Implementing CAST and Designing the STAMP-Enhanced Learning And Reporting System

by
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Abstract

The safety performance of healthcare is concerning. Around 6% of patients are impacted by preventable harm. Adverse events recur because incident reporting systems (IRSs) are not effective and causes are not addressed. In-depth incident analyses, in particular, often focus on frontline human error and are blame-laden. All IRS functions, from data collection to learning dissemination, need to be improved. CAST (based on a state-of-the-art accident causality model, STAMP) is a more effective analysis technique, but its application in healthcare is hindered by time and knowledge constraints. This work investigated how CAST can be introduced and what features are required in a more effective IRS.

Seven enhancements were made, encompassing methodological refinement, reference materials, templates, and training. The enhancements seek to make CAST applications more efficient and consistent for novices. For evaluation, a hospital safety team was trained and analyzed an incident with CAST. The analysis not only identified the unsafe actions by frontline staff but also the underlying reasons. The departmental management's unsafe decisions and their underlying reasons were identified as well. The proposed safety interventions had broad system coverage, the potential for hazard elimination and could prevent dissimilar incidents. More learning was gained than with the conventional technique. Moreover, the analysis—produced with less time, training and without the guidance of a safety science expert—was at least comparable to, if not better than, other CAST analyses done by novices without the enhancements. Self-reported attitude agreement suggests a paradigm change may have been made. However, self-confidence in analysis abilities did not differ substantially, suggesting the training program should be revised to reconcile the mismatch with the improved analysis performance.

For broader IRS improvements, a conceptual design for the STAMP-Enhanced Learning And Reporting (STELAR) system was created. It focuses on improving the interdependencies between IRS functions and with external safety information sources.

CAST can be feasibly learned and applied in healthcare; IRSs can be improved by designing them holistically. This work advances the goal to research, develop, and apply systems engineering tools in healthcare and contributes to a safer healthcare system—by enabling effective safety learning with a systems approach.

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Keywords: Healthcare safety, adverse events, CAST, IRS, incident reporting system, incident analysis, safety intervention design

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So many more people helped whom I cannot fit on this page. Please know that you have made a difference. It has truly taken a village. I am grateful for the opportunity to stand on the shoulders of giants, and I look forward to contributing to humanity with the knowledge I have gained.

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Chapter 1. Introduction

The safety performance of the healthcare system is concerning. While healthcare exists to vitalize and to heal, many patients and healthcare workers are inadvertently harmed. Incident reporting systems (IRSs) are used to improve healthcare safety, but can have a limited effectiveness. The goal of this research is to understand why and to improve them.

Before discussing the motivation of this research in detail, some key terms are defined. An *adverse event* is "an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition of the patient" (Institute of Medicine (IOM), 1999, p. 4). A *near miss* is "an event or a situation that did not produce patient harm, but only because of intervening factors, such as patient health or timely intervention" (Shekelle et al., 2013, p. 405). In this dissertation, an *incident* is used to collectively describe any adverse event, near miss, unsafe condition, and event where a healthcare worker is harmed.

An *incident reporting system*[*] is a mechanism to identify and generate learning from incidents (IOM, 1999; Shekelle et al., 2013). Basically, an IRS comprises four functions. First, it collects data on incidents. Second, it processes the data to achieve a more detailed understanding. The processing may take the form of an (in-depth) analysis of a single incident or an aggregate data analysis. Third, it proposes safety interventions to prevent the incident recurrence. Lastly, it disseminates the lessons learned and the required system changes to all relevant parties. Reporting has helped other high-risk industries (e.g., aviation) reduce accidents by learning the lessons (IOM, 1999).

1.1 Motivation

1.1.1 Patient harm is ubiquitous and costly

During care delivery, various types of incidents can occur. For instance, there are drug-related ones (overdose, wrong drug administration etc.), procedure-related ones (wrong site surgery, retained surgical bodies, etc.), infections (ventilator-associated pneumonia, etc.), etc. (Panagioti et al., 2019). Furthermore, the incidents permeate different settings (hospital, practitioner office, etc.) (Chang et al., 2005). The resultant harm can range from physical to psychological, temporary to permanent, mild to severe—even death.

