Using a Systems Engineering Approach to Design a Quality Management Program for Real-Time Marker-Less Lung Tumor Tracking

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INTRODUCTION

- System theoretic process analysis (STPA) has not yet been used in radiation therapy to create a comprehensive quality management (QM) program.
- STPA was used to devise a QM program for a marker-less lung tumor tracking (MLTT) system (figure 1).
- The operation of the system is as follows:
  - The linac acquires kV projections,
  - The projections are passed onto experimental MLTT software [1] via a framegrabber,
  - The software processes the images and provides a continue or pause recommendation to the treatment staff,
  - The treatment staff act on the recommendation,
  - If a baseline shift of the target is detected, the software calculates the couch shift required to undo it.

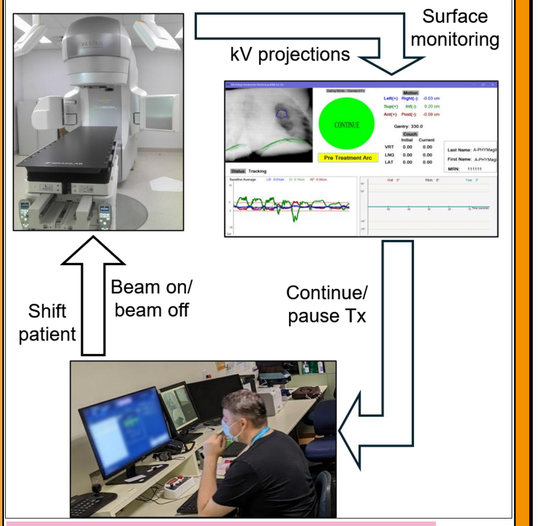

Figure 1: Clinical workflow of the marker-less lung tumor tracking system.

TAKE AWAY

- We demonstrated the first use of system theoretic process analysis (STPA) to create a comprehensive QM program for marker-less lung tumor tracking
- The STPA was undertaken by a limited team and then reviewed for completeness
- STPA resulted in a more comprehensive analysis using a smaller team than FMEA
- The QM program should be transferable between MLTT systems as tests use tolerances based on the system specification
- There were tests recommended by other publications that were deemed not necessary due to the exclusion of scenarios out of the end user's control

METHODS

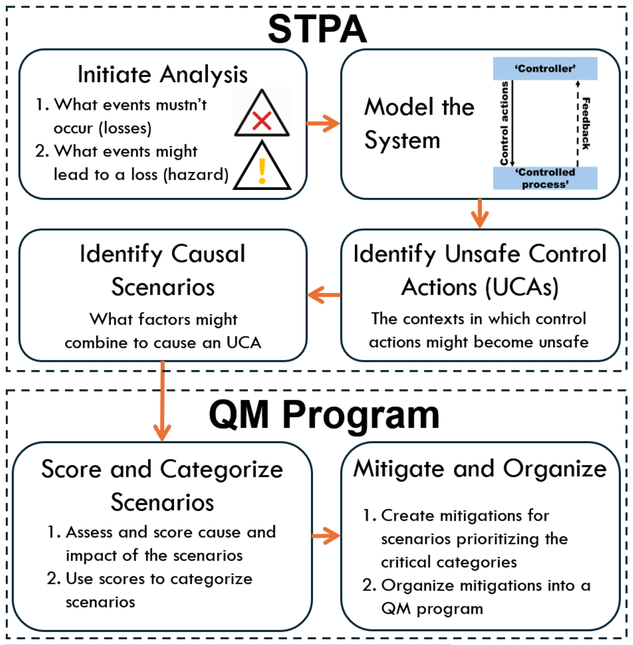

Figure 2: Steps taken to analyze the target system and generate the QM program.

- STPA [2,3] (fig 2) only assessed those items relevant to or influenced by the operation of the marker-less lung tumor tracking system.
- Figure 3 provides details the process of taking the scenarios and developing the QM program.
- The study was performed and led by a medical physicist, with support from three additional medical physicists.
  - The STPA was reviewed by two software developers and two independent medical physicists.
  - The QM program was reviewed by the same two independent medical physicists.

