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A Risk Bias Weighted Approach to FMEA for an Adaptive Radiation Therapy Workflow

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BACKGROUND

Adaptive Radiation Therapy: Varian Ethos

- Ethos developed on Halcyon platform due its high dose rate, rapid gantry rotation, and ability to generate CBCT images quickly
- Tools based on artificial intelligence are used for adaptive planning
- Options available are: On-couch adaptation, off-couch adaptation or no adaptation
- Supports both VMAT and sliding window IMRT delivery
- The clinician decides between delivering original plan and adapted plan at every treatment fraction
- Entire adaptive radiation therapy process can be completed within typical treatment time slot

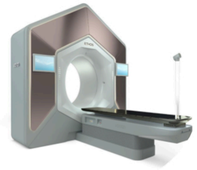

Figure 1: Varian Ethos Platform for Adaptive Radiation Therapy
Image source: https://www.varian.com/products/adaptive-therapy/ethos

Failure Modes and Effects Analysis (FMEA)

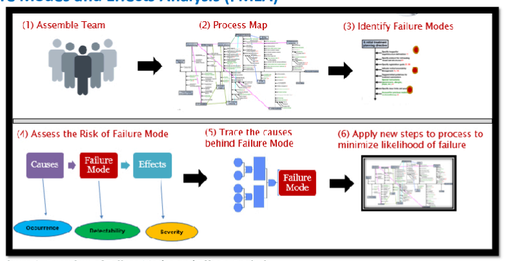

Figure 2: Overview of Failure Modes and Effects Analysis
This diagram illustrates the key steps of FMEA: (1) Assemble an FMEA team, (2) Develop detailed Process Map, (3) Identify failure modes for every step within each sub-branch of the process map, (4) FMEA team members score occurrence, detectability and severity of each failure mode, (5) Fault tree analysis used to trace the causes behind high risk priority failure modes, (6) Mitigation plans and quality management procedures are introduced to minimize likelihood of failure modes in the process

- Conventional FMEA obtains scores for the occurrence, severity and detectability for each failure mode and uses them to calculate a risk priority number (RPN) to evaluate the relative risks.
- Each FMEA team member will inherently have their own level of relevant experience and risk bias when providing evaluation scores. Conventional FMEA approach does not take into consideration the inherent risk and experience bias during the scoring process.

PURPOSE

- Adaptive Radiation Therapy techniques present new challenges when developing effective safety and quality management procedures in the workflow.
- The failure modes (FM) in the workflow of Varian's Ethos Adaptive Radiation Therapy platform have been analyzed by accounting for each FMEA team member's experience and risk bias.

METHODS

Experience and Risk Bias Weighted Formalism

- Suppose there are N individual evaluators in the FMEA team. The final risk priority number (RPN) value for a specific failure mode is calculated using the following equation:

$$RPN = \sum_{i=1}^{N} w_i O_i (v_i S_i) D_i \qquad \text{[Equation 1]}$$

- In the equation, the subscript i denotes the FMEA team member, i, and:
  - w_i denotes the Experience Weighting Factor for FMEA team member i
  - v_i denotes the Risk bias weighting factor for FMEA team member i
  - O_i denotes the Occurrence score given by FMEA team member i
  - S_i denotes the Severity score given by FMEA team member i
  - D_i denotes the Detectability score given by FMEA team member i

Experience Level

- For each failure mode, the FMEA team member's relative experience level (both type and duration) will have an influence on their severity, occurrence and detectability scores.
- To account for experience level, the following experience weighting factor is defined:

$$w_i = \frac{E_i}{\frac{1}{N}\sum_{i=1}^{N} E_i} \qquad \text{[Equation 2]}$$

- E_i is a self evaluated score of the FMEA team member's experience level relevant for that failure mode (see Table 1 for evaluation guidelines).

Risk Bias

- Since the role of the FMEA team member in the radiation oncology department will influence in the perception of severity of a given failure mode, the following weighting factor has been defined to account for this bias:

$$v_i = \frac{P_i}{\frac{1}{N}\sum_{i=1}^{N} P_i} \qquad \text{[Equation 3]}$$

- P_i is a self evaluated score of the FMEA team member's level of clinical responsibility relevant for the failure mode (see Table 1 for evaluation guidelines).

Experience and Risk Bias Scoring guide				
Score:	**1-2**	**3-5**	**6-8**	**9-10**
Experience Level *Two different scales are given depending on which is more applicable*	< 6 months (Task completed few times or less)	6 months – 2 years (Task completed 5-20 times within past few years)	3-6 years (Task completed 20-40 times within past few years)	6 + years (Task completed >40 times within past few years)
Risk Bias Measure	FM almost never involves my clinical responsibilities	FM sometimes involves my clinical responsibilities	FM most of the time involves my clinical responsibilities	FM always involves my clinical responsibilities

Table 1: Experience and Risk Bias Scoring guide
Experience level (E) and Risk Bias (P) are self-evaluated by FMEA team members using the displayed guidelines

Prospective FMEA for Adaptive Radiation Therapy Workflow

- A multi-disciplinary team of professionals with diverse experiences and different clinical roles were assembled for the FMEA study
- The adaptive radiation therapy workflow for Varian Ethos platform was outlined
- Failure modes were identified at each step of the workflow
- Each FMEA team member provided the following data for every FM identified:
  1. Score of Occurrence (O)
  2. Score of Severity (S)
  3. Score of Detectability (D)
  4. Self-assessment of Experience Level (E)
  5. Self-assessment of Risk Bias Level (P)
- Risk priority number was calculated using two methods:
  - A. Conventional RPN : Using only O, S, D
  - B. Weighted RPN : Using O, S, D, E and P (Equations 1 – 3)
- Failure modes were ranked using both the conventional RPN and the weighted RPN to determine relative risk priorities