Patient harm is ubiquitous. According to the commonly cited report *To Err Is Human* (IOM, 1999), up to 98,000 people died in U.S. hospitals each year due to medical errors. The estimate has increased to hundreds of thousands in more recent publications (Bates and Singh, 2018; James, 2013; Makary and Daniel, 2016). In one of the largest systematic reviews on the topic, Panagioti et al. (2019) reported that about 6% of patients worldwide are impacted and about 12% of the preventable harm lead to prolonged, permanent disability, or death.

Patient harm is also costly because the patients affected often require additional medical care and extended hospital stay. For instance, Anand et al. (2019) estimated that surgical site infections and severe pressure ulcers are the costliest, amounting to $30,000 per case. The annual financial impact of medical error is substantial—$17.1 billion nationally (Van Den Bos et al., 2011) and $617 million in

[*] Variations of the name exist: incident learning system, safety learning system, etc. In calling it a "learning system," the emphasis is to understand and to address the safety problem rather than the sheer act of reporting. In referencing "safety" rather than "incident," the emphasis to include unsafe conditions rather than only unsafe events. In this dissertation, the nomenclature "incident reporting system" is retained because it is broadly used, especially given its appearance in the IOM (1999) report. Nonetheless, the importance of learning and the inclusion of unsafe conditions is not forgotten.

Massachusetts alone (Betsy Lehman Center for Patient Safety, 2019). The need for additional care following an adverse event further burdens the already stressed healthcare system.

1.1.2 Healthcare workers are also harmed

Physical injuries are not uncommon. They can result from the use of sharp instruments, workplace violence, exposure to body fluids, the demands of manual patient movement, etc. (Wåhlin et al., 2019). Moreover, about 45% and 24% of healthcare workers have experienced at least a needle stick injury and physical violence, respectively, in the previous 12-month period (Bouya et al., 2020; Liu et al., 2019).

Healthcare workers also experience psychological injuries. The harm is especially pronounced among physicians, who have a rate of suicide higher than that of the general public. The higher propensity is caused by both stress in the care environment and the undertreatment of mental illness (Gold et al., 2013). Importantly, staff and patient harm can be interrelated. “Second victims” are produced when healthcare workers suffer emotional distress, often long-lasting, after a medical error (Dekker, 2011; Santomauro et al., 2014; Ullström et al., 2014). This phenomenon affects as many as 43% of healthcare workers (Seys et al., 2013). In some cases, the “second victims” even die by suicide due to blame and guilt. The impact on healthcare workers provides another salient reason why the safety problem needs to be addressed.

1.1.3 Ineffective safety learning stalls healthcare safety improvement

The extent and persistence of the safety problem suggest that not enough learning is generated from the incidents. For instance, after a patient died from a transfusion reaction at a renowned academic medical center, the Department of Health and Human Services (DHHS) investigation revealed that mislabeled blood specimens or labeling problems occurred in 122 incidents in the four months before the investigation, and effective actions were not taken to rectify the situation (Centers for Medicare & Medicaid Services, 2019). Appendix A describes this case in more detail. Similarly, retained surgical body incidents repeatedly occurred over a 8-year period at another major academic medical center (Kellogg et al., 2017). While IRSs are in use in nearly all U.S. hospitals (Farley et al., 2008), they have not effectively prevented incident recurrence.

Safety learning is ineffective because of numerous reasons, but the superficial and blame-laden analysis output is chief among them. Gosbee and Anderson (2003) described a case where the safety analysts analyzing a surgical incident steered the investigation towards personnel records in search of policy violations and focused on gender differences. In general, analyses commonly stop at identifying the flawed action or decision of a healthcare worker rather than the broad set of flaws around the system (Trbovich and Shojania, 2017). The state of practice is far from the original aim to transform brief reports into detailed and thorough causal factors, or better still, to identify system vulnerabilities broader than what concerned the given incident (Macrae, 2016; Vincent, 2004). With the superficial and blame-laden analysis output, safety interventions may bear the wrong objective.

Nonexistent or ineffective safety intervention recommendations also undermine safety learning. For instance, safety interventions were recommended in only 35% of the analyses generated over eight years at an academic medical center (Kellogg et al., 2017). Of the proposed solutions, training was the most common suggestion, but it neglects the non-human aspects of the system and tends to be less effective than alternatives such as process redesign. Similarly, having reviewed 60 healthcare-related analyses, Card et al. (2012) reported that over 80% of recommendations were administrative controls—another relatively ineffective type of safety interventions when used alone. With few effective safety intervention recommendations, the prospect of safety improvement is slim.

