Application of CAST to Hospital Adverse Events

by

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ABSTRACT

Despite the passage of 15 years since the Institute of Medicine sought to galvanize the nation with its report *To Err is Human*, the authors' goal to dramatically improve the quality of healthcare delivery in the United States has yet to be accomplished. While the report and subsequent efforts make frequent reference to the challenges of designing and obtaining system safety, few system tools have been applied in the healthcare industry. Instead, methods such as root cause analysis (RCA) are the current accepted industry standards. The Systems Theoretic Accident Model and Processes (STAMP) is a model created by Dr. Nancy Leveson that has been successfully applied in a number of industries worldwide to improve system safety. STAMP has the capability to aid the healthcare industry professionals in reaching their goal of improving the quality of patient care.

This thesis applies the Causal Accident Systems Theoretic (CAST) accident analysis tool, created by Dr. Leveson based on STAMP, to a hospital accident. The accident reviewed is a realistic, fictionalized accident described by a case study created by the VA to train healthcare personnel in the VA RCA methodology. This thesis provides an example of the application of CAST and provides a comparison of the method to the outcomes of an RCA performed by the VA independently on the same case.

The CAST analysis demonstrated that a broader set of causes was identified by the systems approach compared to that of the RCA. This enhanced ability to identify causality led to the identification of additional system improvements. Continued future efforts should be taken to aid in the adoption of a systems approach such as CAST throughout the healthcare industry to ensure the realization of the quality improvements outlined by the IOB in 1999.

Thesis Supervisor: Nancy G. Leveson
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Chapter 1: Introduction

"When patients enter a hospital, they reasonably assume that their treatments will make them better, or, at the least, not make them worse."
-Dr. Lucian Leape MD [1]

Motivation

Stakeholders throughout the modern healthcare system in the United States have a common goal; they want the healthcare system to be safe. Medical doctors pledge to follow the Hippocratic oath to "First, do no harm" and nurses often pledge to follow a similar Nightingale Pledge [2]. Similar to medical providers, clinical engineers, technicians, medical device designer engineers, and regulators do not set out to provide unsafe care. Also, the safety of healthcare is also highly personal. For most Americans, healthcare is not entirely avoidable and as Dr. Leape comments, patients assume that the care they receive will not result in harm. In addition to the common goal and vested personal interests, a number of individuals and organizations have attempted to improve the safety of the healthcare system. For example, the Institute of Medicine (IOM) published its pivotal 1999 report *To Err is Human*, a watershed in the industry, which presented alarming statistics of healthcare safety and called for industry-wide reforms. Around the same time, the Department of Veterans Affairs (VA) created the VA's National Center for Patient Safety, which conducted a patient safety initiative to improve the safety of care at the VA's facilities [3]. In the following years, a number of initiatives and policies have continued to focus efforts on improving the safety of the national healthcare system. Despite the increased effort, reports indicate that the safety of the healthcare system still remains inadequate [3].

Efforts have achieved limited success in part because modern US healthcare is a complex, sociotechnical system that is composed of numerous stakeholders and technology. As a complex system, it is inherently difficult to manage and improve in part because of the number of components as well as the degree of coupling. The coupling between system elements increases the difficulty in predicting emergent properties such as system safety. In addition, the healthcare system is dynamic and changes over time. Accident investigations therefore are vital to the effort to improve the safety of the system as investigators strive to both understand why an accident occurred and identify the areas that need to be improved to prevent future accidents. While the IOM outlined changes needed to improve safety, including increased reporting, it did not include a recommendation for changes to the investigation methodology. The root cause analysis investigation approach has remained standard across the industry throughout the past two decades including at the VA.

An alternative system safety approach for accident investigation, the Causal Accident System Theoretic tool (CAST), was developed by Dr. Nancy Leveson and applied in many industries worldwide. CAST is a tool based on the Systems-Theoretical Accident Model and Processes (STAMP), a model created using system theory [4].

Research Objective

The goal of this thesis is to provide a demonstration of the application of CAST, a system based tool, to healthcare. This thesis will provide an example of the CAST tool applied to a hospital accident case. In addition, the outcomes of the CAST analysis will be compared to the outcomes achieved by an independent application of the VA Root Cause Analysis. The intent of the analysis is to increase awareness of the system-based tool and to provide an example for instruction and evaluation of the CAST method for the healthcare industry.

This thesis is organized as follows. Chapter 2 reviews the literature related to the modern healthcare system and accident investigation tools. Chapter 3 describes the methodology used. Chapter 4 presents the case study analyzed using RCA and CAST. Chapter 5 presents the findings of the RCA analysis conducted by the VA. Chapter 6 presents a detailed example CAST analysis. Chapter 7 provides a qualitative comparison between the results of the RCA and CAST analyses. Chapter 8 concludes and offers recommendations for future research.

Chapter 2: Literature Review

Evolution of the Modern Healthcare system

Shift in Management

As Richard Bohmer describes in *Designing Care*, medical knowledge has increased significantly since the 1970s both in terms of volume and specificity [5, pp. 26]. This knowledge increase fueled major evolutions in the overall healthcare delivery system. For example, expanded knowledge led to an increase in the level of specialization among medical practitioners. Patients have also experienced increased access to information, which has shifted their role from passive recipients of healthcare to actively involved and influential stakeholders. Likewise, knowledge and innovation have resulted in an increasing amount of technology in the delivery and management of healthcare. As a result, the overall healthcare system is increasingly adding complexity as it continues to grow and evolve [5].

Bohmer also attributes major evolution of the organization and management of the healthcare industry to the increase of medical knowledge. While in the past, Bohmer indicates there was separation between the care provided and management of the healthcare facilities, this has clearly shifted. The current industry has evolved so that delivery organizations are based on healthcare management,) a result of blending the roles of management and business decision-making with the practice of medicine. This blending occurred in part because increased knowledge allowed for an increase in performance and outcome measurements, as well as an increase in efforts for standardization through the creation of standard operating procedures (SOPs). Standardization has occurred in some areas, which Bohmer describes as linear or sequential applications of care, where the diagnoses and treatment of patients is well understood and can be routinized. However, many areas of the ever-expanding industry remain iterative, and suspected diagnoses are evaluated with tests and treatments which are then further refined and evaluated, without a clear "right path" being apparent [5, pp. 19-49].

Policy Shaped Evolution

In addition to the evolution resulting from increased medical knowledge, national policy changes also continually affect the evolution of the modern healthcare system. For example, legislation in 1965 created the Centers for Medicare and Medicaid Services as well as established the Joint Commission as a national hospital accreditor [6]. By assuming a major increase in the burden of the cost of healthcare delivery through the creation of CMS, the federal government increased its incentive to both monitor and influence the quality and safety of the care provided. As a result, hospitals are required to have quality systems in order to be accredited by the Joint Commission, which affects the reimbursement provided by CMS for care provided. Quality systems include both incident investigation and processes for reporting and tracking investigations and improvement efforts. The Joint Commission and the Veterans Affairs hospitals established their quality system guidelines around root cause methodology [7, 8].

Increased Reporting
Surveillance and reporting continued to increase over time as public and private entities increased the resources dedication to tracking and improving healthcare safety. For example, the Institute of Medicine (IOM), a non-profit organization that published *To Err is Human,* was established in 1970 and the Agency for Healthcare Research and Quality (AHRQ), formed by Congress in 1989, creates annual National Healthcare Quality Reports to monitor the healthcare system [9]. Entities funded by both public and private sectors were also created, such as the National Quality Forum (NQF), founded in 1999, which authored the list of Serious Reportable Events. The NQF indicated that occurrences of these events should be documented and reported by hospitals [10]. More recently, in 2005, the Federal Patient Safety and Quality Improvement Act created Patient Safety Organizations (PSOs), in an additional attempt to increase reporting and analysis of incidents among hospitals. By allowing protection from legal repercussions, PSOs are intended to promote increase sharing of incident information [28]. Despite the efforts of these organizations and numerous others, tracking and reporting is not standardized across the industry; no nationwide reporting tools currently exist, while state-specific reporting tools exist in approximately half of the country [12].

Economic Influences
In addition to added reporting, hospitals have also begun to directly shoulder more of the economic burden of medical errors as insurances companies have shifted to reduce or stop reimbursement when errors occur resulting in harm. CMS reduced reimbursement to hospitals when errors occur that are considered avoidable (sometimes referred to as Hospital Acquired Conditions) and the Patient Protection and Affordable Care Act further increased these economic incentives [13]. It has meanwhile been reported that hospitals have identified a financial benefit to employing resources dedicated to patient safety [16].

Healthcare System Safety

Quality of Healthcare in America Project
In 1998, the IOM undertook the Quality of Healthcare in America Project [14]. The project's goal was to improve the quality of the nation's healthcare system in the following decade. Originally intending to produce a series of reports, the project succeeded in publishing two major reports, the first, *To Err is Human*, in 1999, and the second, *Crossing the Quality Chasm* in 2001 [14,15]. The first report was intended to be a marshaling event to rally the nation around the need to improve the quality of healthcare delivery in the United States. The IOM report brought to light alarming statistics on accidents in hospitals.

The IOM provided a view of public opinion of the safety of the healthcare system at the time of its publication. The public opinion captured by a poll conducted by the National Patient Safety Foundation revealed that the public perception of healthcare was that it was "moderately safe" giving it a score of 4.9 on a scale from 1 (not safe at all) to 7 (very safe). At the time the public viewed hospital care as safer than nuclear power or food handling, but less safe than air travel [14, pp. 42]

The IOM reported that 98,000 deaths/year were attributed to medical errors that were viewed as avoidable [14, pp. 31]. To frame the perception of magnitude, the IOM provided the following relative annual death statistics:

- Medical Errors (98,000)
- Motor Vehicle Accidents (43,458)
- Breast Cancer (42,297)
- AIDs (16,516) [14, pp.26]

The cost to the nation associated with preventable medical errors was also quantified by the IOM as ranging between $17-29 billion [14, pp.27]. The effects of the high number of medical errors went beyond direct costs, including:

- Lost trust
- Decreased healthcare provider satisfaction
- Lost worker productivity
- Decreased school attendance
- Decreased population health status [14, pp. 41]

In additional to increasing awareness and quantifying the scope of the problem, the report highlighted the systemic nature of medical errors [14, pp. 49-67]. Although the report highlighted the need to shift the focus of accident investigations away from blaming providers and acknowledged the limitations of the root cause methodology, a system approach was not included in the IOM's main recommendations, which instead included:

1) The creation of a National Center for Patient Safety
2) A national mandatory reporting system
3) Increased FDA pre- and post-marking processes to improve the safety of drugs [14, pp.5-15]

VA National Center for Patient Safety

The VA's National Center for Patient Safety (NCPS) was established in 1998. In the same year, the NCPS published a survey of patient safety that included the finding that 73% of the VA staff members surveyed "either strongly disagreed or were neutral towards the importance of patient safety" [16]. The NCPS also implemented a patient safety initiative (PSI) in 1998. The initiative resulted in the implementation of three systems that included both a root cause analysis system and a patient safety reporting system (PSRS) [3]. The role of the patient safety managers (PSM) was also created; their responsibilities included reporting adverse events and near misses, creating RCA teams, and communicating safety concerns to other VA facilities [3].

Safety Remains a Concern

While *To Err is Human* succeeded in increasing awareness focusing efforts on medical errors, resulting improvements were seen as incremental [12,15]. In spite of the acknowledgement that "system failures cause most injuries," methods such as root cause analysis are still used today rather than a systems approach. Fifteen years have passed since the IOM fought to rally the nation to improve the quality of healthcare delivery, and yet key opinion leaders including James Bagian, MD, PE, director of the NCPS, have

indicated that as recently as 2005, "very little has changed"[16]. Supporting this assessment, research conducted by the Commonwealth Fund found that in 2011, "1 in 5 adults [surveyed] reported they or their family members ended up with an infection or complication as a result of medical care or said that a health care provider made a surgical or medical mistake [within the past 2 years]" [17].

Accident Causality Models

The ability to create and maintain safe systems is a universal goal that transcends industry affiliation. System designers and operators depend on forming an understanding of how and why accidents occur in order to improve system safety. This understanding is broadly termed an accident causality model. A simple linear causality model was described in the early 20th century and remains pervasive today, creating the foundation of a number of design and accident investigation techniques. The model assumes that a chain of failure events causes an accident.

A founder of one of the earliest described chain of events models, H. W. Heinrich published a description of his Domino Model in 1931. Heinrich's model explains accidents as a series of events or "dominos." In this model, an event, usually a failure, occurs, which then leads to another, which leads to another, cascading eventually to the accident under investigation. The events were assumed to be caused by an operator or worker error. A similar chain of events based causality model, the Swiss Cheese Model, was described by James Reason who attempted to include more than operator error. However, operator error remained the last event in the chain. The Swiss Cheese Model maintained the core elements of the Domino Model. These and other variations of chain of events models are likely appealing because of their simplicity, which allows for the model to be easily conveyed and comprehended [4, pp. 15-38].

The chain of events model has formed the foundation of many hazard analysis and accident investigation techniques. These methods include Root Cause Analysis, Fault Trees, Probability Risk Assessments, Failure Modes and Effects Analysis (FMEA), which are all based on the core concepts of the chain of events causality model [18].

The appeal of a simple model is readily acknowledged; however, the utility has proven to be limited. A chain of events model can allow for seemingly seamless translation from a verbal storyline of an accident, with the familiarity of a novel's beginning, middle, and end. There is comfort in believing that finding and addressing the "root cause" can prevent accidents [19]. Unfortunately, the fundamental model is too simplistic to capture complex sociotechnical relationships because the events (represented by falling dominos or by holes in cheese slices) are treated as independent, an assumption that is not effective for describing complex systems such as modern hospitals. Reliability, or component failures may be unmasked by this approach for example, but component interactions are not [4].

Recognizing the need for a more nuanced causality model capable of capturing additional complexity, Dr. Leveson established the Systems-Theoretical Accident Model and Processes (STAMP). Leveson also created tools based upon STAMP including a tool for evaluating

system design for safety (STPA) as well as a tool for accident analysis (CAST) [4]. In a departure from the historic chain of events approach, STAMP is a causality model based on systems theory. System theory includes emergent properties, a fundamental recognition that due to coupling between the individual elements, a system is more than a sum of its parts. Safety is an emergent system property and therefore cannot effectively be treated with the decomposition approach of traditional chain of events model [18]. Therefore, even if system designers and investigators fully characterize and can correctly predict the behavior of components as they act individually, due to coupling effects, this knowledge is not sufficient in characterizing and predicting the emergent behavior of a system containing those components. Translated into the healthcare domain, this is the reason why a system comprised of all "safe" components does not ensure a "safe" system.

System-Theoretical Accident Model and Processes (STAMP)

To provide a framework to allow for a systems approach, STAMP leverages the basics of control engineering. By modeling the system of interest with a hierarchical control structure, the component relationships can be represented and incorporated into the system analysis [4].

Hierarchical Control Structure

Control structures can be used to provide a visual representation of the components of a system and their relationships to each other. Controllers are system elements that have the ability to issue a command, termed a control action. In control structure diagrams, controllers are displayed as labeled boxes, which are located along the vertical axis according to their level of control. A simple diagram is shown in Figure 1 to illustrate the representation of a single controller acting upon a single controlled process. The controller in this example is an insulin pump, while the controlled process is the physiology of the person with diabetes (PWD), specifically their blood glucose. The arrows connecting the controller and the controlled process indicate the control action as well as the feedback. In this example, the control action is the injection of insulin and the feedback is the measured reading of the PWD's blood glucose.

