

Using CAST for Adverse Event Investigation in Hospitals

Meaghan O'Neil March 27, 2014

Motivation

"As many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented"

To Err is Human Institute of Medicine Report 1999

Overview

- Motivation
- Current Incident Investigation in Healthcare
- VA Collaboration
 - Case Study
 - Current RC approach
 - CAST analysis
 - Ongoing/Additional Work

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

Traditional RC approach became mainstream after "To Err is Human"

CAST

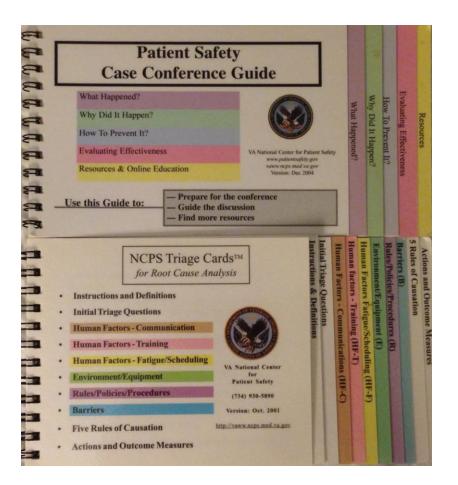
- Based on System Engineering
- Design for complex systems (Recognizes emergent properties)
- Identifies a lager set of causes
- Hardware component failures, component interactions, human and software interactions, systemic accidents (i.e. mode confusion) etc.
- Treats safety as a dynamic control problem

<u>Necessary</u> for complex systems

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VA Incident Investigation Process



- In-house Root Cause method (developed by NASA engineer)
- Patient Safety Officers
 Network with National
 Center for Patient Safety
- Process Driven
- Evaluation & Feedback
 reviews on RC and Action
 Plans
- Accredited by the Joint Commission

VA Collaboration - Case Study

 CAST applied to a Sample Accident (used for RC training)

Pneumothorax Case and Instructors Guide

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

Team Members 1) Radiology resident (not involved in this case) 2) Radiology resident (not involved in this case)

3) Nut 4) Dep Event has occurred before *Corrective ac* on service; ch within 2 hrs, v

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

Summary of the Eve A.B. is a 55-year old male wi upper lobe of his right lung d

preumonia. He are subsequently seen by a pulmosary medicine consulted who advised. a_CT_scap_guided fips needle biopsy of the imag nodule. The clinic physician and nurse both informed the patient there was likely to be minor discomfort after the procedure and it would not be necessary to stay overnight.

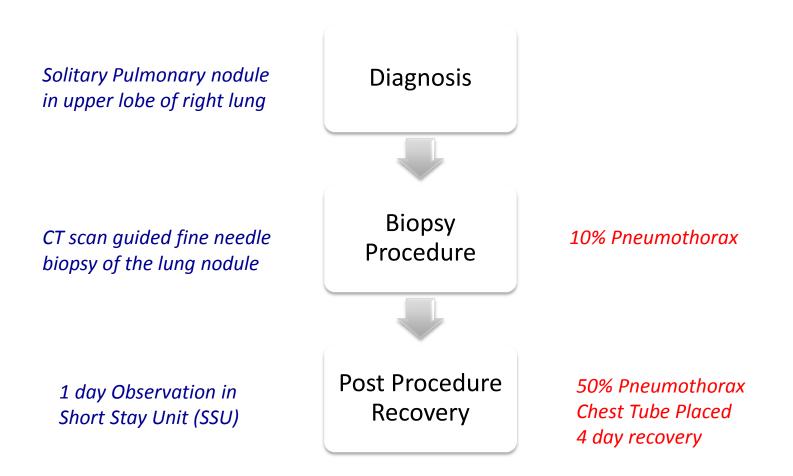
A.B. was admitted to the short stary hospital unit (SSU) on the morning of 11/1/99 to have a CT guided biopsy of the lang nodule by an interventional radiologist. After he was mildly seelated, the patient was transported to the radiology department. The patient also bad an IV catheter inserted and cardiac hythym and blood pressure monitors attached. The interventional radiologist was assisted by <u>zpadjelogy</u> resident. The role of the resident was to learn the technique by assisting with the procedure and monitoring the patient. The CT scan image was used to locate the lesion. The radiologist inserted a needle through the clearst wall into the nodule and aspirated (issue Gr the specimen. After the needle was withdrawn both clinicians noticed a small (~10%) pnesmothorax (air inside the chest vall into the Right lang), a common complication. The partially sedated patient had no complaints and denied any shortness of breast or pleuritic chest pain.

After a 15-minute delay in transport, the patient was taken back to SSU, and monitors were re-stlached. In the next 30 minutes, no staff had directly checked on the patient. During that time, the pulse oximeer alarmed "low oxygen" repeatedly, but the patient began to silence the alarm as he previously had learned to 6d. The patient was surprised that he had right-stelead check pain with inspiration but he did not inform his nurse. He had rationalized this pain as a transient problem that would soon disappear.

