STPA Analysis of Changes in the Process for Stereotactic Radiosurgery

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Patient Safety, or Why Should I Care?

- In 1999, IOM released a report, To Err is Human, saying that healthcare in the US killed 49,000-98,000 people per year.

A 2013 meta-analysis, suggested that with improved measurement tools, we were actually contributing to the premature deaths of 210,000-400,000 people per year.
Hazard Analysis in Healthcare

1999
To Err is Human released

Late 1940’s
FMEA invented

1999
FMEA invented

First mention of using FMEA in healthcare (Cohen, 1999)

2003
AAPM commissions TG-100 to create hazard analysis guidelines

Mid-2000s
Joint Commission requires FMEA for licensure

Mid-2000s to Today
Hundreds of FMEAs are done in hospitals. Several publications are exploring other analytic techniques. General consensus is that we are no safer now than in 1999
Healthcare FMEA Methodologies

- Wide variability in applications that fulfill the Joint Commission requirements
- Many organizations offer worksheets and guidance
  - Institute for Healthcare Improvement
    - Generic and classic FMEA, no adaptation for healthcare

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- VA Healthcare FMEA
  - Copyrighted methodology, adapting FMEA to healthcare specific applications
Healthcare FMEA results

- **Heterogeneous!**
  - Partly due to the wide variety in available tools
  - Additionally, most hospitals do not have system engineering departments to provide engineers who specialize in doing these analyses

### Laboratory Phlebotomy: Failure Modes and Effects Analysis (Wagar, 2006)

<table>
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<tr>
<th>Process Step</th>
<th>Potential Failure Mode</th>
<th>Potential Failure Effects (on Patient)</th>
<th>SEV</th>
<th>Root Causes</th>
<th>OCC</th>
<th>Current Controls</th>
<th>DET</th>
<th>RPN</th>
<th>Strategies</th>
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<td>1</td>
<td>Check patient’s wrist- band (name and MR No.)</td>
<td>Specimen obtained from wrong patient; wrong blood in tube</td>
<td>7</td>
<td>Not checking wristband name spelling, and MR No.</td>
<td>4</td>
<td>Training; competencies</td>
<td>5</td>
<td>140*</td>
<td>Retrain to check patient name, correct spelling, and MR No.</td>
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### Process step  1A  
- **Chemotherapy treatment schedule in chart**
  - Hazard score: 6
  - Causes: Pediatric oncologist did not update schedule in chart
  - Recommendation: Design standard procedure for changes in chemotherapy treatment schedules

- **Chemotherapy treatment schedule misunderstood**
  - Hazard score: 4
  - Causes: Schedule in language other than Dutch or English
  - Recommendation: Translate chemotherapy treatment schedules

(van Tilburg, 2006)
Project Objectives

- We believe that STPA can provide a conceptual framework that can consistently identify hazards and causal factors that can lead to strong systemic recommendations.
  - Grounding in systems theory forces the analyst to consider the environment that the controller is operating within leading to solutions beyond merely re-training.
- We propose a proof-of-concept case study showing that STPA can give meaningful results in healthcare applications.
  - We chose to study a radiation oncology process.
Why Radiation Oncology?

- Strong safety culture
  - After several negative media articles, the field has really begun to pay attention to safety in a way that other hospital areas have not yet

- Medical physicists
  - Radiation oncology is one of the few fields where technical faculty work in patient care applications
  - Bring an engineering perspective to a field otherwise dominated by clinicians with a focus on narrative description

- Device Precision
  - Radiation can be delivered with millimeter precision, which makes process errors and accidents a critical source of mistreatment
Accidents

A-1. Patient injured or killed due to radiation
A-2. Non-patient injured or killed due to radiation
A-3. Damage to equipment
A-4. Death or injury of patient or non-patient not due to radiation
Hazards

**H1. Wrong radiation delivered**

- **H1.1** Right patient, right dose, wrong location
- **H1.2** Right patient, wrong dose, right location
- **H1.3** Right patient, wrong dose, wrong location
- **H1.4** Wrong patient

**H2. Staff is unnecessarily exposed to radiation**

**H3. Equipment subject to unnecessary stress**

**H4. Persons subjected to the possibility of non-radiation injury**
Hospital Administration

7.1 Set performance expectations (dollars and safety)
7.2 Provide staff and equipment resources

Department Administration

8.1 Approve standard operating procedures
8.2 Allocate staff and equipment resources
8.3 Create and maintain department culture
8.4 Maintain equipment (service contracts)

Feedback from Chair and department admins
Feedback from patients on experience
Equipment downtime
Staff and faculty satisfaction survey results
Physics QA results (reports)

Accreditation

IRB
Unions
Benchmarks (e.g., Leapfrog)

10.1 Staff notifies vendor of an issue

Vendor Service

Response to address the issue
Step 1

- Analyzed 21 control actions using classic Step 1 Tables
- Identified 85 unsafe control actions
## Step 1 Tables for Medical Physicist – Radiation Oncologist Hybrid Controller