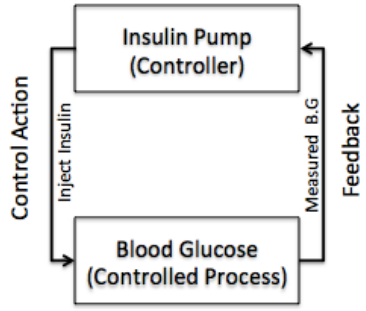


Figure 1: Simple Control Structure Example with 1 Controller

As more controllers are included in the diagram, the hierarchy begins to emerge and is displayed by the vertical location of the controllers. Expanding the insulin pump example, the PWD who is wearing the insulin pump can be included in the control diagram. As a controller, the PWD has the responsibility to supervise the medical device, similar to the role of a plant controller supervising the equipment in a process plant. In this example, the PWD monitors the feedback from the insulin pump including the measured blood glucose and the insulin injection rates and makes control decisions on configuring the device.

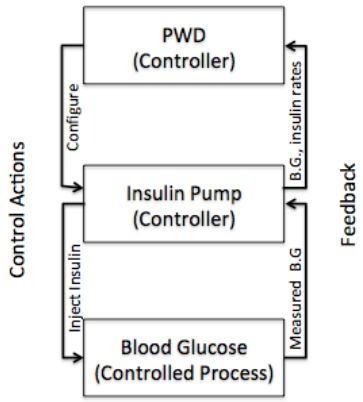


Figure 2: Example of 2 Controllers displayed in a hierarchical control diagram

As the control diagram is expanded in Figure 2, the placement of the controllers along the vertical axis maintains the hierarchical relationships. The placement of system components along the horizontal axis can be adjusted for readability.

The creation of the control diagram is an important feature of the CAST analysis in part because it can help the investigation team build their understanding of the system, including the relationships of the controllers. The control diagram also provides a framework for the investigators to aid in developing an accurate understanding of why an incident occurred, and importantly, to identify what changes are needed to prevent an accident reoccurrence. The control diagram also plays a very valuable role as a communication tool during and after the investigation.

Process Models, Mental Models, and Algorithms

An additional key concept used in STAMP is the recognition of the decision-making process of the controllers. As depicted in Figure 3, controllers receive input, which may be a control action from another controller, feedback from a controlled process, or input about the external environment, for example. The process model (also referred to as a mental model for human controllers) represents the controller's understanding of the controlled process. This includes the current state and system dynamics as well as the effect of control actions on the controlled process. The controller's process model can be influenced by the inputs received from the rest of the system, and the broader system context. In addition, the controller has an algorithm, which is used to derive the control action from the given inputs and process model [4, pp. 41-45].

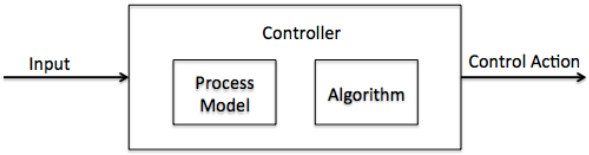


Figure 3: Control actions are the result of the process model and algorithm of the controller

As described by Leveson in *Engineering a Safer World*, accidents are often the result of a controller's inaccurate mental model, which translates to unsafe control actions [4, pp 88]. The example below from *Engineering a Safer World* demonstrates how these fundamental concepts can be visualized in a control structure. This generic example of two controllers, including one human and one software controller, demonstrates the ability of the control diagram to serve as a foundation for understanding system interactions. In addition to demonstrating how external inputs for controllers may include information about the

environment or training procedures, Figure 4 also demonstrates how controlled processes may have multiple process inputs.

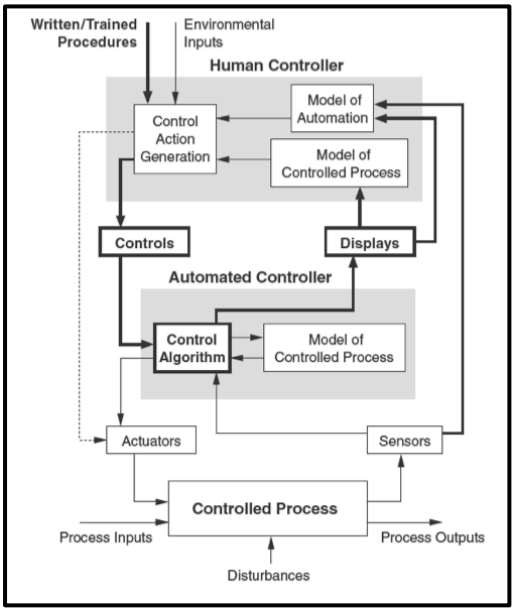


Figure 4: Demonstration of Control Diagram Elements [4, pp. 296]

Safety Constraints

STAMP uses control theory as described above to allow for a systems approach to understanding safety as an emergent system property. In the STAMP model, accidents result when there is inadequate control. For example if necessary safety constraints are not enforced, this may allow unsafe control actions to occur. In the hierarchical control diagram, each level of the hierarchy serves to constrain the level below [4, pp. 80].

Causal Accident System Theoretic (CAST)

CAST (Causal Accident System Theoretic) provides an accident analysis framework for accident investigators to apply the systems approach of STAMP. The tool can enable investigators seeking to understand the causes of the accident and identify necessary system improvement opportunities. Following the CAST framework, the investigator conducts a broad analysis of the relevant sociotechnical system. By examining the system safety control structure, the analyst is then able to locate weaknesses in the control structure and therefore is not limited to only component failures or single point failures. The focus of the CAST analysis technique is on the question "why" rather than simply "what happened." The investigator seeks to answer, "Why did the accident occur?" For example, these questions include:

- *Why did the human operators act as they did?*
- *Why did the physical or software components behave as they did?*
- *Why did the process or mental models of the controllers become misaligned with the true state of the controlled process and proceed to take unsafe control actions?*

The method begins with the definition of the accident and system hazards involved in the investigation. These initial steps allow the analyst to establish a clear charter for the CAST analysis. In the STAMP methodologies, an accident is defined as: "an undesired and unplanned (but not necessarily unexpected) event that results in (at least) a specified level of loss" [18, pp. 175]. The system hazards are then defined as: "A system state or set of conditions that, together with a particular set of work-case environmental conditions, will lead to an accident (loss)" [4, pp.184]. The following steps include the creation of the system control structure as well as a careful examination of the system physical and control structure. Contributions of the broader sociotechnical system are also examined.

The steps of the CAST method will be demonstrated in the application presented in Chapter 6 and are summarized as follows [4, pp. 350-351]:

1. Identify the system(s) and hazards(s) involved in the loss.
2. Identify the system safety constraints associated with that hazard
3. Document the safety control structure in place to control the hazard and enforce the safety constraints.
4. Determine the proximate events leading to the loss
5. Analyze the loss at the physical system level.
6. Moving up the levels of the safety control structure, determine how and why each successive higher level allowed or contributed to the inadequate control at the current level.
7. Examine overall coordination and communication contribution to the loss.
8. Determine the dynamics and changes in the system and the safety control structure relating to the loss and any weakening of the safety control structure over time.
9. Generate recommendations.

A more detailed description of each step and examples from other industries can be found in *Engineering a Safer World* [4, pp. 349-390].

Healthcare Root Cause Analysis

Root cause analysis (RCA), based on the chain of events causality model, seeks to identify the main causes that if eliminated would have prevented an accident. The goal of the technique is described as defining "what happened, how it happened, and why it happened" [20]. Following the domino model imagery, causes that are most closely linked to the resulting harm are often referred to as immediate harms, direct harms, or first-level problems. Farther removed causes may be referred to as higher-level problems or root causes [20,21]. Used across many industries, the method has several similar variants all created to aid investigators based on these main concepts.

RCAs in healthcare typically involve a Cause-Effect Tree in which the main loss is placed at the top of the tree. The goal of the team is then to define the branches of the tree, first by identifying secondary causes and continuing until the team believes they have identified root causes. Typically 2-3 causes are then identified by the team as being considered the

most important for prevention of future incidents and these become the resultant "root causes" of the accident [19].

The process used to identify the causes in which to 'fill out the tree' may vary. In the simplistic form, teams may proceed to use a 5 Why technique, quite literally asking "why" five repeated times. Other teams may use group brainstorming or other propriety guidelines [19,21]. The identified root causes are then typically classified and assigned estimated severity or probability of occurrence estimates [19].

At the VA, the National Center for Patient Safety (NCPS) provides specific guidelines for conducting RCAs. The VA implemented its current RCA system in 2000, replacing a former system referred to as the focused review. The goal of the new system was to shift to a "human factors engineering approach" [3]. The RCA teams at the VA, established by the Patient Safety Managers, are provided Triage Cards™ containing 78 questions which where developed by the NCPS as RCA cognitive aids [3,16]. The initial triage questions include:

- "Were issues related to patient assessment a factor in this situation?
- Were issues related to staff training or staff competency a factor in this event?
- Was equipment involved in this event in any way?
- Was a lack of information or misinterpretation a factor in this event?
- Was communication a factor in this event?
- Were appropriate rules/policies/procedures – or the lack thereof - a factor in this event?
- Was the failure of a barrier designed to protect the patient, staff, equipment, or environment a factor in this event?
- Were personnel or personal issues a factor in this event?" [22]

Based on the team's answers to the initial triage questions, the Triage Cards™ then refer to additional questions in the following categories:

- "Human Factors - Communications
- Human Factors - Training
- Human Factors - Fatigue/Scheduling
- Environment/Equipment
- Rules/Policies/Procedures
- Barriers" [22]

Finally, to add additional structure to the RCAs, the NCPS defined "5 Rules of Causation" which are summarized as follows:

- "Rule 1: Root Cause Statements must clearly show the 'cause and effect' relationship.
- Rule 2: Negative descriptions should not be used in Root Cause Statements.
- Rule 3: Each human error must have a preceding cause.
- Rule 4: Violations of procedure are not root causes, they must have a proceeding cause." [22]

The Joint *Commission's Journal on Quality Improvement* contains the publication of examples of the application of the VA root cause approach to example cases [3]. The VA

RCAs are reported using the Patient Safety Information System (PSIS), which is also referred to, as "SPOT" [16]. The VA's process includes the Safety Assessment Code (SAC), used to prioritize additional effort in further investigation and action.

Chapter 3: Methodology

This thesis presents the outcomes from both a CAST and RCA analysis of a realistic, fictionalized accident. The accident is described by a case study created by the VA in order to train healthcare personnel in the VA RCA method. An excerpt of the case study is presented in Chapter 4.

A current VA Patient Safety Manager (PSM) conducted an RCA independently based on the accident described in the case and knowledge of typical VA procedures. The outcomes of the RCA and the recommendations identified by the PSM are presented in Chapter 5.

Concurrently, and prior to reviewing the results of the RCA, the author applied CAST using the details provided in the case and supplemented with observations from shadowing at a Boston teaching hospital. The detailed application and outcomes of the CAST analysis are presented in Chapter 6.

A qualitative assessment was conducted of the outcomes and recommendations resulting from the RCA and CAST applications. This assessment is presented in Chapter 7.

Chapter 4: VA Pneumothorax Case Study

As a leader in healthcare innovation, including patient safety, the Boston branch of the VA provided a sample hospital accident case study to be used in this thesis. The VA also provided example results from a root cause analysis of the case study, which will be presented in Chapter 5. The VA uses the accident case study as part of its employee training of its internal root cause accident investigation method. While the case does not represent a real accident, the details in the case are based upon realistic events, providing a suitable example for comparing the root cause analysis and CAST methodologies. Permission was obtained to include the case details presented in this chapter [23,24].

CASE Study: Pneumothorax

The following is an excerpt from the VA case study providing the details of the accident to be reviewed.

Event has occurred before --
Corrective actions at that time included: ***awareness training*** *for residents on service;* ***changed procedure*** *to have follow-up chest X-rays done within 2 hrs, unless there was a change in status*

Summary of the Event
A.B. is a 55-year-old male who was found to have a solitary pulmonary nodule in the upper lobe of his right lung detected on a chest X-ray, which was taken for possible pneumonia. He was subsequently seen by a pulmonary medicine consultant who advised a CT scan guided fine needle biopsy of the lung 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 stay hospital unit (SSU) on the morning of 11/1/99 to have a CT guided biopsy of the lung nodule by an interventional radiologist. After he was mildly sedated, the patient was transported to the radiology department. The patient also had an IV catheter inserted and cardiac rhythm and blood pressure monitors attached. The interventional radiologist was assisted by a radiology 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 chest wall into the nodule and aspirated tissue for the specimen. After the needle was withdrawn both clinicians noticed a ***small (~10%) pneumothorax*** *(air inside the chest cavity but outside the right lung), a common complication. The partially sedated patient had no complaints and denied any shortness of breath or pleuritic chest pain.*

After a 15-minute delay in transport, the patient was taken back to SSU, and monitors were reattached. In the next 30 minutes, no staff directly checked on the patient. During that time,

the pulse oximeter alarmed "low oxygen" repeatedly, but the patient began to silence the alarm as he previously had learned to do. The patient was surprised that he had right-sided chest pain with inspiration but he did not inform his nurse. He had rationalized this pain as a transient problem that would soon disappear.

Fifteen minutes later, the nurse noticed A.B. silencing the alarm and grimacing. After checking vital signs, viewing his pulse oximeter and looking at the chart, she requested a follow-up chest X-ray to be done ASAP. She also called the interventional radiologist. Blood pressure, heart rate, and respiratory rate were all elevated. The radiology notes in the chart were impossible to read, and she remembered that the resident usually dictated procedure notes.

The chest X-ray now showed a ***50% pneumothorax****. A thoracic surgery resident was called, and he inserted a chest tube to re-expand the right lung. The chest tube remained in place for 3 days due to a persistent air leak. The patient was discharged home 4 days after the biopsy procedure.*

Immediate Actions:

1) *An X-Ray was taken.*
2) *A chest tube was placed.*
3) *Patient was cared for with IV fluids, pain medications, and watched closely with a cardiac monitor and pulse oximeter.*
4) *The records kept in the radiology department were copied.*
5) *The pulse oximeter was sent to clinical engineering for testing.*
6) *The Facility Director was told about the case on 11/2/99 (24 hours after the event).*

Other Useful Data:

1) *Patients are usually evaluated* ***every 5 minutes*** *after a procedure with continuous pulse oximetry.*
2) *The pulse oximeter was found to have* ***no malfunctioning*** *parts.*
3) *The SSU was a new concept for this VA facility (2 months old).*
4) *The patient signed a consent form.*

Source:
VA Root Cause Analysis Training Instructors Guide [23]

Chapter 5: VA RCA analysis

A Patient Safety Officer at the Boston VA conducted an independent analysis of the case described in Chapter 4 using the VA's root cause analysis process. The following results were provided in order to establish a representation of outcomes achieved using the root cause analysis methodology [25].

Contributing Factors:
After reviewing the details of the case study, the following contributing factors were identified by the VA's patient safety officer [25]:

- 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 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 Cause:
The VA's patient safety officer then identified the following root cause:
"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" [25].

Action:
The VA has a process in place to review and report on the quality of both the root cause analysis and the follow-up action plan in an effort to maintain high quality accident investigations. The following actions were provided as an example expected to receive the highest review score. The actions identified included [26]:

- 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

Chapter 6: CAST Analysis

The following CAST analysis is based on the STAMP methodology described in *Engineering a Safer World* and the sample accident described in Chapter 4 [4,23]. When necessary, details were inferred based on the practices of a Boston-based teaching hospital.