RESULTS

Adaptive Radiation Therapy Process: Varian Ethos Workflow

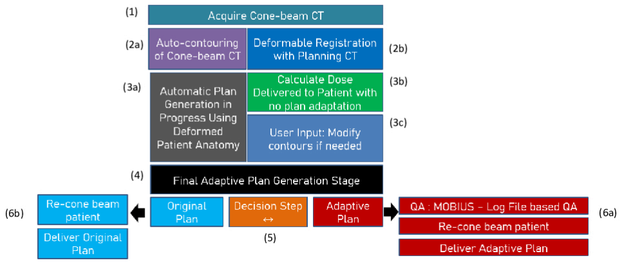

Figure 3: Illustration of the Varian Ethos adaptive radiation therapy workflow
(1) *Acquire Cone-beam CT after patient has been set up on treatment unit,* ***(2a)*** *Auto-contouring process of cone-beam CT begins,* ***(2b)*** *Auto-contoured cone-beam CT is used to perform a deformable registration with the original planning CT,* ***(3a)*** *Automatic adaptive plan generation process begins using the deformed patient anatomy,* ***(3b)*** *Dose delivered to patient for original non-adaptive plan is calculated on the deformed registered image,* ***(3c)*** *Contours from the auto-contouring process can be modified if needed,* ***(4)*** *Final adaptive plan is generated,* ***(5)*** *Decision step: Physician decides between delivering adaptive plan (from step 4) and the original plan (for which dose was calculated in step 3b),* ***(6a)*** *If adaptive plan is chosen, patient specific QA is preformed using MOBIUS, after which an additional cone-beam CT is acquired prior to treatment delivery,* ***(6b)*** *If original plan is chosen, an additional cone-beam CT is acquired before delivery of original plan*

Identification of Failure Modes

Acquire Cone-Beam CT
Incorrect patient set up prior to CT (FM1)
Cone-Beam CT artifact (FM2)
Image detector failure (FM3)
Cone-beam CT calibration error (FM4)
Incorrect CBCT Acquisition Mode (FM5)
Incorrect CBCT Reconstruction Mode (FM6)
Auto-contouring of Cone-Beam CT
Incorrect auto-contour generated (FM7)
Change in patient anatomy from sim causes poor auto contour (FM8)
Deformable Registration with Planning CT
Incorrect registration (FM9)
Change in patient anatomy from sim causes poor registration (FM10)
Calculate Dose Delivered to Patient with no Plan Adaptation
Dose calculation error (FM11)
Optional Manual Modifications to Contours
User accidently makes wrong modification (FM12)
User confuses boundary between structures (FM13)
Final Adaptive Plan Generation
Generated plan not deliverable (FM14)
Adaptive plan generated using incorrect CT (FM15)
Optimizer used incorrect constraints/goals (FM16)
AI algorithm used inappropriate training data (FM17)
Decision between Adaptive Plan and Original Plan
Incorrect clinical decision criteria used (FM18)
Incorrect decision is made (FM19)
Change in patient anatomy during adaptive planning process not detected in final CBCT (FM20)
MOBIUS – Log File based QA
QA passes/fails due to incorrect tolerance# (FM21)
Log files did not record actual delivery error (FM22)

Table 2: Failure modes identified at each Step of the Ethos adaptive radiation therapy process

RESULTS AND DISCUSSION

FMEA Results: Risk Priority Numbers

- Conventional RPN values ranged from 15 – 743
- Weighted RPN values ranged from 32.7 – 1412.7
- Differences were found between risk bias weighted RPN and conventional RPN when examining the relative ranks of the risk priorities (as shown in Table 3).

Rank	Conventional RPN	Risk Bias and Experience Weighted RPN
1	FM7	FM7
2	FM8	FM13
3	FM9	FM8
4	FM10	FM9
5	FM12	FM10
6	FM13	FM12
7	FM19	FM2
8	FM18	FM3
9	FM20	FM1
10	FM2	FM17
11	FM3	FM18
12	FM1	FM19
13	FM17	FM20
14	FM11	FM6
15	FM6	FM16
16	FM5	FM5
17	FM16	FM11
18	FM22	FM15
19	FM15	FM22
20	FM21	FM3
21	FM3	FM21
22	FM14	FM14

Table 3: Relative Risk Priority Ranks of Failure Modes *Failure modes FM1 to FM22 (see Table 2) ranked using conventional RPN approach and risk bias weighted RPN*

Future work: Ongoing FMEA Study

- Improve FMEA data collection approach
- Conduct deeper analysis of key differences between conventional RPN and risk bias weighted RPN approach
- Develop mitigations plans for selected failure modes in preparation for a clinical implementation of adaptive radiation therapy workflow using Varian's Ethos platform

CONCLUSIONS

- The clinical process diagram outlining the Ethos workflow will be valuable for clinicians preparing for introducing adaptive radiation therapy into clinical practice.
- The potential failure modes identified in this work will be valuable when commissioning adaptive radiation therapy technologies and implementing quality management procedures.
- The experience and risk bias weighted approach to FMEA has the potential to provide a more meaningful evaluation of failure modes compared to conventional FMEA.

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CONTACT INFORMATION

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