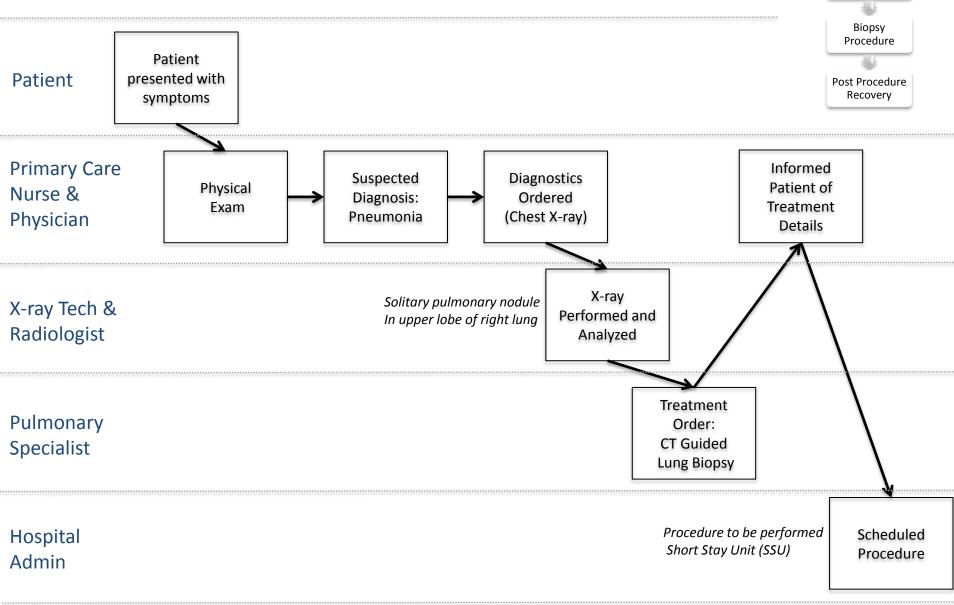
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Accident Overview

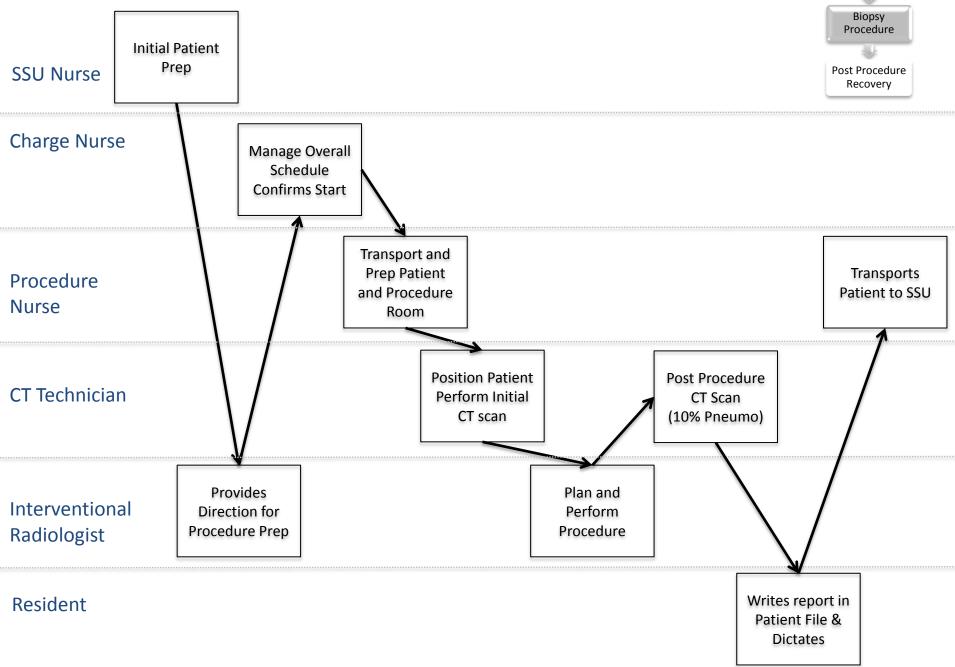


Accident Chronology: Diagnosis



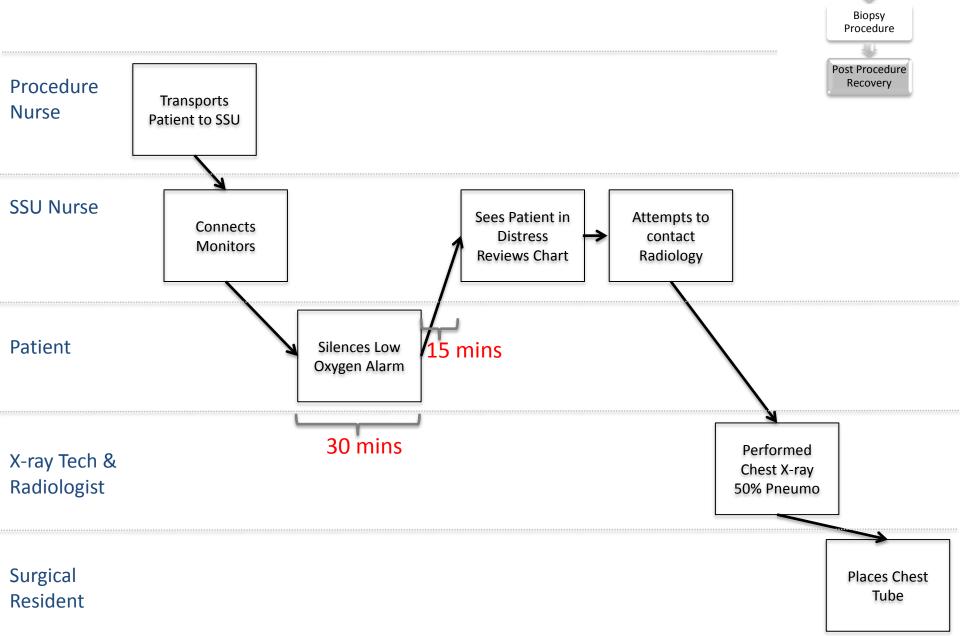
Diagnosis

Accident Chronology: Biopsy Procedure



Diagnosis

Accident Chronology: Recovery



Diagnosis

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Accident had occurred before

Corrective actions at that time included:

- Awareness training for residents on service;
- Changed procedure to have follow-up chest Xrays done within 2 hours, unless there was a change in status

VA Root Cause Analysis

Contributing Factors:

- The <u>complication was not disclosed</u> to the patient or treatment team
- <u>No hand-off of the patient from Radiology to the SSU</u>
- <u>Delay</u> in patient assessment
- <u>Patient is managing his own alarm</u>- alarm safety issues
- This nurse is <u>practicing out of her scope</u> 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 <u>lack of communication</u> to the patient and treatment team regarding the complication which occurred in Radiology. This combined with the delay in <u>patient assessment</u> post procedure and the <u>patient silencing his own alarm</u> eliminated the opportunity to detect the pneumothorax in a timely manner.