For convenience, the case has been divided into the following three segments:

- Phase I: Diagnosis
- Phase II: Biopsy Procedure
- Phase III: Post-Procedure Recovery

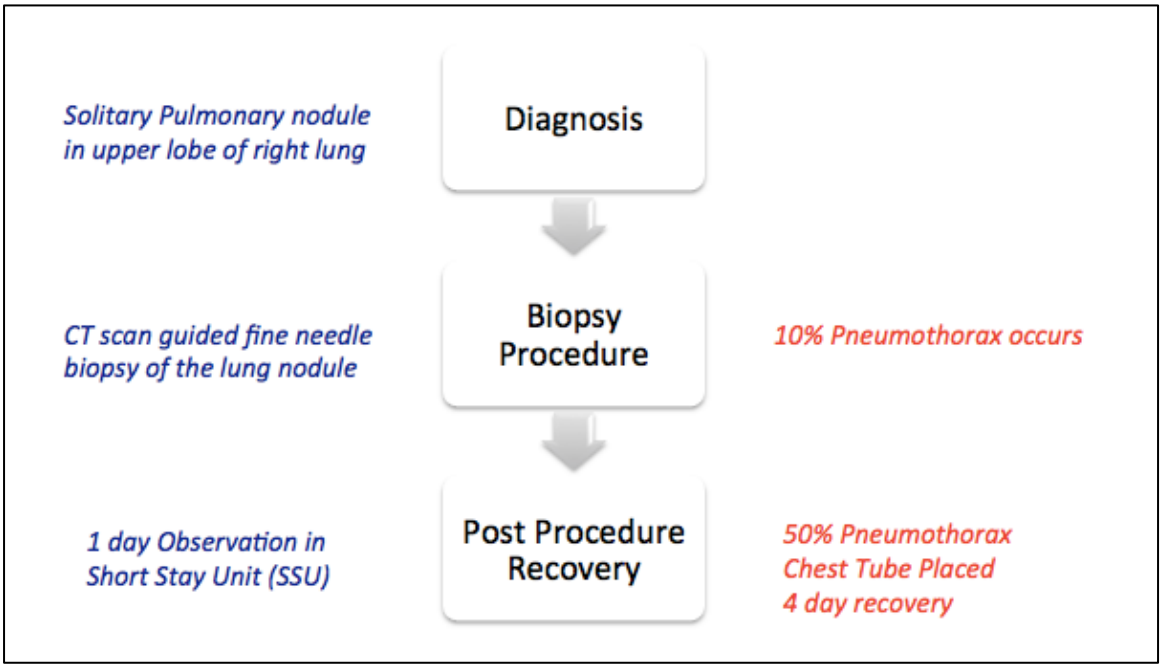


Figure 5: Three-phase definition of the accident description

The CAST analysis will be presented following the method's nine steps:
[4, pp. 350-351]:

1. Identify the system(s) and hazards(s) involved in the loss.
2. Identify the system safety constraints associated with that hazard
3. Document the safety control structure in place to control the hazard and enforce the safety constraints.
4. Determine the proximate events leading to the loss
5. Analyze the loss at the physical system level.
6. Moving up the levels of the safety control structure, determine how and why each successive higher level allowed or contributed to the inadequate control at the current level.
7. Examine overall coordination and communication contribution to the loss.
8. Determine the dynamics and changes in the system and the safety control structure relating to the loss and any weakening of the safety control structure over time.
9. Generate recommendations.

Step 1: Identify the system(s) and hazard(s) involved in the loss

Accident

A generalized wording of the accident, which could be applied broadly to hospital accident investigations, is:

- (General) Patient harmed while under hospital care

While still framed at an abstract system level, a more specific wording of the accident described in the pneumothorax case study is:

- (Specific) Patient's lung is harmed while in the hospital for a procedure to biopsy a lung nodule.

System Hazards

Following the identification of the system-level accident under review, the system hazards are then described. In this case, the system-level hazards, which could lead to a patient being harmed during the hospital stay for treatment of lung nodule, include the following:

H1: Biopsy procedure damages sensitive tissue

H2: Patient is unable to fully recover from procedure

Step 2: Identify the system safety constraints and system requirements associated with that hazard

The System Safety Constraints

The system safety constraints are easily defined from the system hazards are described. The two system safety constraints relevant in this accident are:

C1: Lung nodule must be biopsied without damaging sensitive tissue

C2: The patient must be monitored and treated appropriately while recovering from the procedure

Step 3: Document the safety control structure in place to control the hazard and enforce the safety constraints

High-Level Control Structure

A high-level system control structure was created to capture the major controllers as well as the control actions and feedback flow. Depicted below in Figure 6, the system control structure is generalized to allow for the application to both VA and non-VA hospitals. For example, while the VA hospital system has the National Patient Safety Center that can provide the ability to merge and analyze incident investigations and incident occurrences at hospitals across the country, in non-VA hospitals, Patient Safety Organizations (PSOs) may provide this function.

As indicated in the high-level control structure, the CAST analysis has been performed with a system boundary fixed to include the medical care acting upon the patient as the controller process. The high-level medical care controller includes a number of lower-level controllers as shown in the subsequent phase level control diagrams.

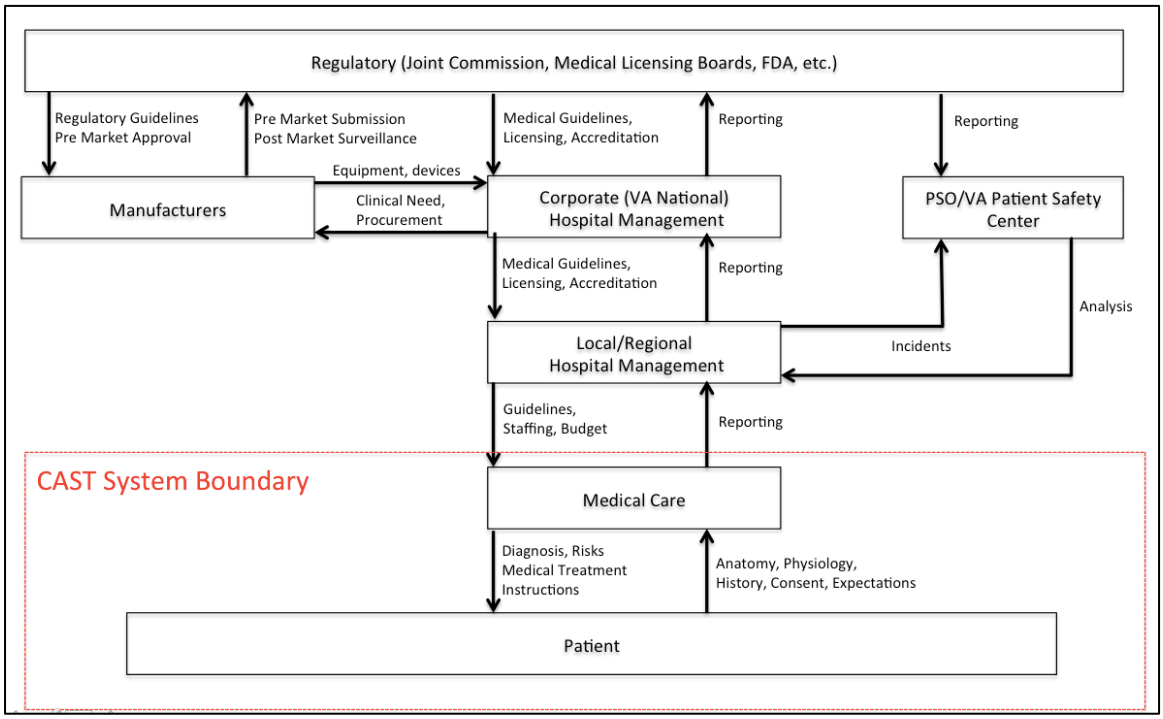


Figure 6: High-Level Control Diagram and CAST system boundary

Each component in the high-level control diagram depicted in Figure 6 has a responsibility in enforcing the necessary system-level constraints to ensure that patients are not harmed as result of the medical care provided by the hospital. Several groups act as regulators for example, including the Joint Commission (JC), which serves as the primary accreditation body for hospitals in the United States. As part of the accreditation process, hospitals are required to demonstrate that they have a process in place for incident reviews. The JC does not dictate the specific methodology; however, they do provide root cause analysis as a model methodology recommended to hospital administrators [7,27]. Another regulator is the US Food and Drug Administration (FDA), which provides regulatory oversight of the manufacturers providing the CT scan equipment for example and other medical devices used by the healthcare providers. In addition, the medical licensing boards help to regulate both the training and the care provided by the medical providers. The hospitals are responsible for providing the medical treatment to the patients as well as providing incident investigations when accidents occur. The details of these investigations are reported internally within the hospital as well as externally to the manufacturers and regulators.

Step 4: Determine the proximate events leading to the loss

Phase I: Diagnosis

1. A 55-year-old male is suspected of pneumonia, chest x-ray is ordered and performed.
2. A solitary pulmonary module in upper lobe of the right lung is detected in the chest x-ray.
3. Patient is referred to a pulmonary medicine consultant.
4. Pulmonary Specialists advises a CT scan guided fine needle biopsy of lung nodule.
5. Clinician and nurse communicate overview of the procedure to the patient. Patient is told it will be an outpatient procedure (no overnight stay) and to expect minor discomfort following procedure.

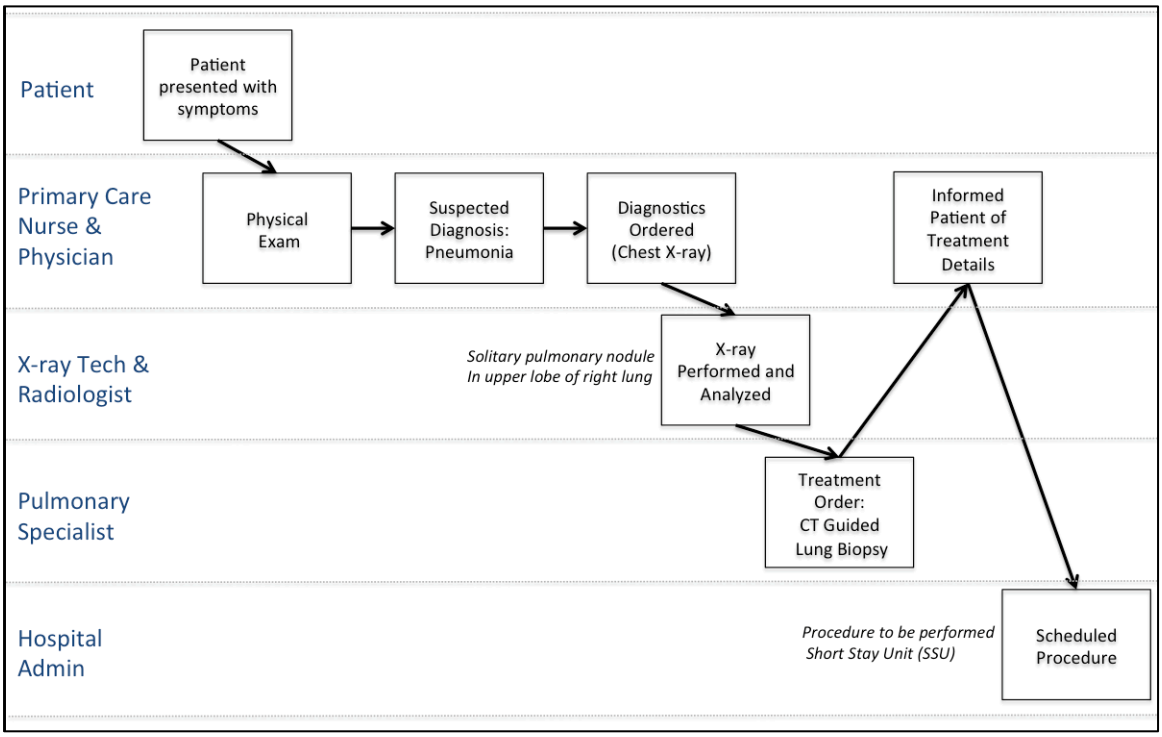


Figure 7: Graphical Summary of Phase I: Diagnosis

Phase II: Biopsy Procedure

6. Patient admitted to a short stay hospital unit in the morning for the procedure.
7. The patient is mildly sedated
8. Patient is transported to the radiology department.
9. Interventional radiologist is assisted by a radiology resident. IV catheter is inserted. Cardiac rhythm and blood pressure monitors attached.
10. CT scan performed to locate lesion.
11. Radiologist inserted needed through chest wall into nodule and aspirated tissue for the specimen.

12. Needle withdrawn.
13. Clinicians detect a small (10%) pneumothorax
14. A 15-min delay in transport of patient from operating room
15. Patient transported to recovery room in SSU

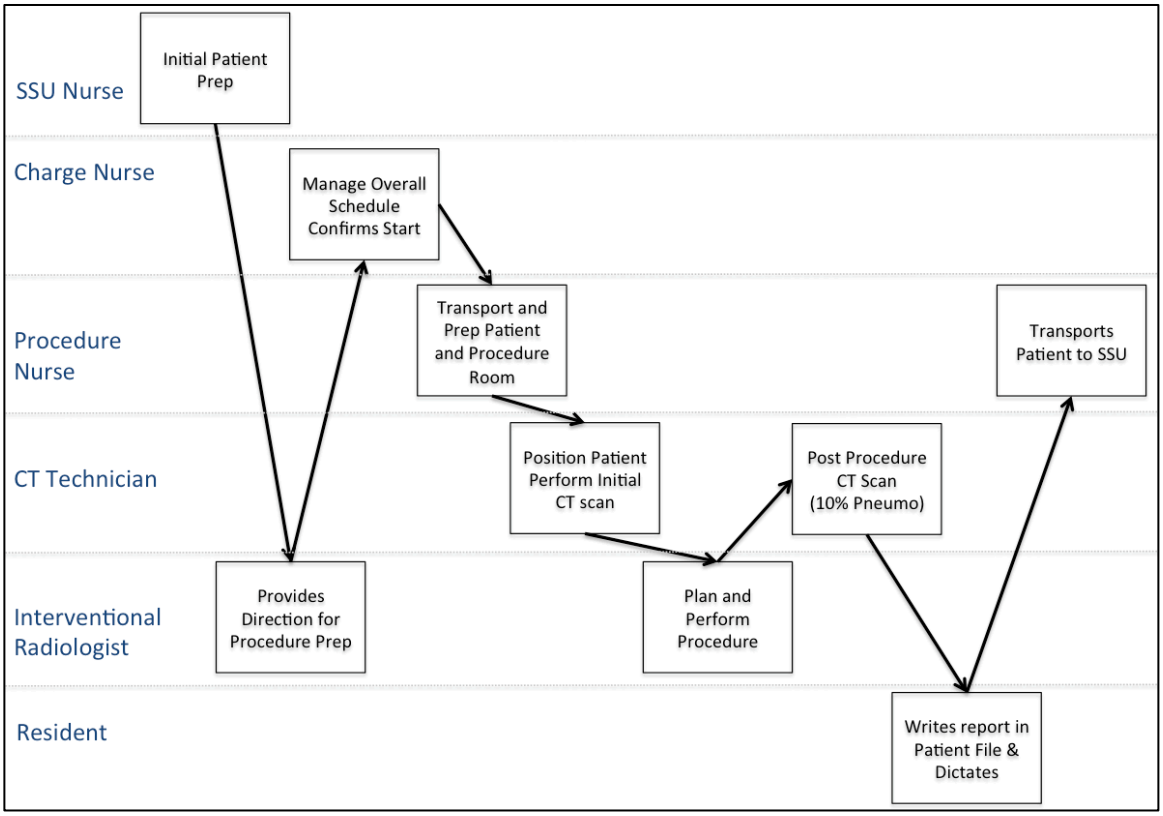


Figure 8: Graphical Summary of Phase II: Biopsy Procedure

Phase III: Post-Procedure Recovery in SSU

16. Monitors reattached
17. No staff contact for 30 minutes. Pulse oximeter alarms "low oxygen" repeated, no staff response, patient repeatedly silences alarm
18. Patient experiences right-sided chest pain with inspiration. Patient assumes pain is transient so does not call nurse.
19. 15 minutes later, nurse sees patient silencing alarm and grimacing
20. Nurse checks vitals signs, views pulse oximetry, and reviews chart. Blood pressure, heart rate, respirator rate all elevated. Charts are illegible to nurse.
21. Nurse requests a follow up check x-ray ASAP and calls interventional radiology
22. Chest x-ray is performed, shows 50% pneumothorax
23. Thoracic surgery resident is called. He inserts a chest turn to re-expand the right lung
24. Chest tube remains in place for 3 days because for persistent air leak. Care for with IV fluid, pain medication, monitored with cardiac monitors and pulse oximeter.
25. Patient discharged 4 days after biopsy procedure.

