MIT STAMP Workshop 2022:

“Introducing STPA to Interventional Radiology within a Large Hospital”

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### Characteristics of Health Systems:

- Information-intensive
- Human-intensive
- Complex
- Imprecise
- Interdisciplinary
- Constantly changing
- Difficult to Predict
- Fragmented

### Safety Approaches:

<table>
<thead>
<tr>
<th>Safety I</th>
<th>Safety II</th>
<th>Safety III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive Approach</td>
<td>Proactive Approach</td>
<td>Systems Approach</td>
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<tr>
<td>Respond to an accident or near miss</td>
<td>Continuously try to anticipate developments and events</td>
<td>Concentrate on <em>preventing hazards</em> while <em>continuously learning</em> from accidents, near misses, and trends</td>
</tr>
</tbody>
</table>

Adapted from [1]
Joint Commission Healthcare Standards

• JC’s Patient Safety Standards [2]:

  LD.03.09.01: Having an organization-wide, integrated patient safety program within performance improvement activities

  LD.03.09.01, EP 3: Requires leaders to provide and encourage the use of systems for blame-free reporting of a system or process failure or the results of proactive risk assessments

  LD.03.09.01, EP 7: Requires hospitals to select one high-risk process and conduct a proactive risk assessment at least every 18 months

• A Learning Organization:

  One in which people learn continuously, thereby enhancing their capabilities to create and innovate. [2]

  Team learning
  Shared visions and goals
  Shared mental model
  Systems thinking
  Individual commitment to lifelong learning
Objective: Apply an analysis method that considers the *complexity and criticality* of the system to systematically *identify, quantify, and track* the potential for risk in an IR procedure based on the *design* of the *system*.
Project Goals

Improve *patient safety* in all Y-90 procedures

Improve *safety culture* and offer *systematic solutions* to hazards

Test the application of *prospective systems analysis* including *Human Factors* in complex patient safety systems
System in Focus:
Radioembolization for hepatocellular carcinoma using Yttrium-90 microspheres (Y-90)

Description:
Glass beads or resin spheres containing Yttrium-90 deliver targeted radiation directly to the liver tumors through the tumor’s main blood supply, via catheter.
Systems Theoretic Process Analysis (STPA)

Finds inadequate control in design of a system & identifies potential hazards

- Non-linear
- Multiple causal factors
- Mitigates bias & blame
- Handles Complexity
- Identifies inadequate control
- External factors

Used in **high-risk industries**: Aviation, Nuclear, Automation, IT, Health Systems, etc.
DMAIC Framework

**Define**
- Multidisciplinary group
- Meeting structure
- Clinical observations
- Defined quality metrics

**Measure/Explore**
- Quality metrics dashboard
- Notification system
- Incident data collection

**Improve/Control**
- Propose Solutions/Recommendations
- Identify Leading Indicators of Hazards
- Track outcomes of analysis

**Analyze**
- Incorporate incident data
- Incorporate public data (i.e. NRC)
- Review of industry standards & regulations
- Apply safety analysis (STPA)
Key Stakeholders

Interdepartmental communication

- Quality & Safety Leadership
- Radiation Safety Leadership
- Quality & Safety Engineers
- Medical Physics
- Interventional Radiologists
Strategy

In-Person

- Clinical observations
- Staff interviews

Virtual

- Introductory meetings
- Structured bi-monthly meetings during analysis
  - i.e. UCAs & Causal Scenarios
- Ad-hoc meetings
- Offline feedback
- Centralized communication platform on MS Teams
STPA

<table>
<thead>
<tr>
<th>General Steps</th>
<th>1) Define the Purpose of the Analysis</th>
<th>2) Model the Control Structure</th>
<th>3) Identify Unsafe Control Actions (UCA)</th>
<th>4) Identify Causal Scenarios</th>
</tr>
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<tbody>
<tr>
<td>Description</td>
<td>System definition of boundaries, losses, hazards, and existing safety constraints</td>
<td>A functional model of system composed of feedback control loops</td>
<td>An unsafe action that, in a particular context and worst-case environment, will lead to a hazard</td>
<td>Scenarios where multiple causal factors that can lead to the UCA and eventually a hazard</td>
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</table>

**Define System Boundary**

Identify losses and hazards

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Adapted from [4]
STPA: Modeling the Control Structure

2.1 Identify and Define Controllers
1. Patient
2. Medical Health Physicist
3. Medical Physicist Dosimetry Team
4. Authorized User (AU)
5. Interventional Radiology Doctor (IR MD)
6. Radiopharmacy (Nuclear Pharmacy)
7. SAIL Team
8. Radiology
9. Anesthesiologist
10. RNs
11. Interventional Radiology Technologist (IR Tech)
12. Interventional Radiology Care Coordinator (IR CC)
13. Hospital Leadership
14. Governing Bodies
15. Vendor

2.2 Define Controller Responsibilities

Controller: Medical Health Physicist
- Prepare dosimetry
- Dose vial delivery
- Monitor Patient Radiation
- Monitor/Survey OR & OR Staff Radiation
- Update written directive
- Coordinate treatment plan with IR MD
- Confirm treatment plan with IR MD & Radiopharmacy
- Prepare pre & post operative measurements

2.3 Iterative Control Structure Modeling & Abstraction
### STPA: Identifying Causal Scenarios

#### Human Factors Element

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<tr>
<td>Define System Boundary</td>
<td>Environment</td>
<td>Identify losses and hazards</td>
<td>Mental Models</td>
</tr>
<tr>
<td>System</td>
<td></td>
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Adapted from [4]
Overview & Outcomes

Comprehensive system definition

- 8 System Losses
- 15 System Controllers
- 11 System Hazards & Safety Constraints
- Multiple High-Level & Detailed Control Structures

Prospective causes of hazards

- 301 Unsafe Control Actions Identified
- Identified Causal Scenarios (w/ Mental Models)
- Identified System Constraints

Modified into Risk Register

- Initiative to Key Clinical Document
- Multidisciplinary Design Sessions
- Workflow & Service Blueprint
- Mock-up & Working Group

Leading/Lagging Metrics to Track Progress

- Key clinical document redesign buy-in

Collaboration with IR MD/AUs, Medical Physics, IR CCs, CIS

Memorial Sloan Kettering Cancer Center
Impacts

Operational
- Redesign of key clinical document

Social
- Expanded approaches to safety
- Multidisciplinary collaboration
- Safe space for discussion

Cultural
- Patient Safety Systems Community of Practice
- How safety is viewed

Just Culture
Lessons Learned

- Organize a multidisciplinary team & ensure alignment
- Communicate the value and approach in a minimally technical manner
- Introductory meetings are worthwhile
- Take your time learning the system in question
- Read up on STAMP/STPA articles and presentations prior to applying
- Emphasize applicability towards outcomes, culture, and harm prevention
References


Thank You!