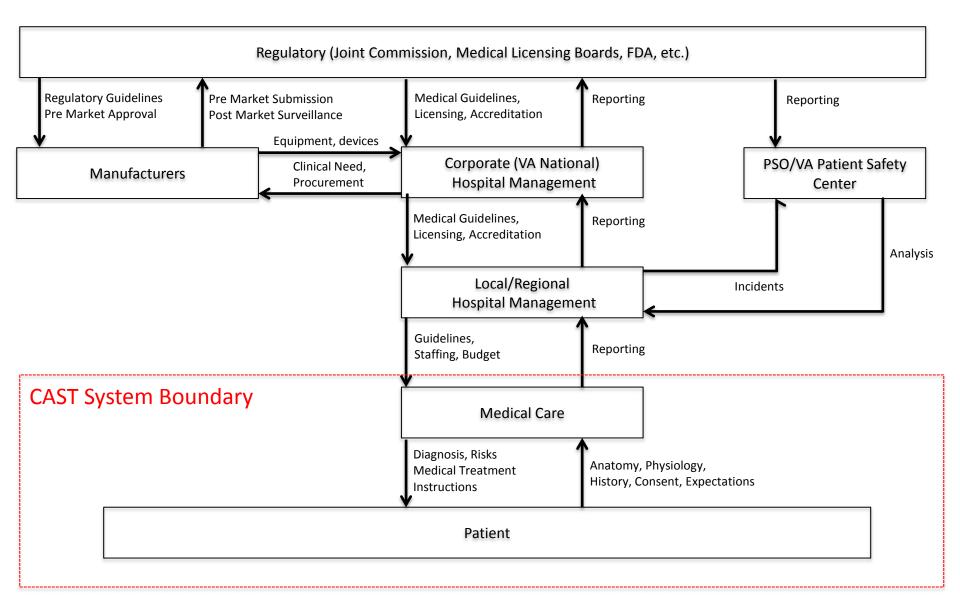
Strongest Actions Proposed

- 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

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High Level Control Diagram



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

Physical System





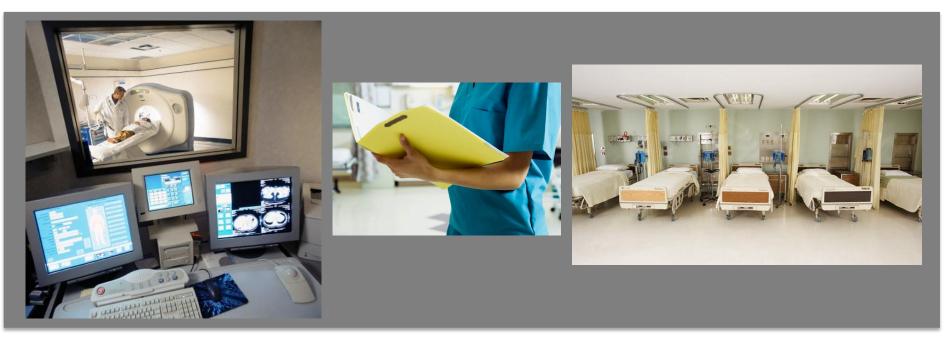






Physical System

- Safety Requirements and Constraints Violated
- Failures and Inadequate Controls
- Physical Contextual Factors



Physical System (partial results)

CT/Fluoroscopy Guided Biopsy



Safety Requirements/ Constraints Violated

- Provide imaging to aid in maintaining a safe pathway to nodule
- Obtain sample without harming patient

Failures and Inadequate Controls

- 10% 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

Patient Record



Safety Requirements/Constraints Violated

 Communicate patient status, actions performed, and procedure complications to all healthcare providers involved in patient's care

Failures and Inadequate Controls

- Illegible writing in physical chart could resulted in lack of procedure details and complications available to SSU nurse and surgical resident
- Delay in transcriptions available in EMR

Physical Contextual Factors

- Physical Patient Files used are populated real time by hand believed to be fastest form of communication. EMR used as long term record, billing
- Staffing/time pressures as well as stress can affect the quality and readability of the information in the chart

Short Stay Unit (SSU)



Safety Requirements/ Constraints Violated

• Provide continuous monitoring of patient status post procedure

Failures and Inadequate Controls

- Did not provide timely physical examination of patient
- Did not provide awareness of patient distress

- Multiple patients are assigned to each nurse in the SSU
- Close proximity and open floor plan assumes nurses will be aware of patients in distress or worsening condition and gives patients the impression that they are continuously monitored
- Newly opened facility

CT/Fluoroscopy Guided Biopsy

Safety Requirements/ Constraints Violated

- Imaging aid maintaining safe pathway
- •Obtain sample without harm

Failures and Inadequate Controls

- 10% Pneumothorax resulted
- Non quantitative method for assessing harm
- Patient movement not prevented or monitored

- 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



Patient Record

Safety Requirements/Constraints Violated

- •Communicate patient status,
 - actions performed, complications

Failures and Inadequate Controls

- •Illegible handwriting
- •Transcriptions delay EMR record update

- •File populated real time by hand is fast/common approach, EMR used as long term record, billing
- Staffing/time pressures, stress can affect quality and readability



Short Stay Unit (SSU)