Expanding the consideration to the other IRS functions, safety learning is also limited because not all incidents are reported to IRSs. Noble and Pronovost (2010) cited under-reporting rates of 4-

50%. Other analyses suggest an even more severe problem. From 1,006 patient admissions in eight different specialties at a hospital, only 17% of the incidents were reported (Sari et al., 2007). Likewise, when the Inspector General of the DHHS examined 785 admissions, an under-reporting rate of 81.6-90.0% was found (Levinson, 2012). Without knowing the incidents, the causal factors cannot be identified and addressed. Furthermore, under-reporting introduces a systematic bias. The DHHS study reveals that safety reports tend to identify the incidents of lower severity. Similarly, Scott et al. (2020) observed that many report originators down-code the severity of incidents. This skew undermines aggregate data analysis and the selection (triage) of incidents for in-depth analyses: If the number of reports is used for assessing problem resolution, a false sense of security is created; if the number is used as a proxy for the likelihood of recurrence, incidents may be under-triaged for in-depth analysis.

The rarity of analyses is another reason why safety learning is ineffective. Extrapolating the data from two academic medical centers of similar sizes (Kellogg et al., 2017; Levtzion-Korach et al., 2010), only one in about 100 incident reports gets analyzed in-depth. In general, in-depth analyses are limited to adverse events (Gandhi et al., 2005; Percarpio et al., 2008; Pham et al., 2013; Thomas et al., 2011). In other words, safety learning is often not generated from near misses—the less costly opportunity to learn (Gnoni and Saleh, 2017). Just as few in-depth analyses take place, aggregate data analyses are not often used either. Despite receiving over 10,000 reports annually, a renowned academic medical center does little with the data (Pronovost et al., 2008). Many learning opportunities are missed.

Lastly, those who file reports are not told the lessons learned, nor is the wider system. Interviews with physicians repeated after a decade showed that many report originators still consider IRSs a “black hole” (Burns et al., 2018). Staff invest time and effort when submitting a safety report, but the lessons learned are not communicated afterwards, so the act seems to be in vain (Benn et al., 2009; Macrae, 2016; Mitchell et al., 2016; Peerally et al., 2017). The impact of IRSs is also obscure to the broader staff beyond the report originators. Only 71% of the surveyed hospitals distributed incident summaries (Farley et al., 2008). Not sharing the lessons learned produces another missed opportunity to improve safety. It also discourages future participation in reporting.

In summary, safety learning is ineffective because of under-reporting, rarity of incident analyses, superficial and blame-laden analysis output, nonexistent or ineffective safety intervention proposals, and a lack of learning dissemination. Ineffective safety learning stalls healthcare safety improvement.

1.1.4 Introducing a more effective incident analysis technique is challenging

The use of a more effective incident analysis technique is needed, but a time constraint hinders the change. The time that safety analysts, who are mostly clinicians, spend on analysis often competes with that for patient care (Blanchfield et al., 2018; Canham et al., 2018; Peerally et al., 2017). For the broader system, safety improvement is also time-critical because human lives are dependent on the care being provided—often with a strict therapeutic window and cannot be interrupted. Therefore, incident analysis and safety intervention implementation face immense time pressure. This is unlike aviation where the grounding of an aircraft type results in financial losses but not typically the loss of human lives. To put this into perspective, each adverse event of the most serious category (resulting in severe harm or patient death) receives, on average, only 28 person-hour of investigation and processing at a renowned hospital, whereas each aviation investigations handled by the National Transportation Safety Board take 13 months on average (Blanchfield et al., 2018; Fielding et al., 2010). In short, any analysis technique with a lengthy process is deemed time-prohibitive in healthcare.

Lack of the relevant knowledge also hinders the introduction of the latest incident analysis techniques, which take a systems view of accident causation (discussed in Chapter 2). While clinicians bring a wealth of medical knowledge to the analyses, they may not have the relevant knowledge of

systems engineering. Systems theory, in particular, is foreign to most in healthcare (Kaplan et al., 2013). The “systems approach” has been misunderstood in healthcare as standardization (e.g., using checklists) and the wholesale surrender of individual accountability (Dekker and Leveson, 2015). Collaboration and idea cross-pollination between healthcare and systems engineering have also been hampered by terminology differences. For this reason, the latest incident analysis techniques are not intuitive to the safety analysts in healthcare (Canham et al., 2018; Jun and Waterson, 2019). Additional training is required for the introduction of the latest techniques, exacerbating the described time cost.

