STAMP applied to Healthcare

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March 25, 2015

This presentation reflects my personal work and views and not of my employer
Adoption of System Safety

Adoption of System Safety

Benefit

Adoption

Post-Loss Analysis

Safety Driven Design
NOTE: This teaching case has elements from many real case studies, but many details were manufactured to provide enough information to accomplish the RCA Team exercise.
## Introduction to System Safety Analysis

### Root Cause
- Based on chain of events model
- Identifies a limited number of “root causes”
- Recommended by Joint Commission based on NASA engineering approach
- Basis of Incident Reporting Tools used by the FDA, Joint Commission, Patient Safety Organizations

### CAST
- Based on System Engineering
- Design for complex systems (Recognizes emergent properties)
- Identifies a larger set of causes
- Hardware component failures, component interactions, human and software interactions, systemic accidents (i.e. mode confusion) etc.
- Treats safety as a dynamic control problem

Traditional RC approach became mainstream after “To Err is Human”

**Necessary for complex systems**
Accident Overview

Solitary Pulmonary nodule in upper lobe of right lung

CT scan guided fine needle biopsy of the lung nodule

1 day Observation in Short Stay Unit (SSU)

Diagnosis

Biopsy Procedure

10% Pneumothorax

Post Procedure Recovery

50% Pneumothorax
Chest Tube Placed
4 day recovery
VA Root Cause Analysis

Contributing Factors:

• The **complication was not disclosed** to the patient or treatment team
• **No hand-off** of the patient from Radiology to the SSU
• **Delay** in patient assessment
• **Patient is managing** his own **alarm**- alarm safety issues
• This nurse is **practicing out of her scope** of practice if she is an RN. She should have called the Resident/physician responsible for the care of this patient.

Root Causes: There was a **lack of communication** to the patient and treatment team regarding the complication which occurred in Radiology. This combined with the delay in patient assessment post procedure and the patient silencing his own alarm eliminated the opportunity to detect the pneumothorax in a timely manner.
Strongest Actions Proposed

• Lock out pulse oximeter so patient cannot manage controls
• Face to face hand offs with check lists
• Practice Issues
  – Addressed by peer review and addressed by supervisor
Accident Description

**Accident:**
(General) Patient harmed as a result of hospital care
(Specific) Patient’s lung is harmed while in the hospital for a procedure to biopsy a lung nodule

**System Hazards (related to this accident):**
- H1 Procedure damages sensitive tissue
- H2 Patient is unable to fully recover from procedure

**The System Safety Constraints (related to this accident):**
- Lung nodule must be biopsied without harming the patient
- The patient must be monitored and treated appropriately while recovering from the procedure
Control Structure Creation

Control Diagram created for each phase displayed in appendix
As Designed and Actual
CAST Analysis

Physical System (partial results)

- CT/Fluoroscopy Guided Biopsy
- Patient Record
- Short Stay Unit (SSU)

Safety Requirements/Constraints Violated
- Provide imaging to aid in maintaining a safe pathway to nodules
- Obtain sample without harming patient

Failures and Inadequate Controls
- Pneumothorax resulted from biopsy procedure
- Non-quantitative method for assessing extent of pneumothorax
- Patient movement is not prevented or monitored

Physical Contextual Factors
- Inadequate imaging provides only intermittent partial views of the safe pathway, need to minimize harm from continuous imaging
- Post CT scan is used to view complications, X-ray used in follow up

Safety Requirements/Constraints Violated
- Communicate patient status, actions performed, and procedure complications to all healthcare providers involved in patient’s care
- Provide continuous monitoring of patient status post procedure

Controller Analysis (partial results)

Patient
Safety Related Responsibility
- Provide accurate and complete information (physical and verbal clinical presentation)
- Follow instructions provided by Health Care Professionals

Unsafe Decisions and Control Action
- Patient may not have conveyed all relevant information to providers regarding pneumothorax risk factors
- Patient may not have been monitored during the procedure

Process Model Flaw
- The patient likely did not know what information was relevant for pneumothorax risk factors
- The patient did not realize that he was in need of immediate medical attention

Context
- The patient likely had strong emotions at the time of this diagnosis (having just been told about the potential for lung cancer), which may have affected the patient’s ability to comprehend the procedure and its implications
- There may have been co-morbidities present which created a high risk of pneumothorax
- The patient may not have been given all relevant details of the pneumothorax procedure
- The patient may not have understood the requirements for the biopsy procedure
- The patient may have had additional questions that he did not ask due to time pressure, embarrassment, or fear of appearing ignorant
- The patient may have had his previous treatment and therefore did not perceive a risk this time
- The information may have been given to the patient only verbally, making it difficult to remember and impossible to review after leaving the office
- The patient expected that he was being monitored
CAST results (partial)

• A number of violated constraints should be addressed both for the physical system and the controllers

• Feedback throughout the system is lacking
  – Ensure a safe pathway to eliminate harm
  – Ensure communication is complete and understood
  – Adequately monitor condition for change
  – Improve the proactive measures to prevent decline
CAST Summary

• CAST provides a number of questions that can aid the patient safety officer investigating incidents

• Analysis uncovers more causal factors than the standard root cause analysis

• CAST allows for the identification of systemic hazards
Adoption of System Safety

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Safety Driven Design
Applying STAMP to Infection Prevention
1:25 hospitalized patients acquire an HAI

1.7 Million HAI’s occurred in 2012

99,000 Patients died of HAI

Source: 2011, CDC http://www.cdc.gov/hai/surveillance/

Providing care that doesn’t result in HAI’s
High-level Hierarchical Control Structure

Oversight

- e.g. CDC, FDA, JC, AMA, CMS, NHSH

Hospital Management

- Oversight
- Report
- Policy, Bundles

Care Delivery

- Samples
- Lab
- Patient
- Instructions
- Consent
- Results
- Diagnose, treat, monitor, bath
- Presentation, bio samples
- Samples

Operations

- IFU, post market surveillance
- Product, IFU
- Funding, Knowledge, Regulatory Approval

Manufacturers

- Product, IFU
- Revenue
- Knowledge, Funding

Research

- Knowledge, Funding
- Regulatory Approval, IFU, post market surveillance

Care Delivery

- Clean Appearance
- Results
- Instructions
- Consent
- Presentation, bio samples
- Diagnose, treat, monitor, bath

Patient Health

- Equipment/Tool Sterility
- Environmental Hygiene
- Hand Hygiene
- Clinical Engineering
- Sterile Processing
- Facilities
- EVS

- Clean Appearance
- Clean Appearance
- Clean Appearance
- Clean Appearance
- Appearance
- Appearance
Sterilizing Re-usable Tools

Controller

Processing Tech

Control Algorithm

Process Model

Equipment/Tools

Controlled Process

Pressures (time, social)

Clean

Observe, test

Feedback

Sterile process, equipment, environment, patient contact

Contact with patients, environment....

IFU, training, social, cultural beliefs
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Safety Driven Design
Living with type 1 diabetes is already complex
Variation in Control Structures
Lessons Learned & Observations

Need
Trade Study
General Concepts

General Control Structure
STAMP Training
Challenges/Opportunities

Design Iterations ↔ STPA Iterations

There is significant value in the process of performing STPA iteratively throughout the design process.
Thank you