Safety Systems Analysis of Brachytherapy Using STPA: A Case Study in Radiation Oncology

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Outline:

What is brachytherapy and how do I derive the control structure?

• Clinical workflow STPA Example: Analyzing a control action to develop a scenario.

• Management level STPA Example: Management influences on patient safety.
Our Case Study:

• Brachytherapy – An advanced cancer treatment where a High Dose Rate (HDR) radiation source is placed in or near a tumor.

• Observed cases of HDR Brachytherapy via Ring and Tandem applicator. A common procedure for patients with cervical cancer.
Process Map:

Preinsertion preparations
Applicator insertion
Plan optimization
Summary of Steps:

• 1. Patient is placed under general anesthesia.
• 2. Applicator is surgically inserted.
• 3. CT scan is taken to visualize the applicator and organs at risk.
• 4. A treatment plan and contour are created from the CT scan.
• 5. Plan is optimized to the patient’s anatomy.
• 6. Radiation dosage is delivered.
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Accidents and Hazards

• A-1: Patient suffers radiological injury due to over-radiation.
• A-2: Patient’s cancer advances due to under-radiation.
• A-3: Patient suffers physical, non-radiological injury.
• A-4: Staff suffers injury (radiological or physical).

• H-1: Persons subject to non-radiological injuries.
• H-3: Patient does not receive treatment.
• H-4: Non-patient receives radiation.
What are the safety implications?

• We analyzed the 11 control actions.

• STPA step 1 was performed, and 26 Unsafe Control Actions (UCA) were identified.

• STPA step 2 is ongoing with 100+ causal factors identified.
UCA: Physicist/RO optimizes a treatment plan that is incorrect.

<table>
<thead>
<tr>
<th>Control Action:</th>
<th>Not Providing Causes Hazard:</th>
<th>Providing Causes Hazard:</th>
<th>Wrong Timing or Order Causes Hazard:</th>
<th>Stopped Too Soon or Applied Too Long</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimize Plan</td>
<td>Physicist/RO does not optimize Tx. Plan that is appropriate. (H-3)</td>
<td>Physicist/RO optimizes Tx. Plan that is incorrect. (H-2)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
UCA: Physicist/RO optimizes a treatment plan that is incorrect.
What went wrong?

CT Scan

Medical Physicist

Pass Treatment plan

Pass contours

Optimize plan

CT Scan

Medical Physicist & Radiation Oncologist

Radiation Oncologist

Patient status
UCA: Physicist/RO optimizes a treatment plan that is incorrect.

• Scenario:
  • Rad Onc finishes applicator insertion, takes CT scan, and tells the physicist to start the Treatment Plan.
  • Now consider the Rad Onc wants to reposition applicator and take another CT scan.
    • Extra causal factor: The physicist is already in another room finishing up the Treatment Plan.

• Working on different CT scans?

• Working on the same old one?
UCA: Physicist/RO optimizes a treatment plan that is incorrect.

• Summary:
  • Two CT Scans that look similar and are taken minutes apart.
  • Communication issues could lead to inadequate feedback. The physicist may not have even known there was a new CT Scan.
  • Radiation Oncologist chooses a CT scan to contour off of and chooses the old one.
  • Both Medical Physicist and Radiation Oncologist mistakenly work on the old CT which passed through the software. This is where the UCA will come from.
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How does management influence contribute to hazard analysis?

Leadership & Management

Let’s go guys!
A different example:

Treatment Preparation

Radiation Oncologist

Nurse

Patient

Laboratory work
Patient chart

Pre-procedure check
Insertion

Patient status
CT Scan

Position Patient

Visual affirmation
of position

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UCA: Nurse moves patient into a sub-optimal position.

• This ties to one of the hazards we identified being physical harm to the patient and/or staff.
  • When people think of hazard analysis in radiation oncology, this is a hazard that tends to be ignored.

• Causal factor: Moving the patient with too few people.
Why too few people?

• Management UCA:
  Provides inadequate budget.
Step 2 Analysis:

• Easy answer: Hire more staff.
  • Why might an inadequate budget get approved?
    • Look at the Process Model.
Step 2 Analysis:

• Other things to consider: Control Algorithm
• MBA vs MD
  • Roles, Responsibility, and Training
• Interesting power dynamic.
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Conclusion:

• STPA can be used to analyze a brachytherapy process.
• The ability to analyze management is unique feature to STPA that FMEA lacks.
• The tension between management and clinical controllers appears to be important and warrants more research.
Questions?
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