1.2 Problem statement

More effective incident analysis techniques exist, but their application in healthcare is hindered by time constraints and a lack of the relevant knowledge. At the broader level, healthcare IRSs have not enabled effective safety learning and thus incidents recur. The first problem being addressed is to identify how to introduce a more effective incident analysis technique into healthcare given the challenges. Another problem being addressed is how to improve IRSs beyond incident analysis.

1.3 Research objectives and scope

The objectives of this research are to create a practical way to introduce a more effective incident analysis technique and to outline the features of a more effective IRS.

IRSs in healthcare organizations are targeted rather than their state and national counterparts. Organizational IRSs are the primary custodian and arbiter of safety information, and they are overwhelmed. Therefore, this subset of IRSs has a critical need of redesign, and it also embodies much untapped potential. Moreover, this scoping decision enabled a direct collaboration with radiation oncology departments, which are fertile ground for system improvement. A “crisis in cancer care delivery” exists because the care provided is often not coordinated, aligned with the latest scientific evidence, nor fitting for the patient (IOM, 2013, p. 1). The collaboration is extra advantageous because radiation oncology has a strong culture of innovation both in care delivery and system improvement.

This research addresses the IRS function of proposing safety interventions but not proposal selection and implementation. The latter functions benefit from other systems engineering and management science research.

1.4 Research questions

The following research questions were investigated:

Q1. How can a more effective incident analysis technique be introduced into healthcare given the constraints?

Q2. What are the features required in a more effective IRS?

1.5 Research approach

This research was completed as systems engineering field research. Similar to other research of this type, the researcher took dual roles: not only as an observer but also as a developer of the practice being trialed (Checkland and Scholes, 1999, p. A39).

The research spanned three broad phases: I) creating the way to introduce a more effective incident analysis technique into a healthcare setting, II) implementing and evaluating the

enhancements, III) proposing the conceptual design of an IRS that incorporates the incident analysis technique.

Overall, a substantial amount of feedback and insights from experts was incorporated into this research. For any tool or practice to be effective in healthcare, customization is needed (Peerally et al., 2017). The inputs from the experts enabled the appropriate customization to take place. Furthermore, involving the potential users (taking a participatory approach) is also recommended for any implementation research because it renders the research more relevant to the problem at hand and improves implementability (Straus et al., 2013). To this end, the user organization was engaged in the research from the formal proposal until the final evaluation. The expert input and end-to-end engagement improved the quality of this research.

1.5.1 Phase I: Creating the way to introduce a more effective incident analysis technique into a healthcare setting

Research and development was conducted to make the incident analysis technique more efficiently learned and applied by healthcare practitioners, who may not be familiar with the theories and concepts underlying the technique.

1.5.2 Phase II: Implementing and evaluating the enhancements

First, the incident analysis technique was introduced at the radiation oncology department of an academic medical center. Then, the technique was used by the local safety analysts to analyze a safety incident. Finally, an evaluation was performed based on the analysis experience, analysis output, and other survey data.

1.5.3 Phase III: Proposing the conceptual design of an IRS that incorporates the incident analysis technique

A conceptual design for a more effective IRS was created. The proposed IRS design incorporates not only the more effective incident analysis technique but also additional features to mitigate the barriers to safety learning.

1.6 Dissertation structure

The remainder of the dissertation is organized as follows:

Chapter 2 reviews the state of the art of safety science and the existing literature on the research questions posed. Specifically, the chapter describes and critiques the models of how accidents happen, the incident analysis techniques, and IRS redesign ideas and past implementation experiences.

Chapter 3 summarizes what is required in a more effective incident analysis technique to address the flaws of conventional practices and details a technique named CAST that has been proposed based on systems theory to achieve these requirements. An example is used to illustrate how a CAST analysis is conducted.

Chapter 4 presents the enhancements created to introduce CAST into a healthcare setting. To set the stage, the chapter first establishes some specific challenges of adopting and applying CAST in healthcare. The enhancements are then detailed and their use illustrated with examples.