<table>
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<tr>
<th>Control Action</th>
<th>Not providing causes hazard</th>
<th>Providing leads to hazard</th>
<th>Wrong timing leads to hazard</th>
<th>Applied too long or too short leads to hazard</th>
</tr>
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<tbody>
<tr>
<td>4.1 Fuse MR and pre-plan to CBCT</td>
<td>UCA 4.1.1: The physicist does not perform the fusion when the images and pre-plan are ready. [H1]</td>
<td>UCA 4.1.2: The physicist fuses the images and pre-plan incorrectly when using the fusion software. [H1]</td>
<td>UCA 4.1.3: The images are fused before the final or most recent CBCT is acquired and transferred for fusion. [H1]</td>
<td>UCA 4.1.4: The fusion takes too long when transferring images or using the fusion software. [H1]</td>
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<td>4.2 Re-optimize and re-calculate</td>
<td>UCA 4.2.1: Suboptimal treatment occurs when a suboptimal pre-plan is scheduled for treatment. [H1]</td>
<td>UCA 4.2.2: An inaccurate dose calculation is provided when the physicist uses the software to perform the re-calc. [H1]</td>
<td>UCA 4.2.3: Re-optimize and re-calculate before fusion is complete [H1.1-3]</td>
<td>UCA 4.2.4: Re-optimization or re-calculation takes too long when using the treatment planning software. [H1]</td>
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<td>4.3 Fusion and final plan approval</td>
<td>UCA 4.3.1: The fusion is not checked by the radiation oncologist when it is suboptimal. [H1]</td>
<td>UCA 4.3.3: The radiation oncologist approves the fusion when it is suboptimal. [H1]</td>
<td>UCA 4.3.5: The fusion is approved after the plan has been scheduled for treatment. [H1]</td>
<td>UCA 4.3.7: The fusion and final plan approval are delayed when they are ready to be checked. [H1]</td>
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UCA 4.3.2: The final plan is not checked by the radiation oncologist when it is suboptimal. [H1.1-3]
Step 2 - The physicist/oncologist does not perform the fusion when the images and pre-plan are ready.

- Controller is unaware that they need to complete the fusion at this time
  - Missing input: If the CBCT is not uploaded into the computer in the normal file location then the physicist may not realize that it is time to complete the fusion. They may also not have received a page or other communication that it is time to proceed.
  - Falsely believe that the patient has moved and therefore the CBCT is not valid to use for the fusion
    - False alarm from the surface imaging
    - Poor quality video feed from the room makes it appear that patient moved

- Controller does not have the files to proceed
  - Missing input: CBCT or MRI with contours and plan not loaded into computer.
  - Missing input: Images are loaded into the computer but in the wrong location
  - Missing input: Images are loaded in the improper file format

- Implementation of control actions is flawed (i.e. scenarios where the controller knows to run the fusion, but somehow the fusion is not created)
  - Fusion software does not create a fusion, but does not give an error message that is obvious to the physicist. The physicist therefore assumes that the fusion proceeded as planned.
  - Physicist does not know how to use the fusion software. This is a likely problem to run into at the start of using this new process or when a new physicist is hired.
Requirements

- Our ultimate goal in this project is to deliver a set of “requirements” for clinicians’ new roles and for the new software
  - These are not traditional requirements in the software engineering sense
  - Rather our goal is to determine what type of behavior each controller, actuator, and sensor needs to ensure that every controller can take the correct and safe control action
- What might this look like?
  - What do we give to a software developer to assist in defining the specifications for this software?
  - What could we give to clinicians to help them best understand their roles in ensuring safe practice as we roll out this new process?
Requirements – Fusion Software

- Behaves as an actuator and a sensor for the medical physicist/radiation oncologist controller
  - Use step 2 results from analyzing the UCAs associated with that controller to place behavioral requirements on the software

- Sample requirements:
  - Software must check both MRI and CBCT image for completeness (UCA 4.1.2)
  - Software must not run fusion if either MRI or CBCT is missing (UCA 4.1.1)
  - Software must complete fusion within X minutes (UCA 4.1.4)
  - Software must output a high quality image, by radiology standards, for fusion evaluation (UCA 4.1.2)
Requirements – Radiation Therapist
Requirements – Radiation Therapist

- **Safety Responsibility:** Positioning the patient
- **Safety Constraints:** adapted from the UCAs
  - Therapist must position the patient according to the SOPs for this new process
  - Therapist must not take too long positioning the patient
  - Therapist must securely immobilize the patient to prevent motion
- **Other System Requirements:** adapted from Step 2 causal factors
  - Adequate pillows, restraints, and foam pieces must be available
  - Patient must be able and willing to tell therapist that they are uncomfortable
  - Positioning SOPs must be clear and unambiguous for therapists. If there is any confusion, therapist must clarify with medical physicist
Strengths of STPA in Process Analysis

- Clear framework for considering safety and the role of the environment in allowing clinicians to make safe control decisions
- Creates a model that can be shared by the entire team involved in the process
  - Shared mental model helps with clarity of communication
  - Just seeing the system and your role in it changes your perspective to consider how your actions impact people beyond your local area
- Create clear requirements for clinician behavior and environmental constraints to promote safety
Conclusions

- STPA works well with healthcare processes for identifying safety concerns
- Next step would be to compare results to findings using FMEA and other techniques promoted by TG-100 working group
  - Potential metrics:
    - Number of causal factors
    - Quality of causal factors
    - Time/effort to complete analysis
- More future work would be in utilizing these requirements and working with social scientists to explore the best way to present these requirements
References