26. Subsequent review of case; pulse oximeter was sent to the clinical engineering department for testing, no malfunction parts were found.

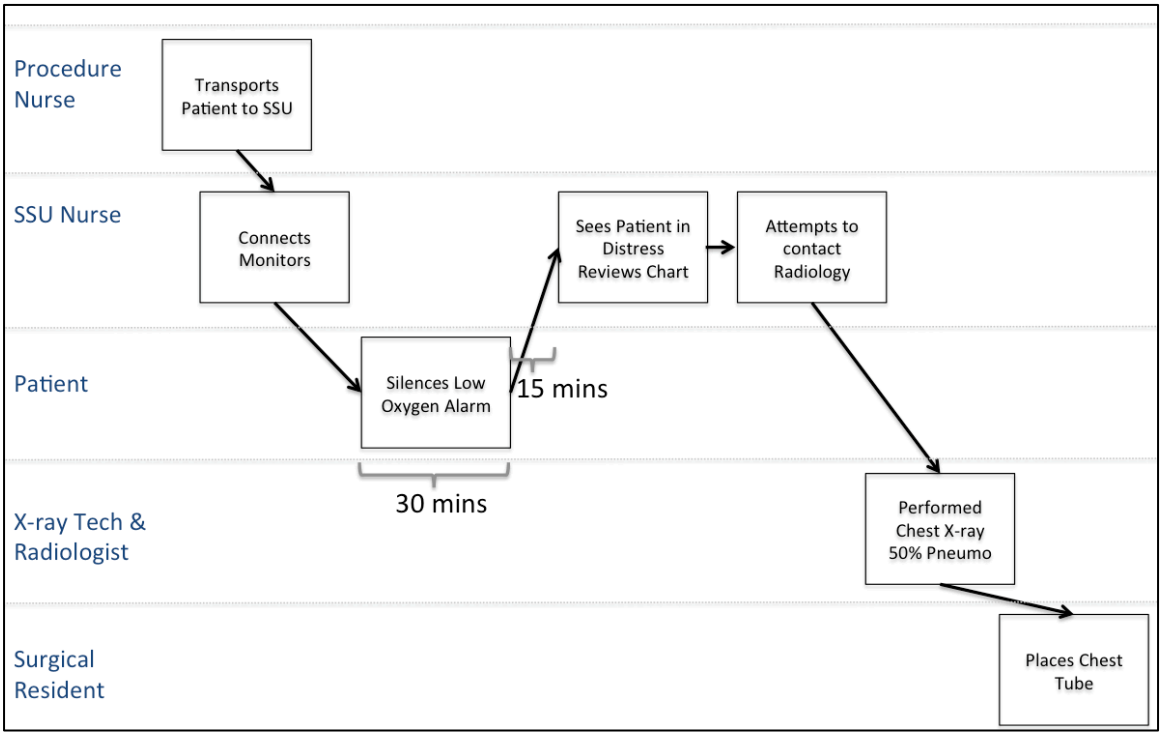


Figure 9: Graphical Summary of Phase III: Post-Procedure Recovery

Step 5: Analyze the loss at the physical system level

The physical system analysis is presented by phase. Per the CAST methodology, each of the identified components in the physical are evaluated for the following:

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

The case indicates there were no specific physical component failures identified in the accident; however, the following physical system analysis provides usefully details of lacking or weakly enforced safety constraints.

Phase I: Diagnosis

Location:

While the case provides limited detail of the diagnosis phase, it does indicate that a "clinic physician and nurse" saw the patient. Therefore, based on the available information, the location of the diagnosis phase is inferred to be a VA outpatient clinic.

Equipment involved in Diagnosis:

The case indicates that an X-ray was taken in order to aid in the diagnosis of the patient who appeared to have symptoms of pneumonia. While not specified, it is also be inferred that the following physical equipment was involved in this phase based upon typical patient experience: Exam table, Stethoscope, Blood Pressure Cuff, Pulse Oximeter, Physical Patient Record Chart, and X-ray equipment.

Additional Systems:

As hospitals have increased the use of technology in the administration of medical care, a number of software systems have been developed. Most widely recognized are the electronic medical record systems (EMR), which include patient history and prior care. Information in the EMR systems are often incomplete however; for example, if the patient had previously chosen to seek medical care from a provider outside the VA, it is likely that this information would not be available in the VA EMR system. A second relevant computer system in this case is the scheduling system that is used to determine the day and time scheduled for the biopsy procedure. The system has a responsibility to aid the administrators in ensuring appropriate resource allocation required to provide safe medical care. If for example, a number of high-risk procedures are scheduled within a short amount of time, medical personnel and physical resources available could be insufficient to provide the necessary care.

Safety Requirements and Constraints Violated

The physical equipment used in the diagnosis phase was primarily responsible for ensuring the patient was correctly diagnosed and aiding in the identification of an appropriate treatment plan. It is inferred in this analysis, based on the details provided in the case, that the correct diagnoses and treatment plan were identified. It is not clear however, that diagnostic equipment fulfilled the safety constraint of providing awareness of risk factors that may have made the patient have a higher than normal risk for a pneumothorax from the biopsy procedure.

In addition to the physical exam in the diagnosis phase, the EMR system along with patient feedback would be required to help identify potential risk factors for use in diagnosis and treatment planning. The EMR system would be used as a system of record, needed to communicate the patient history including potential risk factors, anatomy, and physiology as well as communicate the diagnosis and treatment plan to the multiple providers interacting with the patient. The EMR is also required to help communicate the diagnosis and treatment plan to the administrative scheduler to ensure the availability of the resources required. Finally, the scheduling system has the requirement to provide visibility into resources and staffing availability to ensure optimal scheduling.

Failures and Inadequate Controls

There is no indication in the case that any appropriate risk factors for pneumothorax were identified prior to the biopsy procedure. In addition, the scheduling system appears to have been unable to ensure availability of staff from the radiology department when the patient was in the SSU, as indicated by the inability of the nurse to access the staff in the radiology department after the procedure.

Physical Contextual Factors

It is common that the EMR records do not contain complete patient medical history information as patients often may see medical care at different hospital networks. When they do, often the medical records are not available between the networks so the medical history available to an individual provider during diagnosis is often incomplete. In addition to the limitation of the electronic records, patients themselves often do not know what information should be provided or what would be valuable as they lack medical training.

It is not known how long the patient waited before seeking treatment and how or if this could have affected the diagnosis period. It is possible that the patient had symptoms, which if presented sooner, might have allowed for the biopsy to be performed with less risk for a pneumothorax. It is also possible that the patient may have presented symptoms differently than the norm, and may have anatomical or physiological differences from the normal population which could have contributed to risk factors for pneumothorax. If present, these risks went unidentified but may have contributed to the harm caused in the procedure phase. The presence of comorbidities could have also had an effect on both the diagnosis and the treatment plan and should be included in the consideration of the incident reviewer.

Finally, details are not provided on the scheduling system, but it is possible that the system had limited information and accuracy. More information should be gathered to investigate the scheduling procedure and information visibility. For example, the time to perform the procedure may not be adequate for ensuring required resources are available when patients are in recovery. Hospitals commonly experience a high volume of no-shows, which can have an impact as efforts are made to try counterbalance and could lead to overscheduling resources.

Phase II: Biopsy Procedure

The biopsy procedure occurred in the newly formed Short Stay Hospital Unit. In between procedures, the Radiology staff typically has an area to congregate, which in some hospitals may be referred to as simply "The Specials Room." Typically the charge nurse is found in this area and a large monitor may be used to display the real time schedule for the interventional radiology procedures. Several procedure rooms may be used which contain the equipment necessary for fluoroscopy, CT guided, and ultrasound guided procedures performed by interventional radiologists.

Location(s):

The patient initially arrived for the procedure and was admitted to the SSU, where the preparations for the procedure occurred such as the lab work required prior to the biopsy. The biopsy itself occurred in an Interventional Radiology CT Suite, which houses the equipment included the CT scanner and tools needed for the procedure. Two adjoining rooms typically comprise the suite. In the main room, the CT scanner and tools are located while in the second adjacent room, computer controls are located for the CT technician to use. The providers also use this control room as a safe location while the CT scanner performing a scan of the patient to reduce the amount of radiation exposure to the medical personnel. Finally, as mentioned, the Specials Room serves as an area for the radiology department personnel when they are not in the midst of performing a procedure. When the nurses from the SSU need to contact a member of the Radiology department, they would typically call the Specials Room.

Equipment involved in Biopsy Procedure

There are a number of pieces of physical equipment involved in the biopsy procedure. Upon arrival, the patient was given a patient identification wristband, to confirm the identity of the patient during the treatment preparation. Sedation medication was administered in the preparation stages and equipment such as an IV catheter, cardiac rhythm monitor, blood pressure monitor were attached to provide monitoring and drug delivery during the procedure. The patient was transported on a hospital bed from the SSU area, and then was transferred to the bed of the CT scanner by the nurse and CT technician. During the procedure, a number of physical equipment such as a biopsy needle was used to collect and store the biopsy sample.

Throughout the Biopsy Procedure phase, a physical file was used as a patient chart. The chart, which is normally created prior to the procedure, served as a physical record system to provide communication between the medical personnel. The patient chart was populated with manual handwritten information from the medical personnel including communicating the details of the procedure performed and any complications that occurred during the procedure to the staff in the SSU for recovery.

Safety Requirements and Constraints Violated

During the biopsy procedure, the equipment used was responsible for aiding the radiologist to perform the biopsy of the lung and remove the nodule sample from the patient without causing harm to the lung tissue. The CT scan taken prior to the procedure was used by the radiologist to identity a safe path for the biopsy needle to traverse. During

the procedure, the radiologist used the monitors located in the procedure room along with either a foot pedal, or handheld remote to take fluoroscopy images providing a lower resolution view of the patient's lung to aid in maintaining the needle movement along the safe pathway. The imagining equipment provides typically three 2D images, one set at the location of the nodule as well as one "slice" above and below to be used to determine the location of the biopsy need point along the x, y, and z axis.

Failures and Inadequate Controls

The imaging equipment does not provide a continuous view of the safe pathway; rather the technology provides intermittent, 2D views. While there was no specific component failure indicated, the imaging equipment and the biopsy equipment did not provide adequate safety constraints to ensure the patient's lung tissue was not harmed during the procedure. During the procedure, the radiologist cannot continuously monitor a safe pathway to the nodule.

In addition, the equipment does not monitor or prevent patient movement (external or internal) during the procedure. This is important because if the patient moves, the safe pathway could be compromised or altered. The physical location of the monitors used by the radiologist to review the fluoroscopy images for example could prevent the radiologist from recognizing patient movement.

From the case, it is clear that the procedure details, including the facts relevant to the observed pneumothorax, were not clearly communicated to the staff in the recovery area as the handwritten procedure notes provided by the radiology resident were not legible to the SSU nurse during the recovery phase. Also, as indicated in the case, the resident used dictation to provide the procedure details for the EMR system, so the information was not yet entered into the EMR system in the hours immediately following the procedure.

Physical Contextual Factors

A number of physical contextual factors are relevant in the biopsy procedure phase of the case. First, imaging equipment currently on market is not used to provide a continuous image of the patient, as the radiation exposure would be harmful to the patient and the medical personnel. For this reason, The CT scan taken pre- and post-procedure are high-fidelity images. The images taken during the procedure via fluoroscopy are lower resolution. Biopsy procedures are only one of numerous uses of the CT scanning equipment.

Depending on the location of the nodule, when the patient is in the CT scanner, the radiologist must reach over the patient and into the arch of the unit to guide the needle, or retract the bed out from the scanner. The radiologist views the CT scanner image on a monitor in the control room prior to the procedure to plan the approach, then he/she must translate the safe pathway including the intended needle entry angle and location, as well as the internal anatomy and location of the nodule from the monitor into the actual physical world. Later, during the procedure, when in the procedure room, the radiologist would view the images on smaller monitors typically near eye level relative to the standing radiologist, again requiring the doctor to mentally translate the visual images from the

monitor to the patient on the table. The current design of the equipment does not generally allow for the radiologist to see the imaging details, the patient, and manipulate the location of the needle at the same time.

The CT bed must be moved horizontally, retracting the patient from within the scanner arch towards the radiologist, between the captured images, to a location within closer reach of the radiologist in order to allow the doctor to adjust the location of the biopsy needed. This movement can contribute to the total procedure time and may have allowed the patient or needle movement to occur without provider awareness. The CT bed provides a hard flat surface for the patient, but typically does not provide any constraint of movement. When patients require anesthesia, restraints may be used to prevent a patient from rolling off the bed; however, this is not typical for patients requiring only sedation as indicated in the case.

While needle size is known to be a possible contributing factor in the occurrence of pneumothoraxes, the needle size is currently selected by radiologist preference and does not appear to be typically adjusted from case to case based on the nodule size or location for example.

The patient chart is handwritten and paper forms are still widely used in hospitals. It is common for procedure notes to be dictated by a physician, and these audio recordings transcribed into the EMR, but there can be a delay of up to a day before the notes are available in the EMR.

Phase III: Post-Procedure Recovery

The patient was transported from the procedure room to the SSU for recovery after the procedure.

Location(s):

The post-procedure recovery occurred in the SSU. The patient may have been transported to the x-ray equipment used during this phase, or a portable x-ray may have been brought to the patient

Equipment involved in Biopsy Procedure

The case indicated that a cardiac rhythm monitor and blood pressure monitor were used in the SSU to monitor the respiration of the patient. The patient would have been transported on a hospital bed, to an area located in the open area SSU in view of the nursing station. The nursing station is typically located in the center of the room. The case indicated that the physical patient chart was transported with the patient to and from the procedure room to the recovery SSU area. Also indicated in the case, x-ray and chest tube were used by the medical providers during the recovery phase.

Safety Requirements and Constraints Violated

The physical equipment used in the recovery phase did not successfully alert the medical staff that the patient status or condition worsened in order to allow for appropriate action

to be taken. In addition, the physical chart was required to provide communication between the medical staff involved in the procedure and the staff in the SSU; however, as the handwriting could not be read, this communication did not occur effectively.

Failures and Inadequate Controls

The patient silenced the oximeter alarm. The case indicated the nurse was not aware the device was alarming, suggesting that the nurse was physically out of the immediate area to hear the alarm before it was silenced and that if additional visual indications were available, these were also not seen by the SSU nurse.

Physical Contextual Factors

The case indicates that the patient easily silenced the oximeter alarm in the SSU area. The open architecture of the SSU area may also contribute to the mental models of both the patient and the nurses, as they may believe that if a patient is in need of medical care, a nurse will be able to see them, and be aware of the problem. This may have contributed to the patients' belief that if there truly were a problem as the oximeter alarm indicated, a nurse would have responded. It also may have contributed to the nurse's mental model; she believed that if the patient were in need of attention, she would be aware, either by hearing an alarm or seeing a sign of distress. Because she did not realize that the patient's condition was worsening, additional time elapsed before a physical examination of the patient occurred. Additionally, the management team of the hospital may have allowed for higher patient-to-staff ratios to occur with the expectation that an open space architecture would allow for nurses to be fully aware of the status of all of their patients and to respond more quickly.