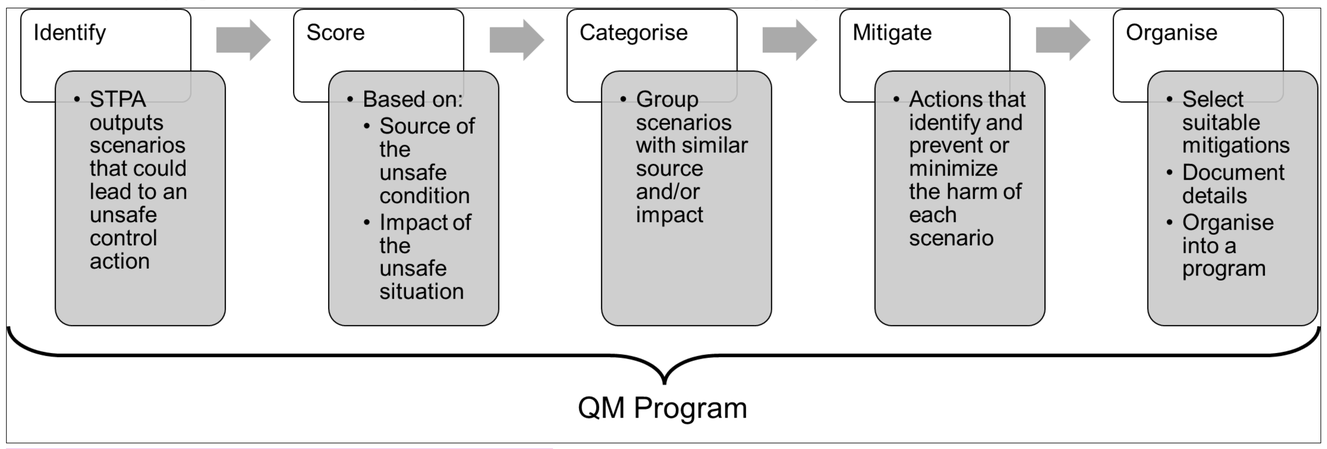

Figure 3: Steps involved in creating the QM program.

RESULTS

- 8 control actions influence the marker-less lung tumor tracking system in its installed form (fig 4).
  - Resulting in 38 unsafe control actions, and 205 causal scenarios.
- Table 1 summaries the QM program.
- The causal scenarios only considered situations which the end user could observe and/or influence.

Table 1: Summary of proposed mitigation strategies for a real-time marker-less lung tumor tracking system designed based on an STPA.

Test category	Description	Frequency	Tolerance
Interface with external systems	Assess the external system interfaces	Commissioning/ update of interface systems	Functional
Dynamic localization accuracy	Assess the accuracy with which the system can track targets	Commissioning/ annual	As per system specification
Co-ordinate system compatibility	Assess the accuracy of the couch shifts reported by the marker-less lung tumor tracking software to correct baseline shifts in all translational directions	Commissioning/ annual	As per system specification
Patient specific tests	Check completeness, accuracy and/or suitability of patient files	Prior to patient's first treatment fraction	Pass
SOPs: • Treatment staff • Planning staff	Create standard operating procedures for the treatment staff that are written according to 'work-as-done'♯ Implement systems to train staff	Prior to first patient	Existing/ available
System behavior	Work with the vendor to : * Demonstrate the system meets the specified system specifications * Validate behavior of the software in edge cases and known scenarios	Commissioning/ annual	As per system specification

♯ Work-as-done is defined as what the operator actually does rather than what a third-party imagines the operator does [4]

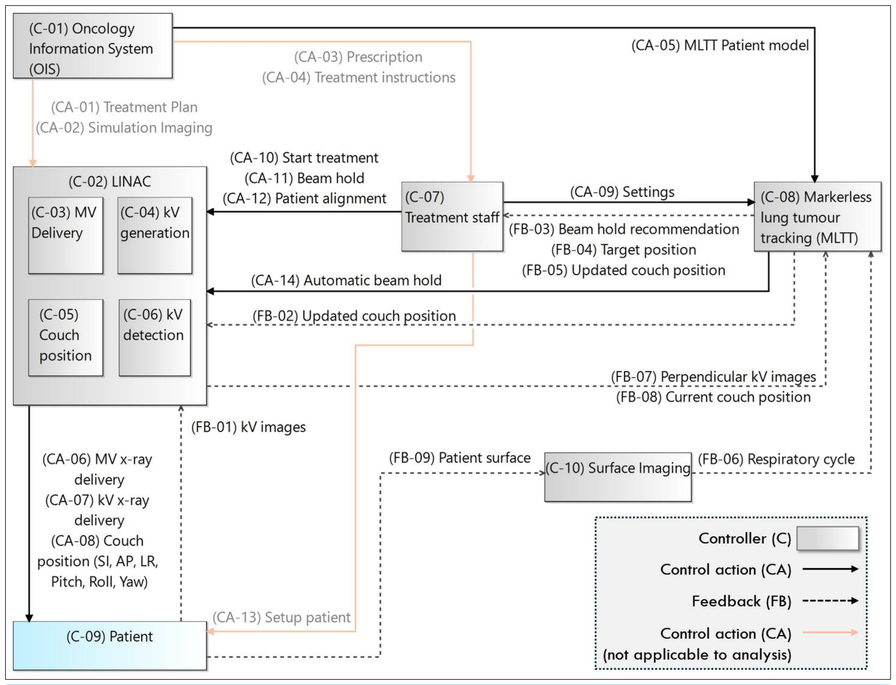

Figure 4: Control structure diagram model of the system layout of the marker-less lung tumor tracking system. The control actions independent of the marker-less lung tumor tracking system were deemed not applicable to the analysis (solid bronze lines).

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