Safety Requirements/ Constraints Violated

Continuous monitoring of patient

Failures and Inadequate Controls

- Lack of timely physical examination
- Patient distress unobserved

- Patient to nurse ratio
- •Close proximity and open floor plan assumes nurses will be aware of patients in distress or worsening condition and gives patients the impression that they are continuously monitored
- •Newly opened facility

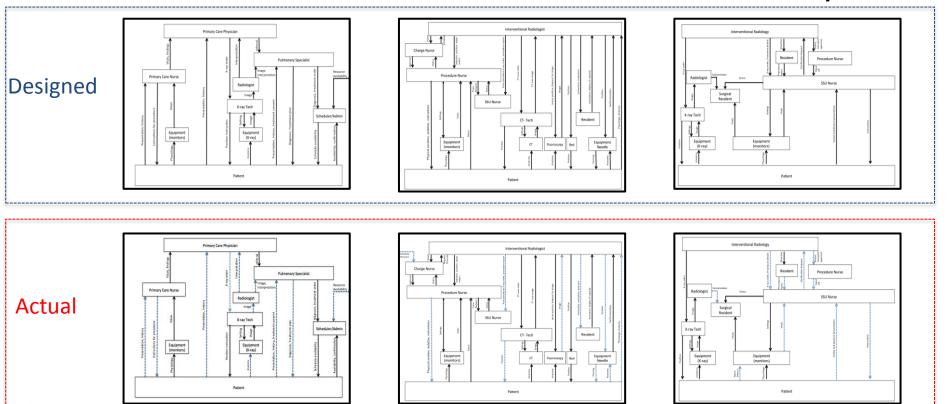


Control Structure Creation

Diagnosis

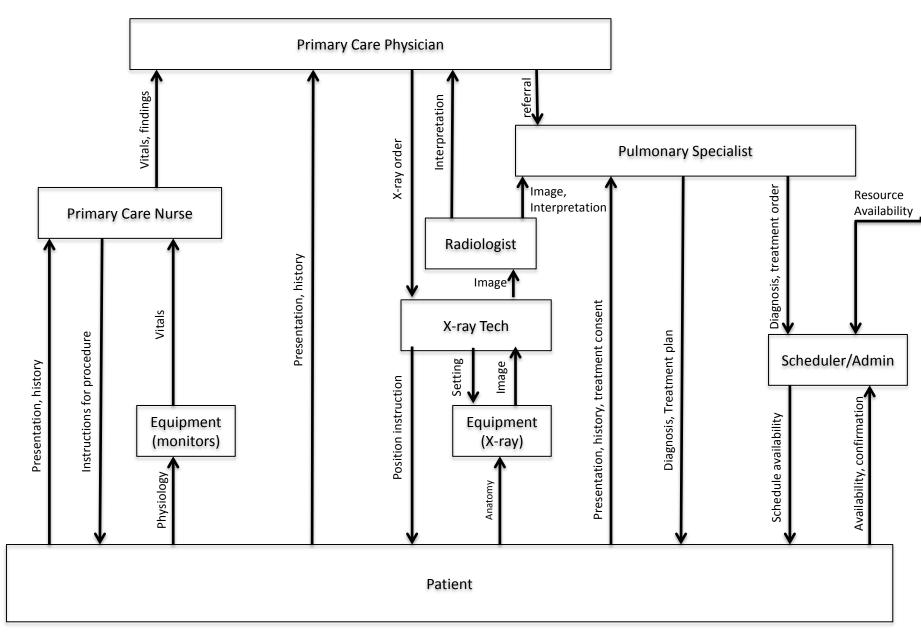
Biopsy Procedure

Recovery

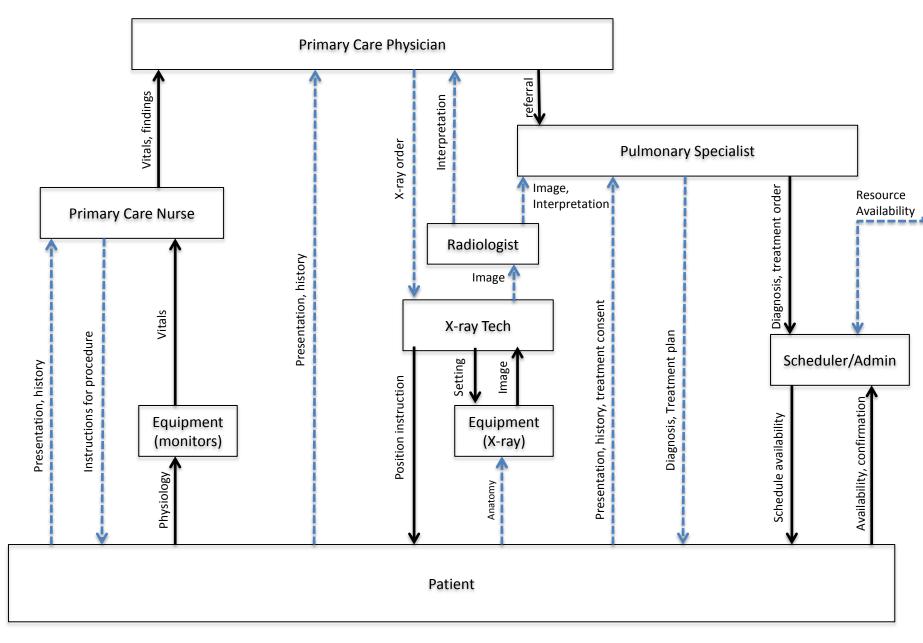


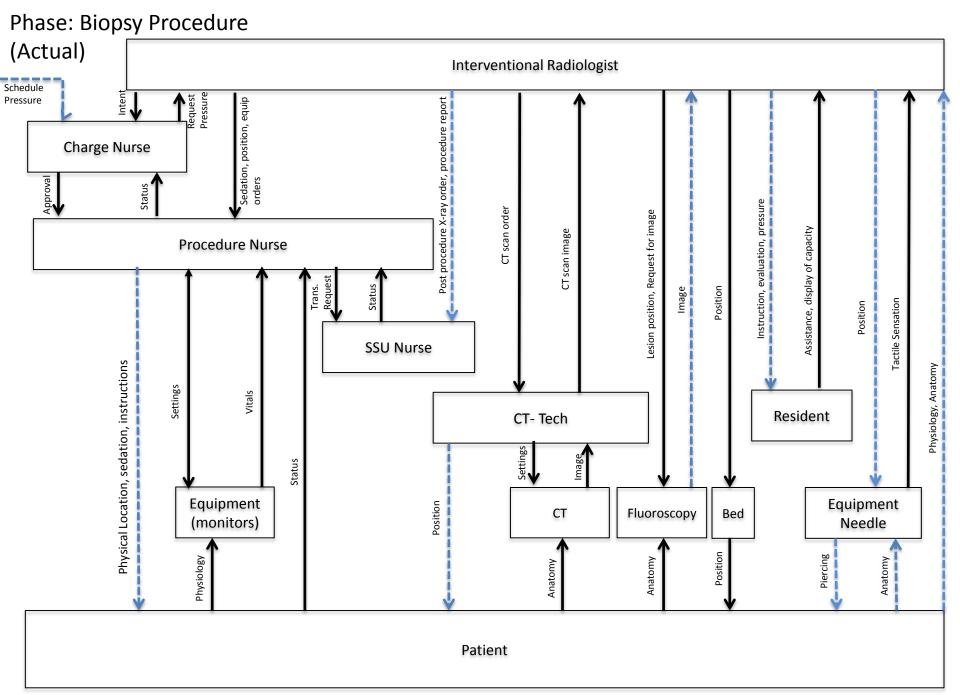
Control Diagram created for each phase displayed in appendix As Designed and Actual

Phase: Diagnosis (Design)

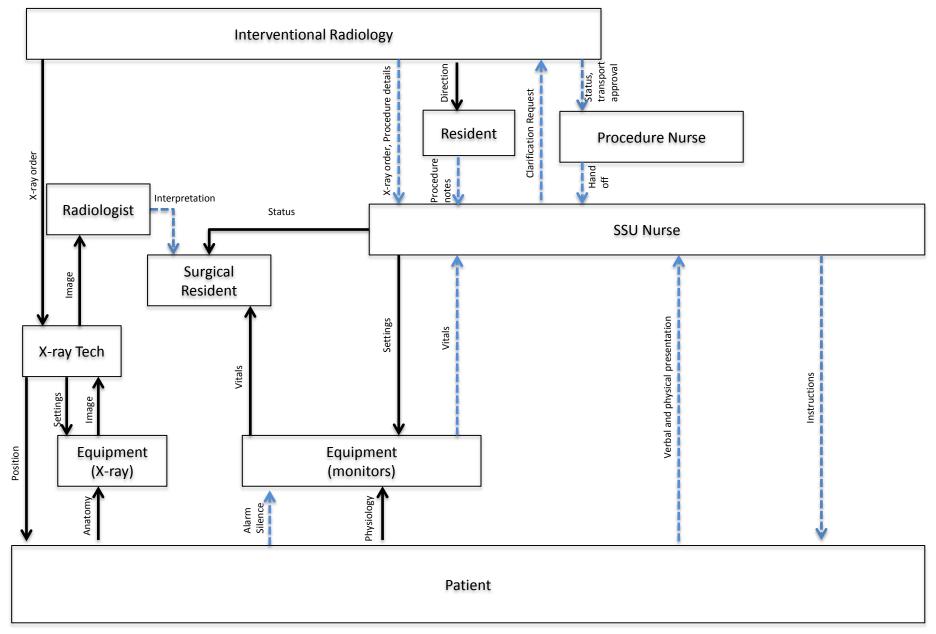


Phase: Diagnosis (Actual)





Phase: Recovery (Actual)



Controller Analysis

Controllers

- Safety Requirements and Constraints Violated
- Failures and Inadequate Controls
- Physical Contextual Factors

Case Limitations

- Standard Font Details from case
- Italics Inferred based on observations from a Boston Teach Hospital
- Questions for further investigation noted

Patient

Safety Related Responsibility

- Provide accurate and complete information (physical and verbal clinical presentation)
- Provide consent and acknowledge understanding of the diagnosis, treatment plan as well as instructions for the procedure
- 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 remained still during the procedure
- Patient silenced the alarming oximeter during recovery in the SSU
- Patient may have been coughing or attempted to get out of bed while in the SSU

Process Model Flaw

- The patient most likely did not know what information was relevant for pneumothorax risk factors
- The patient may not have known he was at a high risk of pneumothorax
- The patient may not have understood the diagnosis or what pneumothorax was
- The patient may not have understood the requirements for the biopsy procedure
- The patient thought the pain he was experiencing was normal and not due to a complication
- 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 have had additional questions that he did not ask due to time pressure, embarrassment, or expectation that he should have known the answer
- The patient may have received 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

<u>Patient</u>

Safety Related Responsibility

Follow instructions provided by Health Care Professionals

Unsafe Decisions and Control Action

- May not have remained still
- Silenced the alarm
- **Process Model Flaw**
- Thought pain was normal
- Did not realize that he was in need of immediate medical attention
- Context
- May have had additional questions that he did not ask
- Expected nurse knew his condition

Patient

Questions about the patient

These questions were produced during the CAST analysis but were omitted from the case study report:

- Was all-relevant information conveyed to the providers that could have helped identify risk factors indicating that the patient was more susceptible to a pneumothorax?
- Was the patient at a high risk of pneumothorax due (for example, co-morbidities)
- What was the patients overall health state? Where there co-morbidities present?
- How much did the patient understand?
 - Did the patient have additional questions that he did not ask?
 - Did he feel time pressure?
 - Was he embarrassed to ask, feeling that he should understand what was being said?
 - Was there medical terms used, such as pneumothorax that he did not understand but did not ask for an explanation?
 - What was the patient's level of education and comfort with English?
 - Was the patient under the influence of medication when instructions were given to him?
- What was the patient's previous medical experiences
 - Had the patient received previous treatment and therefore did not perceive the risk in this procedure?
- What was the patients mental state of mind when the risk of the procedure and instructions where given?
 - It is very reasonable that the patient may have had strong emotions at the time, having been told he may have lung cancer. How did this affect the patient's ability comprehend the information told to him?
- What instructions did the patient receive?
- Was the patient informed of the pneumothorax and symptoms to be aware of?
- How was information conveyed to the patient?
 - Was any of the information given to the patient in writing or only conveyed verbally? If verbal only, how
 accurately did the patient remember once leaving the office?

Patient

Sample questions

- What instructions did the patient receive?
- Was the patient
 - Affected by sedation medication when instructions were given to him?
 - informed of the pneumothorax and symptoms to be aware of?

Interventional Radiologist

Safety Related Responsibility

- Determine the position of the patient in the CT scan based on the reported location of the nodule and the x-ray.
- Identify the size and location of the nodule from the CT scan image
- Select needle size for the procedure
- Predict/determine a "safe" pathway to the nodule to avoid harm to the patient when needed is traveling to the nodule
- Insert the needle into the patient's chest along a safe pathway avoiding harm to lungs or other organs to the nodule, remove sample of nodule
- Retract the needle along a safe pathway avoiding harm
- Analyze the post CT scan to assess the patient for the existence of a pneumothorax following the procedure.
- Order a follow up x-ray to confirm the status of the pneumothorax
- Ensure the procedure notes are have been included in the patient chart and are included in the EMR system as well as complete the paperwork for the diagnostics lab, or assign the resident to complete these activities
- Teach the resident the biopsy procedure method while assessing the skillset of the resident

Unsafe Decisions and Control Action

- Allowed positive-pressure air to enter the negatively pressured pleural space, disrupting this natural vacuum
- Was not available or unable to speak with the recovery nurse
- Estimated the pneumothorax as 10% based on the CT scan

Process Model Flaw

- The Radiologists expects the safe path visualized on the CT scan image remains intact, as the needle is being inserted and removed. This pathway may have been compromised due to external or internal patient movement
- The Radiologist estimated the pneumothorax to be 10% in size based on the appearance of the 2D image available on the CT scan.

Context:

- Pneumothorax occur ~40% of the fine needle biopsies performed, with 17% requiring chest tubes. The exact mechanism that results in the pneumothorax is not understood by the medical profession. It is not know in this case what caused of the pneumothorax.
- The fluoroscopy provides the clinician point in time image of the patient and the number of images taken must be minimized to avoid patient harm from radiation
- After the needle is inserted, the patient's body may have moved (external movement). In addition, their lungs move as they are breathing (internal movement).
- May have been in a procedure and unable to be reached by the recovery nurse
- The sizing of the pneumothorax in the case is indicated as 10% initially. While a numeric value is assigned, the evaluation is not quantitative as one might assume and the appearance could be impacted by the patient's position.

Interventional Radiologist

Safety Related Responsibility

- Predict/determine a "safe" pathway
- Insert the needle along a safe pathway
- Ensure necessary details are in the chart

Unsafe Decisions and Control Action

Punctured lung

Process Model Flaw

- Expected the safe path visualized to remain intact
- Estimated the pneumothorax to be 10%

Context:

- Pneumothorax occur ~40%, with ~17% requiring chest tubes
- Patient movement may have occurred
- 10% sizing

Interventional Radiologist

Sample questions

- Could the pneumothorax have been larger than originally reported?
- Were there schedule or other pressures at the end of the procedure?
- Where there any interruptions or distractions during the procedure?
- Why was the radiologist not available to communicate with the SSU nurse?

SSU Nurse

Safety Related Responsibility

- Participate in an effective patient handoff before and after the procedure with the procedure nurse including confirming information regarding the patient status and post procedure notes were received
- Set up the monitors when the patient arrives at the SSU
- Provide necessary instructions to the patient while in the SSU
- Monitor the patient's status for signs of worsening condition
- Contact the Radiologist responsible for the care of the patient if required
- Ensure the Radiologists order for the follow up x-ray is performed as needed (to be done 2hours after the procedure unless condition worsens)

Unsafe Decisions and Control Action

- Did not review the procedure notes in the patient chart until there was a sign that the patient was in distress
- Was unable to interpret the post procedure notes from the patient chart
- Did not appear to treat the patient as a high risk patient
- Did not check the patient status for 45 minutes after initially leaving the patient once the handoff and equipment set up was complete.