Summary of Physical Safety Controls Key Findings

CT/Fluoroscopy Guided Biopsy	Patient Record	Short Stay Unit (SSU)
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	**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	**Safety Requirements/ Constraints Violated** • Provide continuous monitoring of patient status post procedure **Failures and Inadequate Controls** • Did not provide awareness of patient distress **Physical Contextual Factors** • 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 • Patient was silencing the oximeter alarm

Step 6: Moving up the levels of the safety control structure, determine how and why each successive higher level allowed or contributed to the inadequate control at the current level

Control Structures and Controller Analysis:

Phase I: Diagnosis

The phase begins with the first patient exam at the clinic and ends with the scheduling of the procedure. Although overlooked in the case report, additional controllers would be required in this phase including: a radiologist, x-ray technician, or scheduler, so these controllers have been included in the CAST analysis.

The control diagram was prepared both as the phase would have been expected or designed as well as according to the actual state as was described in the case as shown in Figure 10 and 11. The dotted lines in Figure 11 highlight areas of control or feedback that were either missing or incomplete in the actual case, representing areas that should be reviewed and improved to prevent future occurrences. Although an investigator could overlook the diagnosis phase, this CAST analysis shows there are several areas where additional safety constraints may be needed in the phase. For example in the diagnosis phase, there is no evidence of any attempt to identify risk factors of pneumothorax for the patient. There is also evidence that the instructions provided were either lacking or not fully comprehended by the patient. Finally, it is reasonable to infer that the information available to aid in scheduling the procedure may have been incomplete.

A number of factors have been identified that likely contributed to the lack of awareness of the presence of pneumothorax risk factors. First, the patient himself likely did not have the capability of knowing what information was relevant to convey to the healthcare providers. In addition to the patient's presentation, it is likely that the EMR system did not have complete, up-to-date information regarding the patient's medical history.

As reviewed in more detail in the biopsy procedure and recovery phase discussion, the patient had a mental model that the pain he was experiencing after the procedure was normal discomfort and not an indication of any serious problem requiring medical attention. His mental model was formed in part by the information exchange in the diagnosis phase, when the health care providers discussed the diagnosis, treatment, and instructions with the patient. During this time, the patient may have been emotionally affected by the news of the diagnosis. There is no evidence that there was a confirmation that the patient adequately comprehended the information.

Similarly, later in the case there are indications that resource availability may have been a contributing factor, for example, the delay in transporting the patient to the SSU for recovery, the inability of the interventional radiologist during the recovery phase to respond to the SSU nurse, and the SSU nurse's delay in physically examining the patient during the recovery phase. The scheduling of the procedure, which should be further reviewed, may have influenced all of these factors.

Figure 10: Phase I Control Structure: Diagnosis (as Designed)

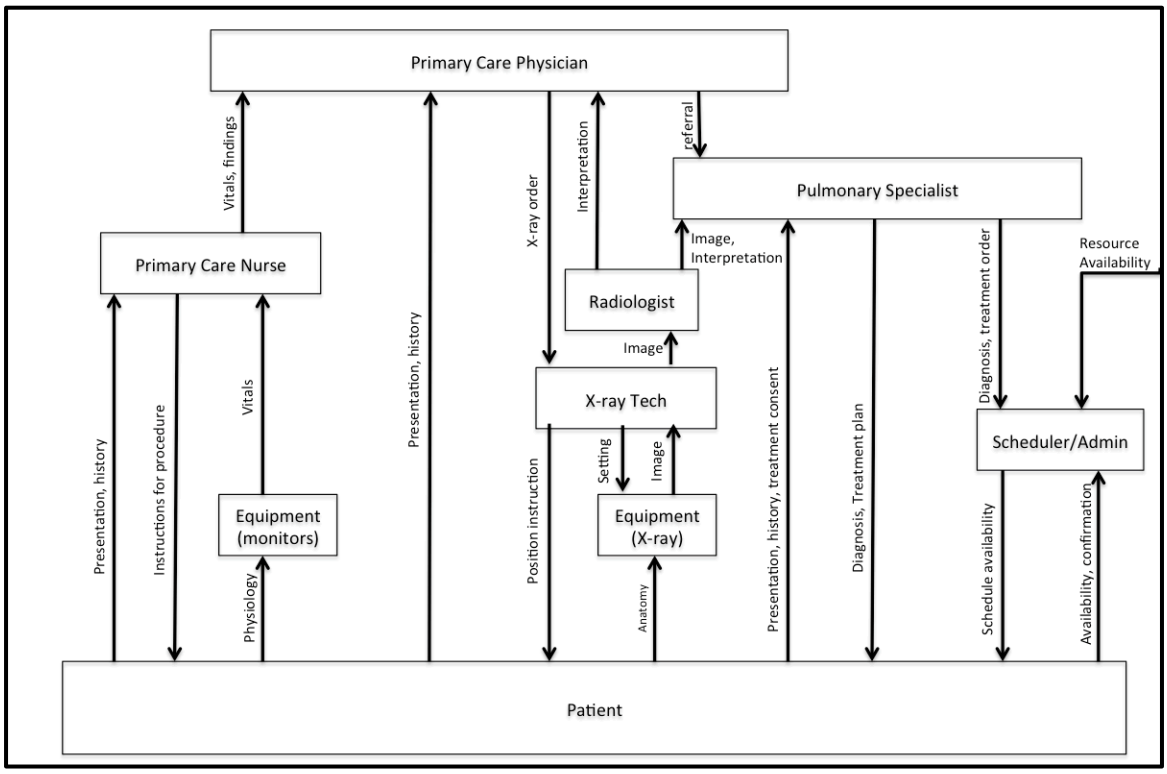
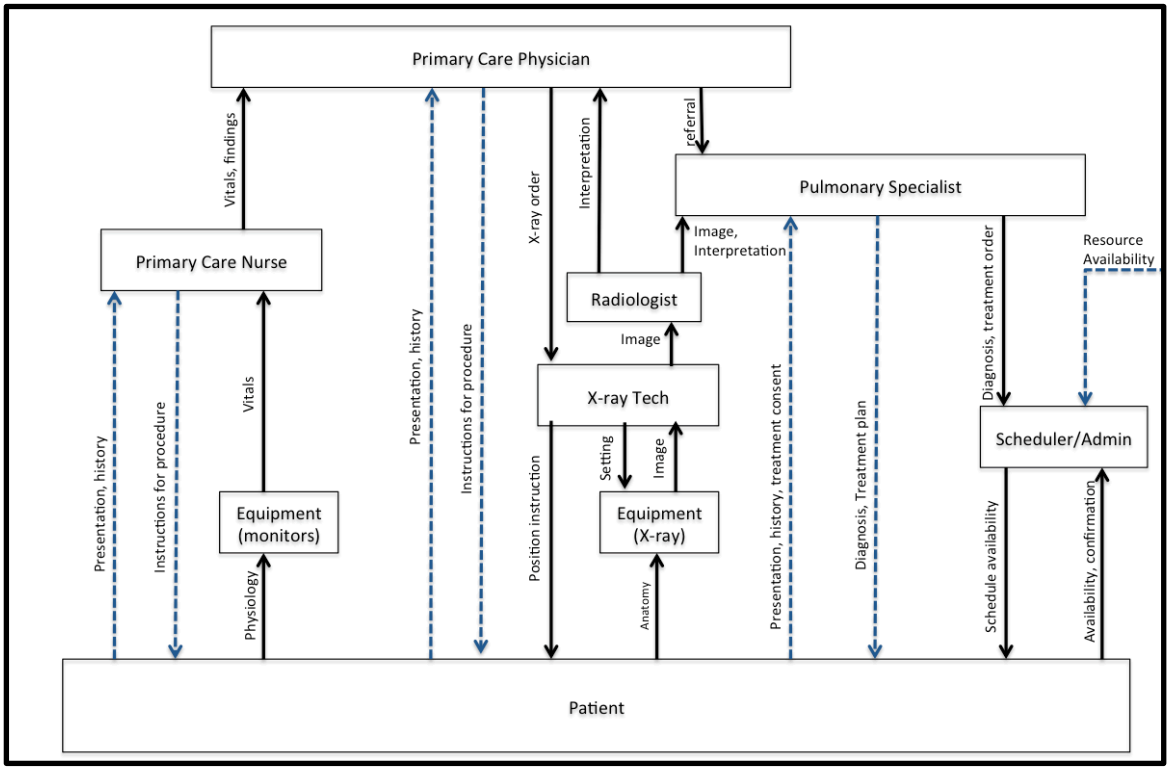


Figure 11: Phase I Control Structure: Diagnosis (Actual)



Phase I Controller Analysis:
The seven controllers involved in Phase I include the following:

1. Patient
2. Primary Care Nurse
3. Primary Care Physician
4. Pulmonary Care Specialist
5. X-ray Technician*
6. Radiologist*
7. Scheduler/Administrator*

*These controllers were inferred and not specifically detailed in the case.

Following the CAST methodology, each of the controllers was reviewed below for the following:

- Safety-Related Responsibility
- Unsafe Decisions and Control Action
- Process Model Flaw
- Context

1. Patient

The patient has a number of safety-related responsibilities in the diagnosis phase. First, he is responsible for providing accurate and complete information to the medical staff both during the physical exam and in the verbal exchange with the clinicians who are trying to access the clinical presentation of the symptoms to diagnosis the patient. The patient is also responsible for providing consent of the proposed treatment and acknowledging that he has an understanding of the diagnosis and treatment plan, and of the instructions provided for the procedure including the preparation and recovery period.

The case has limited details of the patient actions during the diagnosis phase. It can be inferred that the patient did provide consent for the procedure. The context of the diagnosis phase should be considered. The patient had at arrived at the clinic with symptoms the medical staff had original believed to be pneumonia. The patient however was in fact diagnosed with a lung nodule, possibly cancerous, which would require a biopsy procedure. It can therefore be concluded that the patient may have been experiencing strong emotions during the time that the explanation of the diagnosis and the treatment plan where discussed.

A number of questions arise about the patient's actions and the context in the diagnosis phase that could not be answered with the details provided in the case. The investigator should consider the following questions if this was a live case allowing for further information gathering:

- Was all of the 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 (for example, co-morbidities)
- What was the patient's overall health state? Were 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?
  - Were there medical terms used, such as pneumothorax, which he did not understand but did not ask for an explanation?
  - What was the patient's level of education and comfort with English?
- What were 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 patient's mental state when the risk of the procedure and instructions were 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?
  - 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?

2. Primary Care Nurse

The primary care nurse who first examined the patient in the diagnosis phase had a number of safety-related responsibilities. First, the nurse is responsible for measuring and documenting the patient's vitals signs as well as collecting and assessing the patient's history and details of clinical presentation of the illness. The nurse is then responsible for providing the details of the patient's history and presentation details to the primary care physician. Finally, the primary care nurse is responsible for assisting the primary care physician in assessing the patient's understanding of the diagnosis and treatment plan including instructions for the procedure such as expectations of discomfort.

It can be inferred from the case that the primary care nurse believed the patient understood the necessary details regarding the procedure, including the appropriate expectation of the discomfort post-procedure. The case however leaves a number of questions unanswered regarding the unsafe decision and control actions as well as the process model flaws related to the primary care physician. These questions include the following:

- How did the nurse assist in assessing the patient's understanding?
- How was information conveyed to the patient?
  - Was any of the information given to the patient in writing or only conveyed verbally?
- Was time or performance pressure present?
  - What was the nurse's workload?
  - What policies were in place relevant to the communication to patient?

- Did the nurse believe that the primary care physician had answered any questions that the patient had?
- Did the nurse assume that the SSU staff would reiterate the information necessary to the patient?
- Did the nurse understand that the patient understood the information conveyed?
- What assumptions were made regarding the patient's state of mind and level of education/medical knowledge?
- How did the patient's verbal and non-verbal communication affect the nurse's assessment?

3. Primary Care Physician

The safety-related responsibilities of the primary care physician during the diagnosis phase began with assessing the patient and ordering diagnostic tests and medical referrals as needed to determine the diagnosis. The primary care physician was also responsible for ensuring that the patient understood the diagnosis and treatment plan, including the potential risks involved in treatment and instructions for the procedure.

The case indicates that, similar to the primary care nurse, the physician was responsible for conveying the information of the treatment plan to the patient. It can also be concluded therefore that the physician has a similar process model flaw as the nurse did in believing that the patient understood the necessary details regarding the procedure, including the expectation of the discomfort post-procedure.

The CAST framework identifies a number of questions that are not answered given the details provided in the case, including:

- Did the primary care physician adequately convey the potential risks involved in treatment and instructions for the procedure?
- How did the physician assess the patient's understanding?
- How was information conveyed to the patient?
  - Was any of the information given to the patient in writing or only conveyed verbally?
- Was time or performance pressure present?
  - What was the physician's workload?
  - What policies were in place relevant to the communication to the patient?
- Did the physician believe that the primary care nurse had answered any questions that the patient had?
- Did the physician assume that the SSU staff would reiterate the information necessary to the patient?
- Did the physician believe the patient understood the information conveyed?
- What assumptions were made regarding the patient's state of mind and level of education/medical knowledge?
- How did the patient's verbal and non-verbal communication affect the physician's assessment?
- What did the primary physician believe about the communication of the pulmonary specialist and the patient?

4. Pulmonary Specialist

As the case indicates, a consult was requested from a pulmonary specialist when the patient's chest x-ray did not support the initial diagnosis of pneumonia. The pulmonary specialist had a number of safety-related responsibilities. First, the pulmonary specialist was responsible for interpreting the patient's chest x-ray. Next, he/she would have been responsible for the diagnosing the patient based on the available information, including the patient interview, the physician exam and x-ray. The specialist would then be responsible for determining and ordering the appropriate treatment plan for the patient and communicating the diagnosis and treatment plan to the patient. After obtaining the patient's consent for treatment plan, the pulmonary specialist would have been responsible for communicating the diagnosis and treatment plan order to the primary care providers and to the hospital schedule administration.

Similar to both the primary care nurse and primary care physician, it is inferred that the pulmonary specialist believed the patient understood the necessary details regarding the procedure, including the expectation of the discomfort post-procedure, or else the specialist may have believe that the primary care providers would be responsible for this.

The following questions should be considered:

- Was the diagnosis and treatment plan appropriate given the medical knowledge at the time and the information available?
- Were alternative diagnosis and treatment plans available and if so were they considered?
- Would additional information led to an improved diagnosis or treatment plan?
- What did the pulmonary specialist convey to the patient and to the primary physician and nurse?
- What was the state of the medical knowledge at the time of the incident? Was the diagnosis and treatment plan appropriate?
- Was an alternative treatment plan available?
- Was there atypical anatomy or presentation that may have affected the diagnosis or treatment?
- Were there any indications that the patient would be at risk for a pneumothorax and if so, was this considered in the treatment plan decision or communication to the interventional radiologist?
- What information was conveyed to the patient and how?
- Was time or performance pressure present?
  - What was the specialist's workload?
  - What policies were in place relevant to the communication to patient?
- Did the specialist believe that the primary care physician or nurse would answer any questions that the patient had?
- What assumptions were made regarding the patient's state of mind and level of education/medical knowledge?
- How did the patient's verbal and non-verbal communication affect the specialist's assessment?

5. X-ray Technician

As the case indicated a chest x-ray was performed in the diagnosis phase, it is therefore inferred that there was an x-ray technician involved. The safety-related responsibilities of the technician would have included positioning the patient and configuring the x-ray equipment in order to capture the image requested in the primary care physician's x-ray order. It can be assumed that the x-ray technician believed the x-ray image was appropriate given the order requested by the primary physician for the diagnosis for pneumonia.