Chapter 5 reports the implementation and evaluation of the enhancements in a hospital setting. It documents the training experience and the challenges. It also presents the evaluation results and discusses the derived insights.

Chapter 6 proposes the conceptual design for a more effective IRS, which incorporates CAST and other novel features. The chapter first reviews the requirements for a healthcare IRS. The specific features of the IRS being proposed are then described.

Chapter 7 draws conclusions and outlines the future work. Ideas to further improve the enhancements and to mature the IRS design are the main focus. The broader contribution of this work is also discussed.

Chapter 2. Literature review

This chapter describes and critiques the models of how accidents happen, the incident analysis techniques, and IRS redesign ideas and past implementation experiences. To recapitulate, the causal factors in an incident are identified by applying incident analysis techniques. These techniques embody different models of how accidents happen. At the broader level, the designs of IRSs determine when incident analysis techniques are applied, what preliminary information the analyses build upon, and how analysis output is used and disseminated. Knowing these topics is essential to improving safety learning in healthcare.

2.1 Accident causality models

Accident causality models describe how accidents happen and inform how accidents can be prevented. For instance, the basic energy models depict accidents as resulting from uncontrolled or undesired energy flow impacting an object (Leveson, 1995). Under this premise, accidents can be prevented with barriers to the energy flow. Different simplifying assumptions are made in the models, e.g., the basic energy models do not consider the role of humans. Due to the differences between the models, the applicability varies. For instance, the basic energy models cannot describe logical errors or be applied to losses such as the loss of mission or reputation. Choosing which accident causality model to use is important.

The chain-of-events models and the systemic models are especially relevant to this research. The chain-of-events models are the foundation of commonly used incident analysis techniques, and the systemic models represent the state-of-the-art understanding of contemporary accidents. Both are the focus of this section, but readers interested in a description of the more historical models are referred to other reviews (e.g., Kjellen, 2000; Leveson, 1995; Pasman et al., 2018; Yang and Haugen, 2018).

2.1.1 Chain-of-events models

The chain-of-events models characterize accident causation as a linear process. Based on these models, an adverse drug event may be described as follows: a multidose vial of insulin is left next to a vial of heparin on a bedside cart, insulin is inadvertently drawn up from the multidose vial and administered to the patient, and the patient suffers from profound hypoglycemia (Figure 1). Each of these events is directly linked to the preceding event.

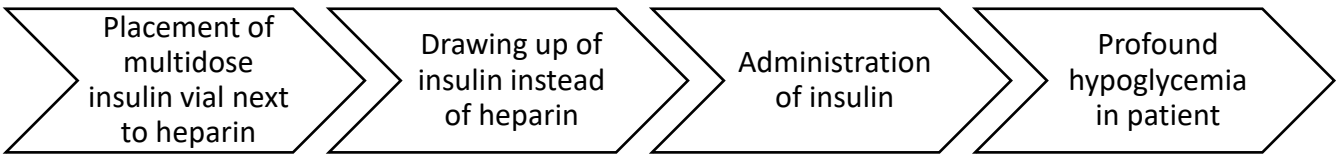


Figure 1 The progression of an adverse drug event

2.1.1.1 Heinrich's Domino model

Of the chain-of-events models, Heinrich's (1931) Domino model is a historic example. In this model, an accident results sequentially from factors concerning the social environment, which cause a fault of the person involved, who performs an unsafe act, which causes the accident, leading to injury (Figure 2). The description of the adverse drug event above, though abbreviated, fits into this model. By this logic, if the vial of insulin was kept in the refrigerator—where it was supposed to be—the insulin would not have been inadvertently drawn up and administered. Therefore, preventing the recurrence of

the adverse event hinges on ensuring staff compliance with the storage requirement. The Domino model provides an intuitive explanation of incidents, and safety interventions can be easily identified.