Process Model Flaw

• During the 45 minutes the patient was unattended, the SSU nurse believed that the patient's status was normal

Context

- The SSU nurses are responsible for a multiple patients
- The nurse assumed that the oximeter would alarm if the patient had declining respiratory function
- The patient denied having any pain when he arrived

SSU Nurse

Safety Related Responsibility

- Effective handoff with SSU nurse
- Instruct patient
- Monitor patient status

Unsafe Decisions and Control Action

- Did not review the procedure notes until patient was in distress
- Did not treat the patient as high risk
- Unaware of patient status for 45 minutes

Process Model Flaw

• Believed patient status was normal

Context

- Patient denied having any pain at handoff
- Assumed that the oximeter would alarm

Questions about the SSU Nurse

These questions were produced during the CAST analysis but were omitted from the case study report:

- What was the environment of the SSU area that the day of the procedure?
- What was the hand off policy between the SSU area and the procedure nurse?
- What caused the nurse not to confirm the status of the patient for 45 minutes when the case states that patients are usually evaluated every 5 minutes?
- Why did the SSU nurse not hear the oximeter beeping? Did it sound only once before being completely silenced? Were there other nurses in the SSU area who heard the alarm or saw the patient appear to be in discomfort? If they did, did they take any action? If not, why not?
- Was the SSU nurse occupied with another patient or activities during the 45 minutes?
- Why was the nurse not able to reach the Interventional Radiologist? Why was the resident not called when the Radiologist was not available?
- Were there alterative actions that could have been taken to reduce the harm to the patient besides requesting a chest x-ray? Was the chest x-ray performed a mobile x-ray or did the patient have to be transported? How long did it take to get the x-ray and results?
- Did the nurse order the X-ray or did that order already exist?
- Who did the nurse contact when unable to reach the radiologist?

SSU Nurse

Sample Questions

- Hand off policy?
- Why the 45 min delay?
- What were the details of the alarm?
- Why was the Radiology department unreachable?

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

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Ongoing & Future Work

Complete CAST analysis will be available in masters thesis

Future Goals:

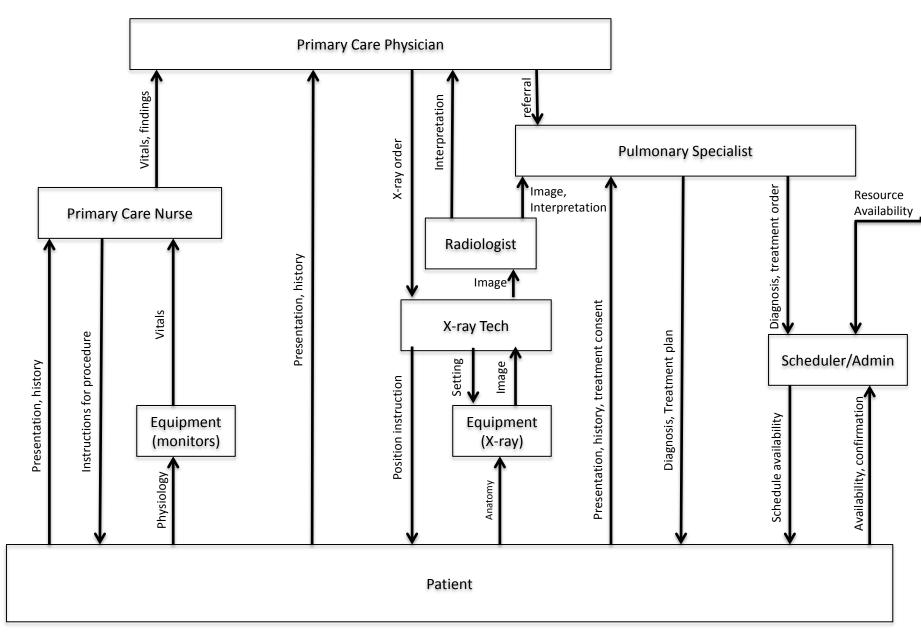
- Enable the application of CAST to "real" accidents
- Increase the use of STAMP throughout biomedical & healthcare community