Questions regarding the x-ray technician that cannot be answered with the details provided in the case include:

- Did the chest x-ray convey the appropriate details relevant in this case?
- Could the positioning of the patient have affected the information captured in the image?
- Was the x-ray image quality or content a factor in this case?
- How did the original hypothesis of pneumonia affect the x-ray process?
  - If the primary physician had suspected cancer not pneumonia, would this have affected the x-ray order and therefore the resulting image?
- What factors may have affected the x-ray process?
- Was there time pressure?
- For example, was the patient in pain or did he have limited mobility?
- Did the patient have trouble maintaining the desired position?
- Was communication, for example a language barrier, an issue?

6. Radiologist

Similar to the x-ray technician, it can be inferred that there was likely a radiologist who reviewed the x-ray image taken of the patient's chest. The safety-related responsibility of the radiologist would have been to interpret and communicate the results of the chest x-ray image. It can be assumed that the radiologist believed the necessary information was interpreted and communicated.

In this case, the following questions should be considered regarding the radiologist:

- Was the interpretation of the x-ray correct and complete?
- Was information available that was not recognized and communicated?
- What information was available to the radiologist who interpreted the x-ray? Did this have an impact?
- What did the radiologist believe his or her responsibility was? For example, perhaps the radiologist believed that risk factors that may have been present in the x-ray would be recognized, or the responsibility of another clinician, such as the pulmonary specialist or the interventional radiologist?
- What factors may have affected the x-ray interpretation?
- Was there time pressure?
- Did the image quality or patient position have an effect?
- Was there atypical anatomy?
- How did the interpretation of the x-ray have an effect on the diagnosis or treatment plan?

7. Scheduler/Administrator

The final controller in the diagnosis phase who is also inferred from the details provided is an administrator who provided the function of scheduling the patient for the biopsy procedure. The safety-related responsibility of the administrator would have been to schedule the patient and necessary hospital resources for the biopsy procedure. The assumed process model is that the scheduler believed the resources were available for the procedure

- How was the schedule of the procedure determined?
- What pressures could have impacted the schedule of the procedure?
- What visibility did the scheduler have of the workload and availability of the staff and physical resources?

Phase II: Biopsy Procedure

As described in the case, the patient was scheduled for a biopsy procedure in the new created SSU. The phase begins with the arrival of the patient at the SSU and ends with the transportation of the patient from the procedure room back to the SSU area for post-procedure observation. While the case does not directly mention the Charge Nurse, Procedure Nurse, and CT technician, these controllers were inferred in the analysis.

Similar to the first phase, the control diagrams in Figure 12 and 13 were created for both the as-designed and actual state and a number of both control actions and feedback channels are highlighted as areas of concern, such as the lack of system safety constraint and feedback on the position of the patient and maintenance of the safe pathway to the nodule. Also discussed in detail are the human factors and contextual factors that may increase the difficulty in ensuring there is a safe pathway maintained during the procedure.

Figure 12: Phase II Control Structure: Biopsy Procedure (as Designed)

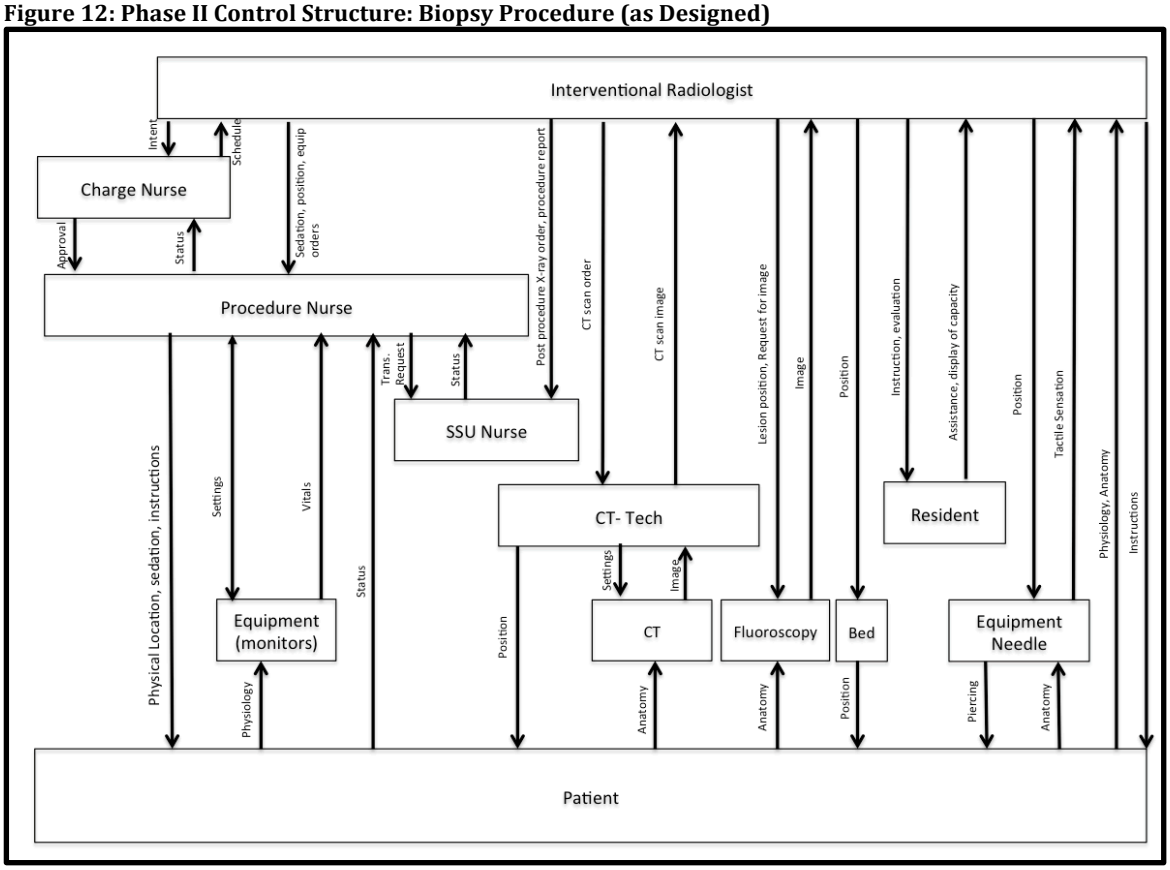
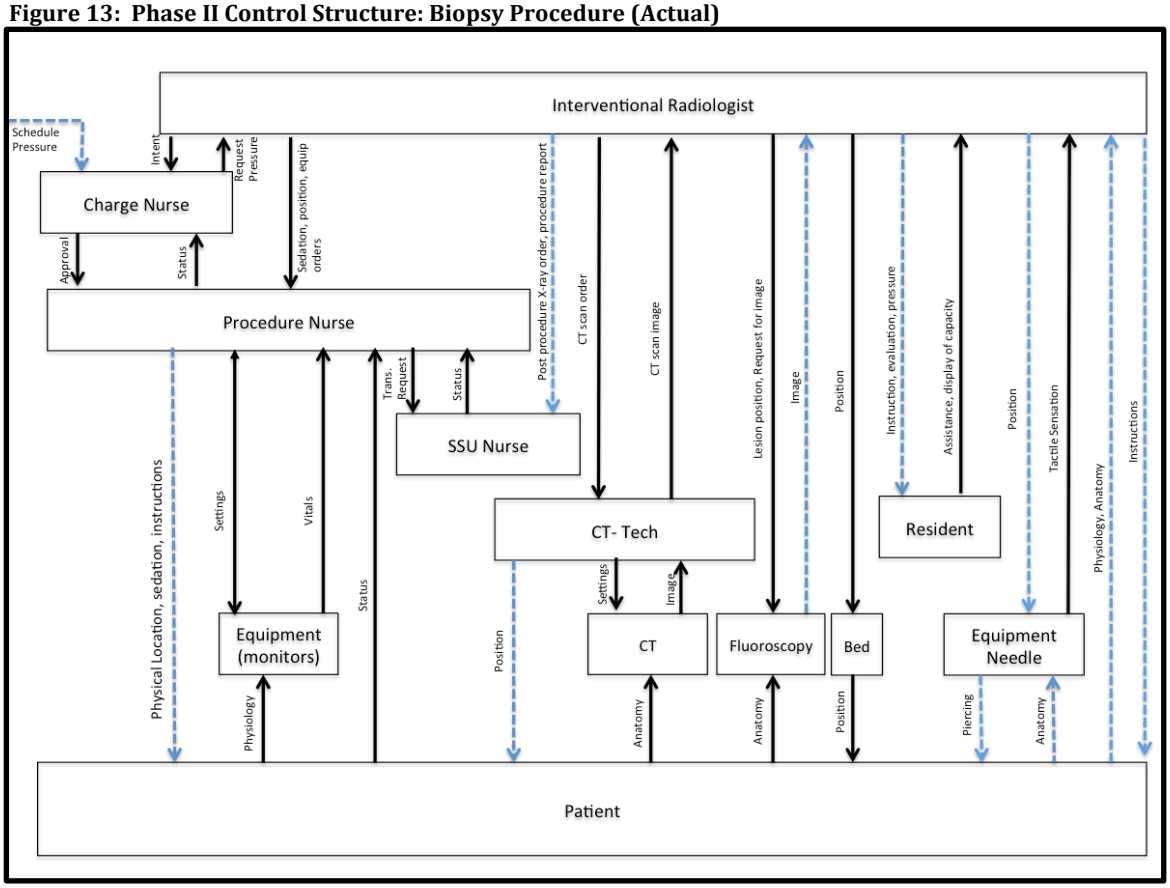


Figure 13: Phase II Control Structure: Biopsy Procedure (Actual)



Phase II Controller Analysis:

The seven controllers involved in Phase II include the following:

1. Patient
2. Charge Nurse*
3. Procedure Nurse*
4. SSU Nurse
5. CT-Technician*
6. Interventional Radiologist
7. Radiology Resident

*These controllers were inferred and not specifically detailed in the case.

Following the CAST methodology, each of the controllers was reviewed below for the following:

- Safety-Related Responsibility
- Unsafe Decisions and Control Action
- Process Model Flaw
- Context

1. Patient

Similar to the diagnosis phase, during the biopsy procedure phase the patient was responsible for providing accurate and complete information in his physical and verbal clinical presentation as well as for providing consent and acknowledging his understanding of the diagnosis, treatment plan and instructions for the procedure. In addition, during the procedure phase, the patient's safety responsibilities included maintaining the position instructed by the procedure nurse or technician and minimizing his movement during the biopsy procedure including both his external or macro body movement and his respiratory movement as instructed. It is possible that the patient may have believed he was remaining still, when he actually may have moved, compromising the safe pathway of the needle to the nodule. The context of the procedure is important to consider. While lying on the hard procedure table, the patient may have felt cold and uncomfortable as the temperature in the procedure rooms was likely chilly and he was dressed only in a hospital gown. It is not indicated how long he was asked to lie still in a specific position, but this could easily have exceeded 30 minutes as the nurse or CT technician would have positioned the patient during the procedure setup for the initial CT scan. In addition, the knowledge that the procedure would involve a needle insertion into his lung as well as the possibility that he may have lung cancer may have contributed to feeling scared or anxious. While it is not specified if he was informed that a pneumothorax occurred, if he was told, it is also not a given that he would have understood what this medical term meant, or what actions might increase the severity of the injury.

Questions that remain unanswered from the case details regarding the patient include:

- Did any of the instructions the patient received the morning of the procedure conflict with the instructions he received previously in the diagnosis phase?
- Was there evidence of patient movement during the procedure? If so, what actions were taken and what affect could this have had on the accident?
- Was the patient given instruction about his breathing during the procedure, if so did the patient understand what he was being asked to do?
- What was the patient's overall mental and emotional status during the procedure while under sedation? What affect may this have had on the accident?
- What was the patient's overall physical state? Could it have been painful or uncomfortable to remain still in the position as instructed?
- Was the patient in discomfort (for example he may have been cold from the cool temperature of the procedure room, or uncomfortable on the CT bed)
- How long was the patient on the CT bed? It is possible the patient may have waited for a significant time before the procedure began as well as during the procedure if a delay occurred which is not detailed in the case.

2. Charge Nurse

The charge nurse's safety-related responsibilities include coordinating the staff and resources in the interventional suite including schedule and unexpected cases. The charge nurse is responsible for confirming that all hospital required procedures have been completed as needed prior to the start of the procedure, for example confirming that pre-

procedure labs have been reviewed, that a translator is available if required, an anesthesiologist is available if required, patient consent has been obtained etc. The charge nurse is also responsible for obtaining the approval of the interventional radiologist to begin the pre-procedure set up and once approval is received for instructing the procedure nurse and CT-technician to begin the procedure setup, including transferring the patient from the SSU to the procedure room.

It is likely that the charge nurse may have believed the staff was ready to begin the procedure or that the schedule was a realistic one as she gave the indication to begin setup for the procedure. From observations of hospital teams, it is very likely that there may have been tension or stress between the charge nurse and the interventional radiologists. While the charge nurse may have pressure from management to meet corporate goals for on time performance, the charge nurse can try to influence indirectly, but has no direct ability to control the actions of the interventional radiologist. The charge nurse also typically would have no feedback on the estimated time of completion or progress of the procedure while it was underway. Different radiologists may perform the same procedure at different speeds and unscheduled cases may be requested for the hospital's admitted patients. Also, the SSU unit was new, so the performance of the newly created processes and staff may have been under close scrutiny of the management, adding additional stress to the performance of the charge nurse.

Additional questions related to the charge nurse that the CAST analysis raises are:

- Were all the hospital required procedures completed as expected?
- What scheduling decisions were made the day of the procedure? How did these decisions affect the patient or the staff?
- What was the schedule of the radiology suite that day?
- Was there overall schedule pressure from management to complete the procedures as close to the original schedule as possible?
- Were there unanticipated procedures or other delays that impacted the schedule? For example, were there any difficulties in obtaining the patient consent, or lab results?
- What was the overall environment and team dynamics?
- Did the charge nurse have difficulty obtaining the go ahead to begin the procedure from the Interventional Radiologist?

3. Procedure Nurse

The procedure nurse's safety-related responsibilities would have begun with transporting the patient between the SSU area and the procedure room once the charge nurse indicated that the procedure setup could begin. Then the procedure nurse would have administered the sedation medication according to the radiologist's order and assisted the CT technician in transferring the patient between the hospital bed (from the SSU) and the CT bed.
Then the nurse would have been responsible for ensuring that the procedure room was set up for the procedure according to the instructions from the Radiologist. The nurse would be responsible for setting up the patient monitoring equipment in the procedure room as well as monitoring and recording the patient's vitals during the procedure (approximately every 5-10 minutes). Prior to the procedure and during the procedure, the nurse would

interact directly with the patient throughout the procedure with instructions as needed and to confirm patient status, which typically may include walking around the arch of the CT-scanner in order to be near the patient's head. The nurse would be responsible for receiving feedback from the Radiologist on the status of the patient at the conclusion of the procedure and coordinating with the SSU staff to confirm transportation of the patient from the procedure room to the SSU area once the procedure was completed. The procedure nurse would then be responsible for a handoff of the patient to the SSU nurse, including relaying any necessary details regarding the patient, procedure, and procedure outcomes.

The case indicates that there was a 15-minute delay in transporting the patient to the SSU but does not specify the reason for the delay. It can be inferred that during this time, the patient's monitoring equipment would have been disconnected as monitors typically remain in the procedure room. It would not be unlikely that the patient was on a hospital bed waiting in the hallway outside the procedure room during the delay. Relevant details on the context relevant to the actions of the procedure nurse should be further investigated, for example, to understand what caused the delay, and if this affected the communication during the handoff between the nurses.

