Experiences with STPA in Radiation Therapy

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The Healthcare Safety Problem

• "98,000 people die in hospitals each year…"
  • Institute of Medicine (1999). To err is human: building a safer health system.

• "…true number of premature deaths… was estimated at more than 400,000 per year.
  • James, JT (2013). Journal of Patient Safety, 9(3), 122-128
The New York Times

Radiation Therapy Accident

Occurred: 2007
Reported: 2010
Outline

• What is radiation therapy?

• Initial experience with STPA

• Using STPA to change clinical practice

• Some future directions
Cancer Treatment Options

Diagnosis  Surgery  Chemo  Radiation  Follow-up
Brachytherapy
“Close therapy”
Radioactive sources ($\gamma$-rays) placed within a tumor

Teletherapy
“Therapy at a distance”
Linear Accelerator
(X-rays and electrons)
An Investigation of the Therac-25 Accidents

Nancy G. Leveson, University of Washington
Clark S. Turner, University of California, Irvine

STPA in Radiation Therapy

Consult  Simulation  Planning  Treatment  Follow-up
Accidents and Hazards

1. Patient injured or killed from radiation exposure
2. Staff injured or killed from radiation exposure
3. Physical injury to patient or staff during treatment (not from RT)
4. Damage to equipment
5. Damage to patient or staff satisfaction, or hospital reputation

1. Wrong dose, location, or patient
2. Staff is unexpectedly exposed to radiation
3. Persons are subjected to the possibility of non-radiological injury
4. Equipment is subject to unexpected stress
5. Workflow is subject to unexpected stress, delays in starting treatments
Radiation Oncologist
- Pass Rx & contours
- Approve pre-plan
- Approve fusion & final plan

Planned treatment
- Dose distribution
- DVHs

Medical Physicist
- Comfort
- Stability

Combining Image 1 and Image 2

Radiation Therapist
- Ensuring patient is relaxed
- Immobilization and positioning

New Software
- Recalculated plan
- TPS
- Combine Image 1 and Image 2

Treatment Delivery
- Radiation
- CBCT Image

Machine Status
- Patient info

Clinical status
- Clinical outcome

Patient candidacy
- Set up acceptable

Set-up procedures
# Results – STPA Tables

<table>
<thead>
<tr>
<th>Control Action</th>
<th>Control action is not given</th>
<th>Control action is given incorrectly</th>
<th>Control action is given at wrong time or order</th>
<th>Control action is stopped to soon or applied too long</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combine Image 1 and Image 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Result – STPA Causal Scenarios

CA: Combine image 1 and image 2
UCA: Combining the images takes too long [H1]

• Example causal scenarios identified for this UCA
  • Medical physicist is distracted with other non-related clinical issues
  • Image 2 is not imported to the new software
    • Not automatically stored correctly or imported
  • Software crash that the medical physicist cannot recover from
    • Assumes if the software can be restarted again then all future operations will be safe
Results

• 10 Control Structures
  • 23 Control actions
  • 83 Unsafe control actions
  • 472 Causal scenarios

Application of systems and control theory-based hazard analysis to radiation oncology
Todd Pawlicki, Aubrey Samost, Derek W. Brown, Ryan P. Manger, Gwe-Ya Kim, and Nancy G. Leveson
STPA (472)

- Organizational management: 35%
- Technical: 21%
- Human behavior of individual staff: 19%
- Patient-related circumstances: 14%
- Procedural issues: 6%
- Other: 4%

FMEA (132)

- Organizational management: 40%
- Technical: 23%
- Human behavior of individual staff: 27%
- Patient-related circumstances: 6%
- Procedural issues: 3%
- Other: 4%
Using STPA to Change Clinical Practice

2010  →  2018

Simplification
Automation
Initial Results

- # of Control Structures = 23
- # of CAs = 54
- # of UCAs > 150 (so far)
  - and still working on causal scenarios
Our research focuses on building a substantive body of theory-based insights to establish a scientific basis for design. We study best practices in design, across a range of domains from health autonomous vehicles, to online education and civic engagement.

HALCYON™
Transformative radiotherapy designed to improve clinician experience and patient comfort.

Welcome, Healthcare Professionals.
Clinical Research

STPA

HCD

[Diagram showing the relationship between STPA and HCD in clinical research]

UC San Diego

RETHINKING MEDICAL PHYSICS

STAMP Workshop | MIT | March 2018
Evaluate Changes

- **Quality** → Radiation dose to the tumor
- **Safety** → Near-Miss Risk Index
- **Workload** → NASA Task Load Index
- **Efficiency** → Duration from Simulation to the Start of Treatment
- **Safety Culture** → AHRQ Safety Profile Assessment
Future Directions

• How to apply and disseminate to healthcare?

• Top down approach
  • Re-do hospital FMEA

• The Joint Commission

The Joint Commission Journal on Quality and Patient Safety
Future Directions in the Clinic

• After an accident or significant near-miss happens
  • You have to do something
  • You have limited time to identify and address the causes

• Bottom up approach
  • Is it possible (or useful) to do a quick STPA or CAST?
  • How to educate and train front-line staff?
**Radiation Oncology Safety Course**

*how to create a safer radiotherapy environment*

Discipline of Radiation Therapy, School of Medicine, Trinity College, Dublin, Ireland

21st – 24th August, 2017

- Perform a prospective safety assessment
  - Groups 1 – 2 use FMEA
  - Groups 3 – 4 use STPA

- Group discussion
  - Watch error video
  - Was your analysis effective?
Summary

• STPA is applicable to radiation therapy
  • Additional research pending

• Still need to disseminate to other specialties

• Engage and train front-line staff
  • Must work in LIMCs