Thank you

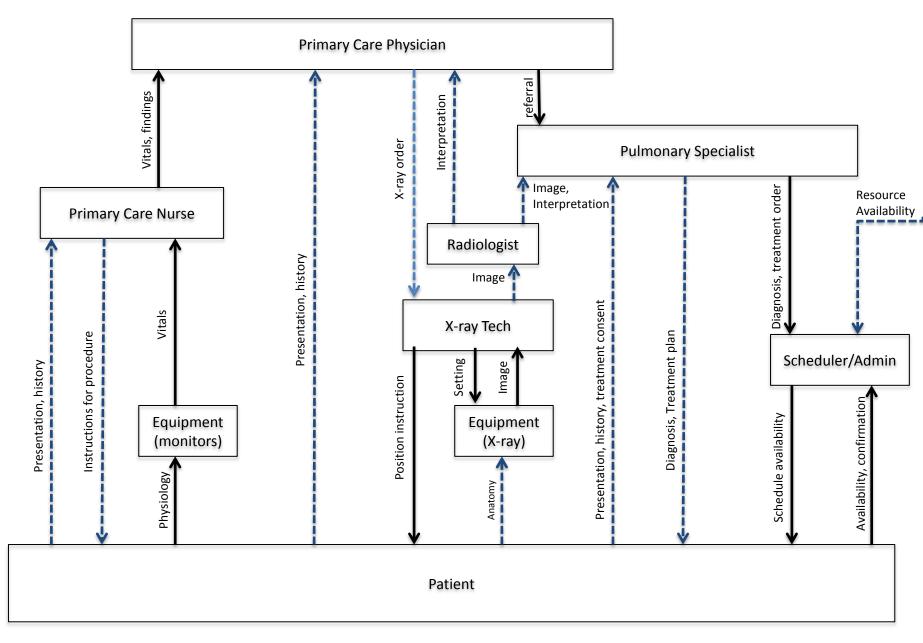


Appendix

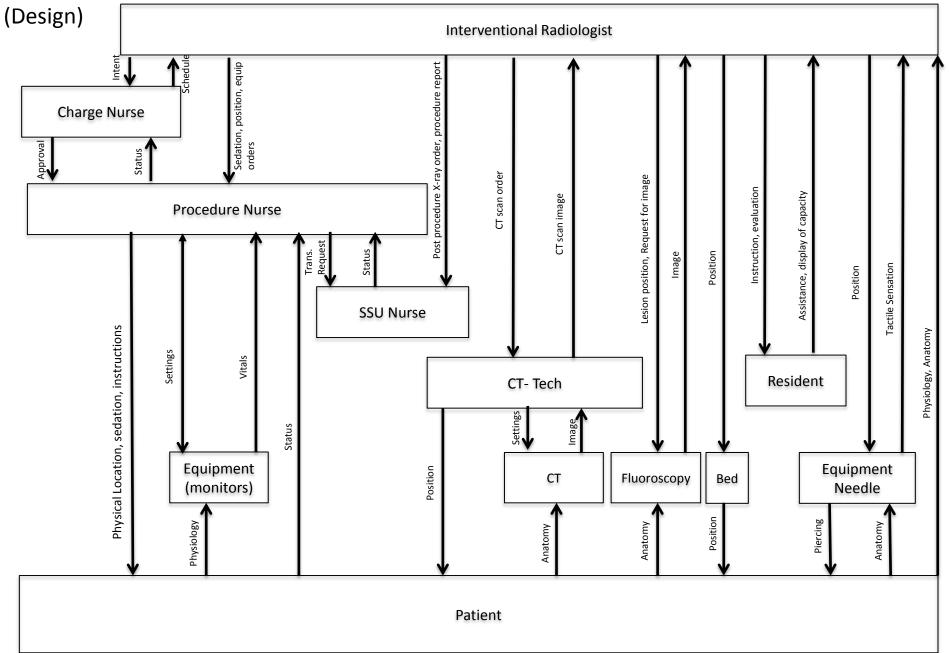
Phase: Diagnosis (Design)

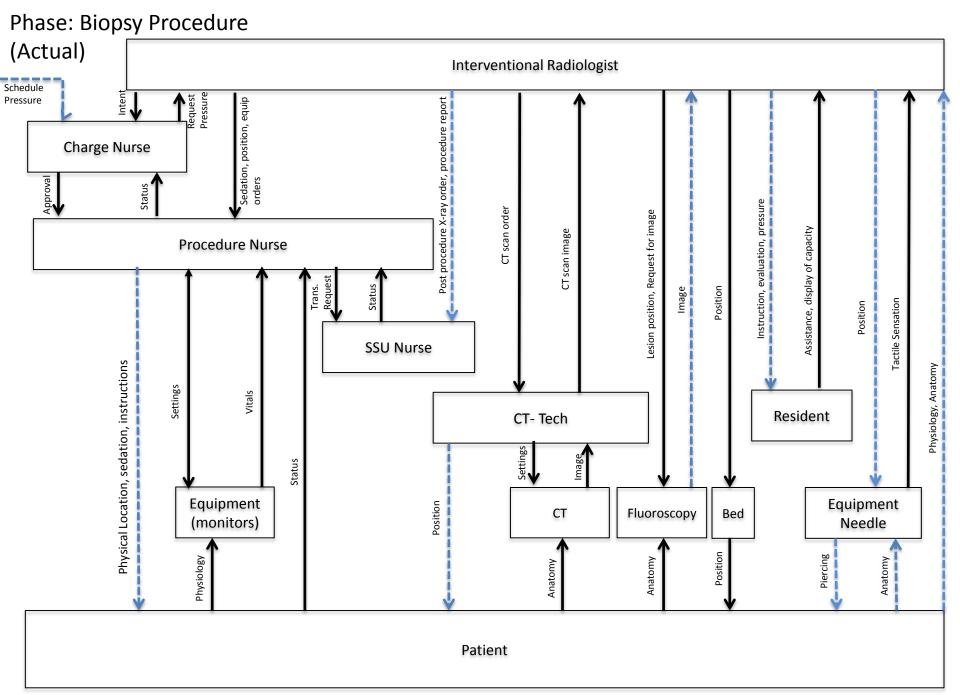


Phase: Diagnosis (Actual)

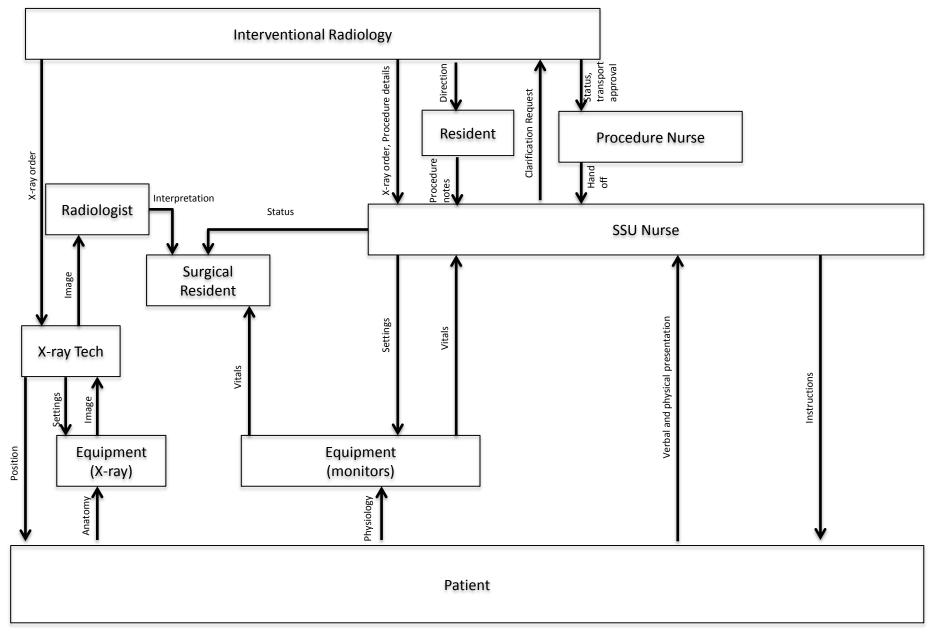


Phase: Biopsy Procedure





Phase: Recovery (Design)



Phase: Recovery (Actual)