- Did the procedure nurse have knowledge of evidence to suggest that the patient was at a higher risk for a pneumothorax?
- How was the patient sedated for the procedure? How long was the procedure? Could sedation have been in effect after the procedure? Did the nurse believe the patient was no longer under the effect of the sedation when his status was checked after the procedure?
- What was the reason for the delay in transporting the patient to the SSU? Was there difficulty in reaching the SSU nurse?
- What information was conveyed from the Interventional Radiologist and the Resident to the nurse? Was the presence of the pneumothorax communicated to the procedure nurse?
- What occurred in the handoff between the procedure nurse and the SSU nurse? Was the existence of the pneumothorax conveyed to the SSU nurse? What was the typical handoff procedure between the procedure nurse and the SSU nurses? Was there a deviation from the normal procedure? Did the procedure nurse believe that the SSU nurse would have all the information she needed from the patient chart? What was status of the SSU and the SSU nurse when the handoff was performed?
- What was the working relationship between the members of the staff, particularly the SSU nurse, the charge nurse, the Radiologist and the resident?

4. SSU Nurse

The SSU nurse was responsible for the patients care before the procedure. She was responsible for providing accurate and complete information about the incoming patient to the procedure nurse before procedure and expected to provide a safe handoff of the patient to the procedure nurse when the procedure preparation was started.

In order to assess if there were unsafe control actions taken by the SSU nurse prior to the procedure, it would be important to further investigate whether any of the instructions the patient received the morning of the procedure while in the SSU conflicted with the instructions he received previously in the diagnosis phase. Also, it should be considered if there were any signs that the patient would be at a high risk for a pneumothorax while in the SSU area prior to the procedure and if so, if this information was communicated to the procedure nurse.

Questions to further probe the context of the SSU nurses activities would include:

- What was the environment of the SSU area that the day of the procedure?
- What was the handoff policy between the SSU area and the procedure nurse?

5. CT Technician

The CT technician would have been responsible for positioning the patient on the CT bed as well as controlling the CT scan according to the orders from the Interventional Radiologist. While the details in the case do not specifically point to an unsafe decision or control action, it could be reasonable to review the CT scan results and consider if the positioning of the patient or the setting of the equipment could have had an effect on the accident.

Questions related to the technicians control actions include:

- How much time elapsed from the original setup including the patient positioning and pre-procedure CT scan to when the biopsy procedure actually began?
- How was the instruction from the Radiologist conveyed to the technician? Were the instructions clearly understood?

6. Interventional Radiologist

The interventional radiologist who performed the procedure had a number of safety-related responsibilities including first determining the position of the patient in the CT scan based on the reported location of the nodule and the x-ray and then identifying the size and location of the nodule from the CT scan image. The radiologist would have selected needle size for the procedure and determine a "safe" pathway to the nodule to avoid harm to the patient when the needle is traveling to the nodule. Then, during the procedure the radiologist would be responsible for inserting the needle into the patient's chest along a safe pathway avoiding harm to lungs or other organs to the nodule, remove a sample of the nodule, and retracting the needle along a safe pathway avoiding harm. Following the procedure, the radiologist would then be responsible for analyzing the post-CT scan to assess the patient for the existence of a pneumothorax following the procedure and ordering a follow-up x-ray to confirm the status of the pneumothorax. The radiologist would also need to ensure the procedure notes have been included in the patient chart and in the EMR system; complete the paperwork for the diagnostics lab, or assign the resident to complete these activities; and teach the resident the biopsy procedure method while assessing the skillset of the resident.

As a pneumothorax occurred, at some point during the procedure, the radiologist allowed positive-pressure air to enter the negatively pressured pleural space, disrupting the natural

vacuum, resulting in damage to the patient's lung tissue. The Radiologists may have expected the safe path visualized on the CT scan image to remain intact, as the needle was being inserted and removed; however, this pathway may have been compromised due to external or internal patient movement.

While the case specifies that the radiologist identified the pneumothorax as 10% based on the CT scan there is not a quantitative method for sizing the damage. Rather this is an estimate based on the visual review of the post-procedure CT-scan. The case indicates the radiologist ordered an immediate post-procedure CT-scan, but not an x-ray.

The context surrounding the actions of the radiologist is important to consider. It is not known in this case what was the cause of the pneumothorax. It is known that the current imaging equipment may pose challenges in maintaining the safe pathway. The CT scan 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). The patient's lungs would have been moving as they were breathing (internal movement) although this may have been minimized as the nodule was located in the upper lobe.

Question to consider regarding the radiologist include:

- Was the radiologist under pressure during the procedure?
- Were there any complications or interruptions during the procedure?

7. Radiology Resident

The radiology resident would have been responsible for assisting the radiologist in determining the position of the patient in the CT scan as well as identifying the size and location of the nodule. In addition, the case indicates that the resident was given the responsibility for writing the procedure notes including noting the pneumothorax to communicate to the recovery staff (including recovery nurse and clinicians).

The case indicates that the resident did not clearly write the procedure notes in the patient's file and did not dictate the notes until after the procedure for the EMR. The resident's process model flaw included assuming that the staff in the recovery area would be able to interpret his handwriting or that the details would not needed.

The context of the resident's actions includes the responsibility of the resident to assist with the procedures as part of their medical training. The resident was likely under pressure to perform well as the radiologist would be evaluating his performance. While the case details specify that residents had previously had awareness training as a result of a similar incident, it is not clear what this training included and if the resident involved in this accident participated in the previous training. It can be assumed that the resident was still relatively early in his training, as he was not given the responsibility to actually perform any of the biopsy tasks.

Question to consider regarding the radiology resident include:

- What training had the resident received regarding completion of the patient chart following the procedure?
- Did the resident make assumptions about the handoff procedure between the nurses and if so, did this affect his documentation?
- What pressure was the resident under when he was completing the chart details?

Phase III: Post-Procedure Recovery

After the biopsy procedure was performed, the patient was transported from the procedure room back to the SSU area to be monitored by the SSU nurse. While at the SSU area, the patient's status is monitored until he is discharged. The phase begins with the arrival of the patient at the SSU and ends when the patient is discharged from the hospital.

While the case study under review contains some detail regarding the events that occurred following the procedure when the patient was in the SSU area, similar to the two earlier phases, some details were inferred in the following CAST analysis.

As was the case in the diagnosis and biopsy procedure phases, the CAST methodology demonstrates that the events in the recovery phase may have contributed to the accident and should be included in the investigation. Questions raised by the CAST analysis are listed below in the detailed review of the controllers involved in the recovery phase. While the case does not directly mention the Procedure Nurse, X-ray technician, or the Radiologist (in the Reading Room), these controllers were inferred in the analysis.

As indicated in the control diagrams shown in Figure 13 and 14 for the recovery phase, a number of unsafe control actions occurred, and there are a number of missing or incomplete feedback flows related to the accident. Several of these relate to the communication or awareness of the patient's status including the increasing severity of the pneumothorax. In addition, the patient's mental model as formed in earlier phases is again discussed in the detail review of this phase.

Figure 13: Phase III Control Structure: Post Procedure Recovery (as Designed)

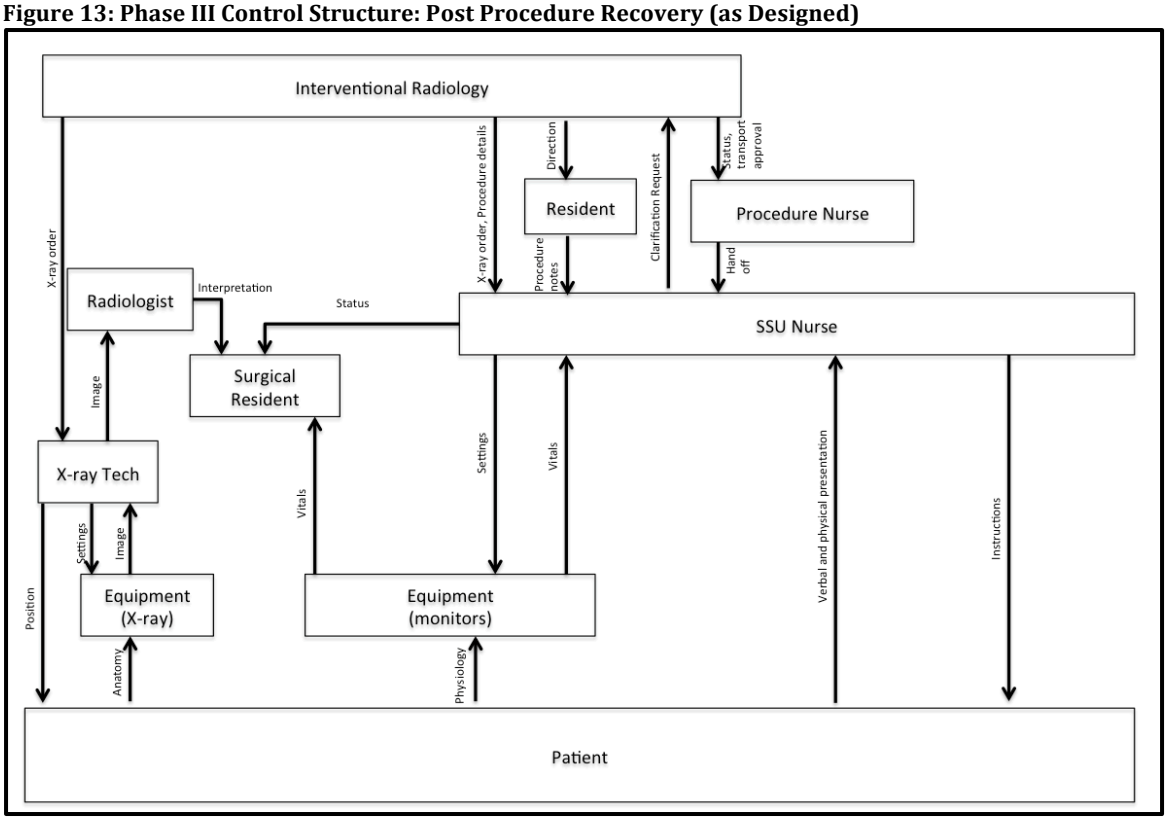
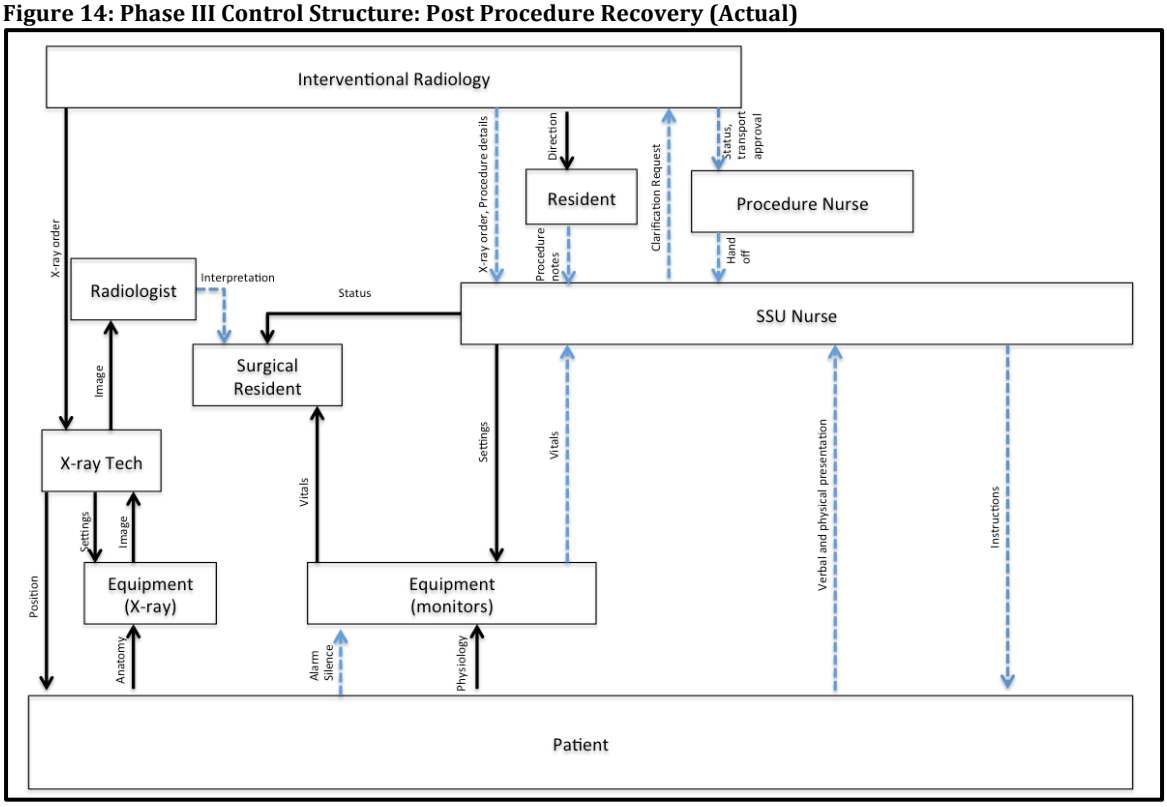


Figure 14: Phase III Control Structure: Post Procedure Recovery (Actual)



Controller Analysis:
The eight controllers involved in Phase II include the following:

1. Patient
2. Procedure Nurse*
3. SSU Nurse
4. Interventional Radiologist
5. Radiology Resident
6. X-ray Technician*
7. Radiologist (in Reading Room)*
8. Surgical Resident

*These controllers were inferred and not specifically detailed in the case.

Following the CAST methodology, each of the controllers was reviewed below for the following:

- Safety-Related Responsibility
- Unsafe Decisions and Control Action
- Process Model Flaw
- Context

1. Patient
Consistent with the earlier two phases, the patient's safety-related responsibilities included providing accurate and complete information (physical and verbal clinical presentation) which would have included including contacting the SSU staff if status worsened as well as following instructions provided by the SSU staff

In the recovery phase, the patient performed several unsafe control actions, which began with silencing the low oxygen alarm on the oximeter. This action prevented the SSU nurse from hearing the alarm and contributed to the lack of awareness of the patient's true physical status. The patient also did not alert the SSU nurse of the symptoms indicating the pneumothorax, specifically the pain experienced when breathing.

The case indicated that the patient had previously been told some discomfort was to be expected and he believed that the chest pain experienced was normal and did not need to be conveyed to the SSU nurse. It also indicates that the patient had previously learned to silence the alarm on the monitor, which may have been due to observations from watching the nurses perform this task or from experimentation. While it is clear that the patient originally denied having any pain, he was still partially sedated and therefore may not have been aware of the discomfort. It is also not indicated what instructions the patient received if any once he was returned to the SSU nor are his actions while in the SSU fully described.

This leads to a number of questions regarding the patient:

- Did the patient realize the noise emitted from the oximeter was an alarm indicating that it needed to be reviewed by the SSU nurse or did he believe that is was simply a nuisance, perhaps even a malfunction of the machine?
- Did the patient understand that he had a pneumothorax, and what that meant? Or did he believe that no harm was present and that he only needed to wait a required amount of time before returning home?
- The case indicated the patient had previously learned to silence the low oxygen alarm on the oximeter. Why was this? What was the situation: had he observed staff silencing the machine and rationalized it was not important to allow it to continue to alarm, or had he been advised previously that it was permissible to the silence an alarm?
- What instructions did the patient receive and what did he understand?
- Were there any contributing factors that might have impacted the progression of the pneumothorax? For example, was the patient coughing? Did he attempt to sit up or stand up?

2. Procedure Nurse

As the recovery phase begins with the patient's arrival at the SSU, the procedure nurse had a safety responsibility of ensuring all necessary information was communicated in the handoff to the SSU nurse before leaving the SSU. It does not appear that the procedure nurse informed the SSU nurse of the pneumothorax before leaving but it is unclear what factors may have contributed to this.

