preparation,
- 45 during adaptive treatment, and
- 11 during offline monitoring.

FMEA Analysis

Failure modes were classified under human error, automation/AI related or system limitation. Human errors may be mitigated with training and/or checklists.

24 potential FM's (15%) had low detectability (S≥8) and 9/24 had RPN above 150.

Quality assurance is best placed within the adaptive plan creation and offline monitoring where novel automation steps dominate, such as generation of synthetic CT and DIR for dose accumulation, respectively.

Attention should also be given to auto-planning, technical structures, previous treatment and synthetic CT

Tables A, B, C *show number and rank of failure modes across three institutions summarising which process holds the highest risks and need for a quality assurance step.*

(A) Institution 1	Configuration	Treatment Preparation	Adaptive Treatment	Offline Monitoring
#RPN > 150	4	9	4	5
#RPN > 100	7	20	13	7
Top 10 FM	0	2	4	4

(B) Institution 2	Configuration	Treatment Preparation	Adaptive Treatment	Offline Monitoring
#RPN > 150	0	4	1	2
#RPN > 100	0	10	5	5
Top 10 FM	0	6	1	3

(C) Institution 3	Configuration	Treatment Preparation	Adaptive Treatment	Offline Monitoring
#RPN > 150	0	12	8	2
#RPN>100	0	23	14	6
Top 10 FM	0	6	2	2

KEY FINDINGS

1. Online adaptive workflow presented 161 potential failure modes
2. Human error presented majority of potential failures at System configuration (77%) and treatment preparation (57%) stages. Easily mitigated with trained staff and/or checklists.
3. Novel automation steps presented risks in adaptive treatment (16%) and offline monitoring (55%) stage . Detectability low for 24/161 FMs.
4. Risk rating varied across 3 institutions, further analysis ongoing

CONCLUSIONS

The AI driven adaptive system was assessed for risk towards development of a quality assurance program. This gives the international community a platform from which to safely implement the system in their clinic.

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