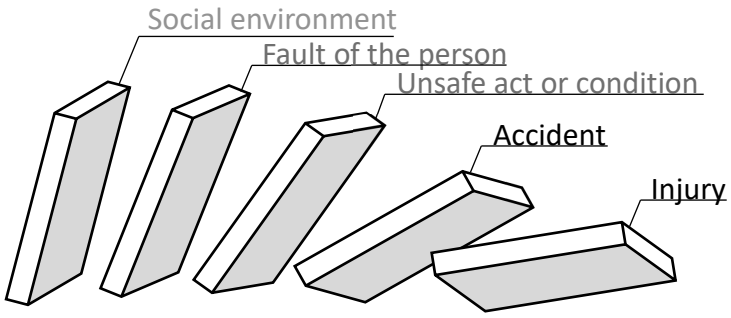


Figure 2 An illustration of Heinrich's Domino model

Despite having the benefit of simplicity, the Domino model often leads to frontline personnel being blamed. While the consideration in the model supposedly extends to the role of the social environment, the emphasis is placed on the person involved in the incident. In fact, when describing an accident in which a saw operator lost a thumb, even Heinrich himself emphasized the operator's repeated violation of the instruction to use a push stick (Lundberg et al., 2009). This focus on the person, rather than the system, creates blame and impedes a holistic consideration of safety interventions.

2.1.1.2 Reason's Swiss Cheese model

Reason's (2000) Swiss Cheese model is another incarnation of the same chain-of-events model but with a slightly different metaphor. An accident is assumed to occur when hazards are not stopped by a series of defenses, barriers, and safeguards, which are weakened by latent conditions and active failures. Latent conditions and active failures refer to the problematic strategic decisions and the unsafe acts performed by the people involved (e.g., manufacturers and managers vs. doctors and nurses). Graphically, the defenses, barriers, and safeguards are like slices of Swiss cheese—laden with holes representing the latent conditions and active failures (Figure 3). An accident occurs when the holes between the slices are aligned. This linear depiction of accident causation is identical, for all practical purposes, to the Domino model.

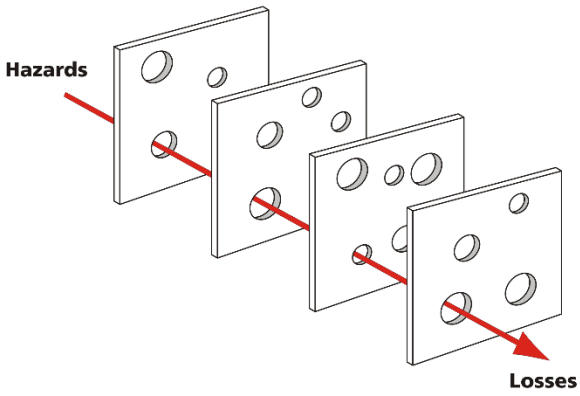


Figure 3 Swiss cheese model accident trajectory. (Davidmack, CC BY-SA 3.0, via Wikimedia Commons)

The Swiss Cheese model is not a systemic model. Reason (2000) suggests it describes "system accidents" and underscores the role of system design in accident causation, but the model lacks detailed

characterization to advance safety thinking in this regard. For instance, Reason mentions that accidents are the result of more than individual acts, and the error-inducing system context takes an important role. However, this relatively crude consideration of the system has been present even in the Domino model and does not help identify the flaws in the system, e.g., systemic factors, comprehensively.

2.1.1.3 Limitations of the chain-of-events models

The primary problem with the various incarnations of chain-of-events models is that they focus on events but not the reasons why the events occurred. These reasons (e.g., systemic factors) provide the information necessary to prevent accidents.

What are systemic factors? They are the causal factors that can overwhelm many, if not all, the defenses. In reality, factors such as financial pressure can undermine the safety effort in both management and operational settings: equipment with advanced safety feature may be forgone for a lower-cost model during procurement, frontline roles solely dedicated to safety (e.g., medication safety officer) may be left vacant to reduce overhead, clinicians may lack time for safety-related activities, which are not directly billable or reimbursed. Indeed, as hospital profit margin decreases, the likelihood for patient safety events increases (Encinosa and Bernard, 2005). In chain-of-events models, accidents are assumed to only occur when the failure events occur by chance—systemic factors are not considered.

Second, a linear depiction of accident causation cannot fully describe the dynamics underlying accidents when different parts of a system interact in reality. For instance, management decisions do not depend solely on government regulations but also the information passed from frontline operations. In the Therac-25 accidents, a patient was overdosed at the Kennestone facility and the manufacturer was notified (Leveson, 1995). The fact that many more patients were overdosed before the system was recalled shows that the IRS was ineffective. This consideration is missed in the linear models.