Questions related to the procedure nurse would help inform the context of the nurse's actions including:

- Was the procedure nurse aware of the pneumothorax? If not, why not?
- If the procedure nurse left without informing the SSU nurse of the pneumothorax, did she believe the SSU nurse had or would see it in the patient chart?
- What were the activities occurring around the time of the patient handoff between the procedure nurse and the SSU nurse? Was the procedure nurse feeling pressure to return quickly from the handoff from the charge nurse or other staff?
- Why did the procedure nurse believe the SSU nurse had all the information needed? Did the procedure SSU nurse see the SSU nurse look at the chart and assumed she had read about the pneumothorax?

3. SSU Nurse

Similar to the safety-related responsibilities of the procedure nurse, the SSU nurse was responsible for participating in an effective patient handoff before and after the procedure with the procedure nurse including confirming that information regarding the patient status and post-procedure notes were received. The SSU nurse would also have been responsible for setting up the monitors when the patient arrived at the SSU, providing necessary instructions to the patient while in the SSU and monitoring the patient's status for signs of worsening condition. If there were a status change, the SSU nurse would be responsible for contacting the Radiologist responsible for the care of the patient if required. Finally, the SSU nurse would be responsible for ensuring the Radiologist's order for the

follow-up x-ray was performed as needed (as the case details this would have to be done 2 hours after the procedure unless condition worsened).

The case indicated the SSU nurse made a number unsafe decisions and control actions without fully providing the context to understand why these occurred. During the recovery period, the SSU nurse did not appear to treat the patient as a high-risk patient who needed to be monitored closely. She did not check the patient status for 45 minutes after initially leaving the patient once the handoff and equipment setup was complete. In addition, the SSU nurse did not review the procedure notes in the patient chart until there was a sign that the patient was in distress. Once she did review the chart, she was unable to interpret the post-procedure notes from the patient chart.

It is not clear why the SSU nurse had a flawed process model of the patient's status. For example, it is not clear why the SSU nurse did not review the procedure notes in the chart when the patient first arrived. It can be assumed that the SSU nurse believed that the procedure nurse had conveyed all the necessary information verbally. She was likely influenced by the patient's denial of chest pain after the procedure, but it is not clear that the SSU nurse understood that the patient had a pneumothorax that needed to be monitored as a result of the procedure. While it is not clear what caused the delay in examining the patient, during the 45 minutes the patient was unattended, it is inferred that the SSU nurse believed that the patient's status was fine. The physical architecture described earlier may likely have contributed to the false perception that if the patient were in need of care, the SSU nurse would have known it. She may have in fact been assisting another patient only feet away, but visually separated by a curtain for example.

A number of questions are raised by the CAST method regarding the SSU nurse's actions and the context surrounding her decisions including:

- What was the environment of the SSU area that the day of the procedure?
- What was the handoff 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 with a mobile x-ray or did the patient have to be transported? How long did it take to get the x-ray and results?

4. Interventional Radiologist

During the recovery phase, the interventional radiologist would have been responsible for the care of the patient until he was discharged. He was not available or unable to speak with the recovery nurse, however, although it is not clear why.

It is inferred that the radiologist believed that the information regarding the pneumothorax had been conveyed to the SSU nurse and that the patient would be closely monitored for any changes in status. It can be assumed that the radiologist would have likely believed that changes in the patient status would have prompted a timely x-ray per his order during the procedure phase.

It is likely that the radiologist may have been in another procedure and therefore was unable to be reached by the recovery nurse. Also, as the resident was delegated the responsible for writing the post-procedure notes in the patient chart, the Interventional Radiologist may have been unaware that the handwriting was difficult to read. The Radiologist would likely then have assumed that the details of the pneumothorax were communicated verbally by the procedure nurse to the SSU nurse and by the resident in the patient chart.

- What was the context of the radiologist's actions during the recovery phase? Was he performing another procedure?
- Was the radiologist aware of the patient's status during the recovery phase?
- Did the radiologist order the surgical resident to place the chest tube? If yes, was that typical?

5. Radiology Resident

The radiology resident was responsible for assisting the radiologist in caring for the patient. Similar to the radiologist, the radiology resident did not appear to be available to speak to the SSU nurse and similar questions are raised:

- Did the SSU nurse request the resident or was the radiologist the only person requested?
- Was the resident available or assisting with another case or activity?

6. X-ray Technician

Similar to the chest x-ray performed in the diagnostic phase, the x-ray technician would have had safety related responsibilities to position the patient and control the X-ray according to the orders from the Interventional radiologist. It is not clear how much time elapsed and what actions where involved. For example, was a portable or fixed x-ray used? These actions themselves could have contributed to the extent of the pneumothorax, for example.

Details in the case are very limited regarding this activity, so a number of questions are raised:

- What was the process of obtaining the X-ray? Were any of these decisions factors in the accident?

- How much time elapsed during the X-ray process including capturing the image, and the analysis?
- Was the X-ray technician aware that the patient had a pneumothorax that was suspected of having worsened?
- What was the process of obtaining the x-ray? Was a portable or non-portable X-ray machine used? Was the patient required to stand or walk to the X-ray table?

7. Radiologists (inferred, in the Reading Room)

The radiologist in the radiology reading room would have had the responsibility to interpret the post-procedure X-ray to determine the extent of the pneumothorax. From the 2D x-ray, the pneumothorax was estimated as being 50%. While a numeric value is assigned, the evaluation is not quantitative as one might initially assume. The size of the pneumothorax was estimated based on the 2D image. The appearance of the pneumothorax on the x-ray could be affected by the patient position when the x-ray was taken and the location of the gas external to the lung. For example, if a portable x-ray was used and the patient was partially slouching, this could affect the appearance of the pneumothorax. This case does not mention that a post-procedure X-ray was performed so it was inferred that only a CT image was taken immediately following the procedure and that the original finding of the pneumothorax was based on the CT image. While this is not uncommon and varies between facilities, the result was that while the radiologist was interpreting the CT image to determine the change in the patient's pneumothorax, he did not have an X-ray to compare to.

8. Surgical Resident

The surgical resident had the responsibility to appropriately respond to the patient's condition. The case indicates that the surgical resident placed a chest tube, which was in place for 3 days. The case indicated that the surgical resident concluded that a chest tube must be placed immediately to inflate the patient's collapsed lung based on the finding that the pneumothorax was assessed to be 50%. Similar to the radiology resident, the surgical resident may have been under pressure to complete tasks quickly or had a high workload. It is not clear from this case, however, why the surgical resident was the one who placed the chest tube, if that was typical, and what the details of the chest tube and the procedure to place it were.

Additional questions related to the surgical resident's actions include:

- Was an alternative approach possible or desirable?

Summary of Key Finding of Controller Analysis

Diagnosis Team

Safety Related Responsibility

- Diagnosis patient and determine appropriate treatment plan
- Schedule procedure appropriately
- Educate patient adequately
- Obtain patient's consent for treatment
- ID risks and mitigation for treatment as appropriate

Unsafe Decisions and Control Actions

- Inadequate education of patient
- Lack of verification to confirm patient comprehension
- Lack of identification of patient's risk for pneumothorax

Process Model Flaw

- Provider believed communication to patient was adequate
- Administrator believed resources would be available as needed for procedure

Context

- Limited interaction with patient may have reduced the ability to appropriately assess comprehension
- Expectation that patient will consent to the provider determined treatment plan
- Medical terminology (such as pneumothorax) is well understood by providers but is not common knowledge among average patient

Treatment Team

Safety Related Responsibility

- Identify and maintain safe pathway for biopsy needle
- Remove biopsy without damaging sensitive tissue
- Communicate as needed to recovery staff
- Communicate instructions to patient as needed
- Assess patient status post procedure adequately

Unsafe Decisions and Control Actions

- Failed to maintain safe pathway, damaged lung tissue resulting in pneumothorax
- Written communication in patient record was illegible to SSU nurse
- Verbal communication to SSU staff and patient was inadequate
- Delayed transcription of procedure details for EMR

Process Model Flaw

- Radiologists believed safe pathway was identified and traversed
- Resident believed handwriting was legible
- Treatment staff believed recovery staff would have information required

Context

- Continuous view of safe pathway is not available
- Mechanism of pneumothorax is not fully understood
- Pneumothorax is a fairly frequent result of procedure and often does not require treatment
- Delayed dictation was normal for resident
- SSU was a new to the hospital
- Providers may not have been aware that patient was partially sedated when questions post-procedure

Recovery Team

Safety Related Responsibility

- Monitor patient status following procedure every 5 minutes
- Ensure follow up chest X-ray within 2 hours or sooner if status declining
- Communicate instructions appropriately to patient
- Identify risks that may result in patient harm or treatment need

Unsafe Decisions and Control Actions

- Did not adequately monitor patient status
- Did not identify decline in patient status in timely manner
- Did not identify risk present due to pneumothorax
- Did not provide timely response to decreased status

Process Model Flaw

- SSU nurse believed patient status was not in decline
- SSU nurse believed that she would be alerted if patient health declined
- SSU nurse believed the patient chart was legible and complete

Context

- SSU was a fairly recent addition to the hospital
- SSU staff was within close proximity the to patient throughout the recovery phase
- SSU nurse expected information would be available in patient chart as needed
- Semi sedated patient had denied chest pain or shortness of breath before transport to recovery so treatment staff may not have adequately convey sense of risk present

Patient

Safety Related Responsibility

- Convey relevant information for risk identification
- Comprehend, follow instructions provided, and communicate to staff as needed

Unsafe Decisions and Control Actions

- Did not communicate status decline to SSU nurse
- Silenced oximeter alarm

Process Model Flaw

- Believed procedure would not cause harm requiring treatment
- Believed status was normal and not in need of treatment
- Believed pain was consistent with normal discomfort
- Believed recovery staff was aware of status while in SSU

Context

- Medical terminology familiar to providers often unfamiliar to patients
- Patient desire and expect treatment to occur without complication so may discount signs of problems
- Had previously silenced oximeter alarm which may have been ion an occasion when it an invalid alarm
- Pneumothorax is a fairly frequent result of procedure and often does not require treatment
- Patient does not have training to understand what the oximeter alarm was indicating
- Patient was partially sedating after the procedure when questioned regarding status

Step 7: Review contributions of coordination or communication failures

There is evidence of communication failures in each of the phases between the medical providers and the patient as well as between the providers. In the diagnosis phase, the communication between the providers and the patient did not result in the appropriate level of patient comprehension. This was evident from the incorrect patient mental model, which led him to believe that the pain he was experiencing after the procedure was normal and did not require medical attention. Also during the diagnosis phase it is not clear that there was adequate information available to the administrator to appropriately schedule the patient's procedure.

In the procedure phase, the lack of continuous information on the safe pathway may have contributed to the resultant pneumothorax. The lack of communication from the procedure team to the SSU staff was also present due to the resident's illegible handwriting in the patient record, inadequate verbal communication between the procedure nurse and the SSU nurse, and the delay in transcription of the procedure details into the EMR. The sedation of the patient also contributed to communication failures, as the case indicated the patient was partially sedated when he was questioned about his perceived health status following the procedure.

Finally, during the recovery phase, the lack of communication from the procedure team affected the ability of the SSU staff to appropriately predict and assess the health decline of the patient. The SSU nurse was also unable to reach the radiology staff by phone for follow-up when necessary. Finally, the patient did not communicate his pain to the nurse and, by silencing the alarm, prevented the equipment from communicating his true health status to the nurse.

Step 8: Determine the dynamics and changes in the system and the safety control structure relating to the loss and any weakening of the safety control structure over time.

The control structure for each phase reveals inadequate feedback throughout the system. Feedback is necessary to confirm communication and comprehension both between the providers and the patient as well as between providers. In addition feedback is necessary to ensure that risks of pneumothorax are identified and mitigated as appropriate to prevent harm from occurring. Finally, feedback is necessary to both appropriately identify harm that does occur and allow for appropriate monitoring and response to the patient's health status. The dashed lines in the actual hierarchical control diagram identify the areas of the system where weakness occurred that resulted in errors in process models and unsafe control actions.

Step 9: Generate Recommendations

The areas of weakness identified in the control diagram should be addressed to improve the safety of the system in the future. The following recommendations are aimed at providing the necessary safety constraints to avoid unsafe control actions.

Short-Term Recommendations:

- Incorporate known risk factors in the review of patients prior to procedure and identify actions to prevent pneumothorax from occurring during the procedure.
- Create written instructions for patients and include a process to evaluate and confirm comprehension of the patients' understanding of the diagnosis, procedure, potential complications, and patient responsibilities.
- Reduce patient movement and incorporate procedure to monitor for movement.
- Incorporate risk evaluation of patients entering into the SSU recovery area.
- Treat patients with pneumothorax as high risk and increase observation and physical exam frequency during recovery.
- Evaluate patient mental status including sedation level upon arrival in SSU recovery area and modify expectations and/or treatment as needed.
- Provide instructions to patient upon arrival at SSU including explanation of any complications or risks and of the monitoring capabilities and incorporate a process to evaluate and confirm comprehension.
- Create specific process for patient handoff between providers including confirmation of verbal and written information and of comprehension of status and risk factors.
- Improve procedure for contacting radiologist to guarantee communication is available when needed.

Long-Term Recommendations:

- Improve knowledge of the causes of pneumothorax and prevention.
- Improve human factors of CT guided procedures.
- Incorporate ability to reduce and monitor patient movement while on CT scanner.
- Improve imagining capabilities to provide continuous awareness of safe pathway.

CAST Conclusion

The CAST analysis provides awareness of the enforcement of safety constraints in each of the three phases, diagnosis, biopsy procedure, and post-procedure recovery. Throughout the three phases, risk factors that may have been identified to help avoid the initial pneumothorax from occurring and later from worsening were not identified, communicated, or acted upon. In addition, issues resulting from the lack of effective communication either to the patient or between healthcare providers was identified numerous times in the case. Throughout the case there appears to be ineffective confirmation that the recipient received and comprehended the vital information that needed to be conveyed.

Chapter 7: Comparison of Root Cause Analysis and CAST

Through the development and analysis of the system hierarchical control structure, the CAST methodology provided the context leading to a more complete understanding of the reason why the accident occurred than the traditional Root Cause Method. The CAST method resulted in a broader, more comprehensive set of recommended accident causes and recommendations compared to the results provided by the Root Cause Methodology.

The root cause recommendations are limited to the recovery phase, and are very specific, including locking down the oximeter alarm and creating a checklist for the handoff. System changes that could have resulted in preventing the harm from occurring were not identified by the root cause analysis. The root cause method also did not fully reveal the reasons why the health decline of the patient during the recovery phase occurred. As a result of the simplified accident causality model, the recommendations are limited and appear to be inadequate based upon the discussion provided by the CAST methodology.

The CAST analysis allowed for the identification of a larger set of causal factors that contributed to the accident and revealed a much broader set of actions that can be taken in both the short and long term to prevent future incidents. The CAST methodology also provided a framework for guiding the investigator in identifying additional questions to confirm details not provided in the case. The hierarchical control framework provided the foundation to achieve a greater understanding of the reason why the accident occurred. Not only did it provide the ability to identify the unsafe control actions that occurred throughout the three phases, it also provided the perspective needed to consider the incorrect process models and the related context.

Chapter 8: Future Work

Future work should include the application of CAST to non-fictitious medical accidents to demonstrate the full capabilities of the methodology. It is recommended that the healthcare industry begin to evaluate and adopt system approaches such as STAMP in order to improve the quality of care provided. Regulatory bodies such as the Joint Commission can aid in the effort to promote awareness of the need and effectiveness of system-based methodologies for accident investigation, as well as seeking to ensure the broad adoption across the healthcare industry.

Efforts to improve information flow between stakeholders of the broad healthcare system, including regulatory bodies and manufacturers, through the reporting of medical errors should seek to incorporate the results of system-based investigations.

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