Third, considering human errors (work deviations) as a causal factor does not meaningfully improve safety. In actuality, deviations are common because work instructions are not comprehensively specified and adaptations are often made—in response to financial pressure or simply efficiency and working with limited resources, for example (Rasmussen, 1997). Even when one deviation is addressed, many more remain and can still cause an accident. Focusing on work deviations only predisposes incident analyses to hindsight bias and produces a superficial understanding of incidents.

Fourth, the models mistake reliability as safety. Failure (i.e. the nonperformance of the required functions) is the focus of the models, but reliability—the inverse of failure—does not guarantee safety (Leveson, 2004). For instance, Therac-25 treated thousands of patients without incident (Leveson, 1995). This reliability created a false sense of security, which prevented the safety problems to be addressed promptly. Unreliability does not always result in accidents either. Human operators sometimes intentionally deviate from specified procedures, thereby being “unreliable”, but succeed in averting accidents. By focusing on reliability as a proxy for safety, an assumption is made that systems are well-designed. However, having the wrong design is, for example, a causal factor in nearly half of the accidents in chemical and nuclear industries (Pasman et al., 2018; Taylor, 2007). The assumption is often invalid and impedes a thorough safety analysis. To sum up, reliability cannot be equated with safety, and an accident causality model ought to consider more than reliability.

Finally, the obvious strategy of accident prevention motivated by the linear modeling may cause more problems than it fixes. To reiterate, defenses and barriers being breached are how accidents occur in the chain-of-events models. Therefore, the strategy of adding barriers (defense-in-depth) is logically used for safety improvement (Rasmussen, 1997). Contrary to the intent, the redundant barriers can actually render unsafe conditions invisible. For instance, when the Therac-20 software misconfigured the system to produce excess radiation, the electromechanical interlocks prevented the electron beam to be actually generated. While no patient was harmed with Therac-20, the flaws with the software were

not discovered, and parts of the software were reused in Therac-25, leading to patient harm. The opaqueness in a defense-in-depth approach predisposes an unsuspecting actor to unleash an accident without knowing that the defenses have been systematically degraded over time. Put differently, unsafe conditions can be buried by the attempt to fix the safety problem identified based on linear models.

2.1.2 Systemic models

To overcome the shortcomings associated with the chain-of-events models, researchers have proposed systemic models. Systemic models portray accident causation as a complex process instead of a linear sequence of events. Also, the organizational and social aspects of a system take on a much more significant role in accident causation. These systemic models are based on systems theory, not reliability theory.

Systems theory focuses on the whole but not the parts. In general, two approaches can be used to analyze systems: a reductionist approach and a systems one. The former involves dividing systems into parts and analyzing the parts by themselves. It has enabled the creation of immense amount of knowledge and many achievements since the industrial revolution. However, its limitation became obvious in early twentieth century (Hitchins, 2007; Leveson, 2011a). Correspondingly, research has been done to better understand systems where “the whole is more than the sum of its parts”, and this knowledge is especially important for some systems. For instance, the human body comprises many systems (e.g., pulmonary, circulatory, etc.), but no single system holds the key to life—they must all work in concert. Accounting for the interactions between the parts of a system is the essence of taking a systems approach. Applying this principle has improved healthcare. For instance, “time is brain” is a guiding principle in stroke care (Saver, 2006). However, increasing the ambulance transport time by bypassing the closest hospital may actually improve the outcome for some stroke patients when they are transported to more capable facilities (Jayaraman et al., 2020). The formalization and continued development of systems thinking have led to systems theory.

A complete review of systems theory and its history is beyond the scope of this work, and interested readers are referred to some previous work (e.g., Aslaksen, 2013; Checkland and Scholes, 1999; Flood and Carson, 1993; Hitchins, 2007; Senge, 2006; Weinberg, 1975). Selected concepts and terms are discussed below as the systemic models are introduced.

2.1.2.1 Rasmussen’s model

Rasmussen (1997) argued that gaining a better understanding of accidents requires a change of focus. Specifically, effective accident prevention demands not focusing on the behavior but the underlying behavior-generating mechanisms and making the boundary of safe operation visible.

To achieve these objectives, Rasmussen forwent the linear, task-based perspective in previous models but adopted a socio-technical one in his modeling. The interactions between government, industry groups, company management, frontline worker, and the work process are explicitly captured (Figure 4). For instance, staff decisions are not dictated by the plan issued by management; they also incorporate live observations in the field. Environmental stressors such as fast-paced technological changes also influence the decisions at this level. The nonlinear modeling offers a groundbreaking perspective.

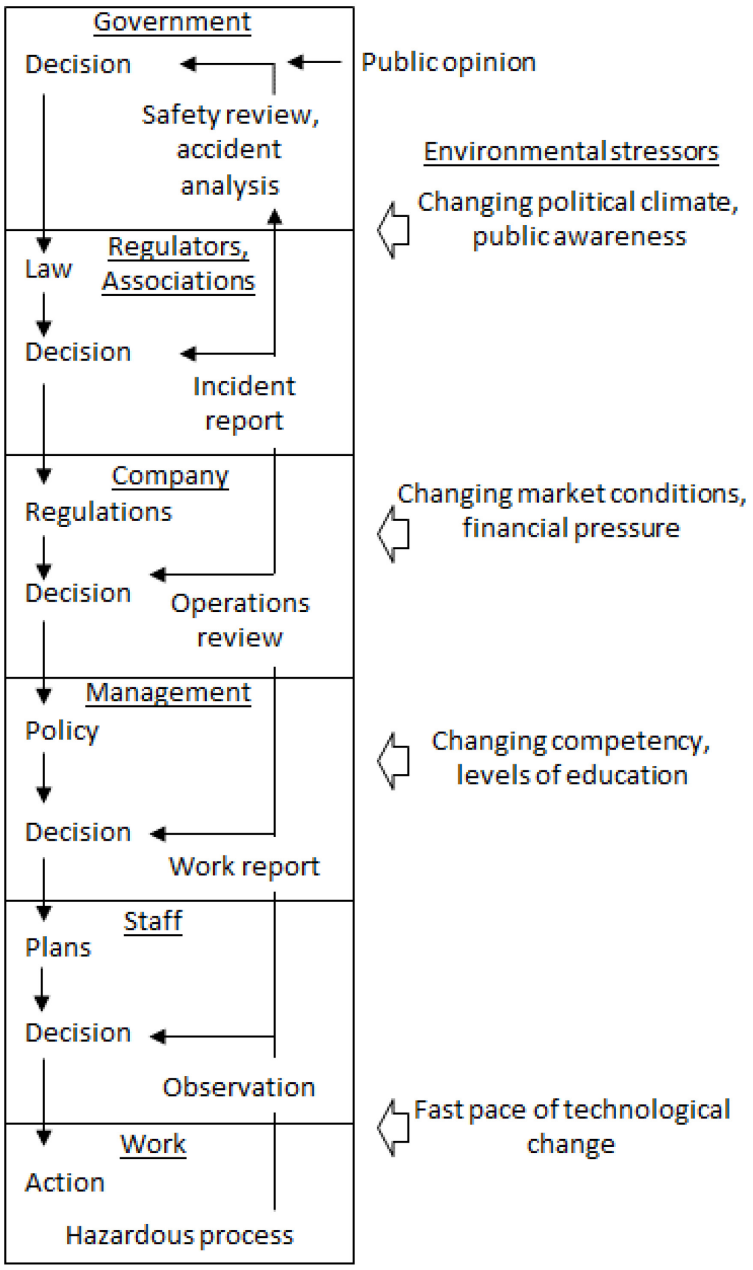


Figure 4 Safety management with a socio-technical system. Adapted from Rasmussen (1997).

With the new perspective, accident prevention is treated as a control problem. Decision makers, known as *controllers*, make decisions that collectively cause or prevent accidents. The boundary of safe operation for one controller may be contingent upon the decisions of other controllers. For instance, performing certain interventions (e.g., intravenous medication) on a patient waiting to be transferred to a different hospital is advisable so long as the dispatcher sends an ambulance crew who can manage and continue the intervention. An accident occurs when a controller makes decisions based solely on the local context.

In the same vein, accident prevention often requires feedback control. Even when the system is in a desirable, non-hazardous state, continuous control is still required to counter external disturbances. For instance, the distribution of COVID-19 vaccines gained momentum until a severe weather system disrupted the delivery network and necessitated adjustments. Information, known as *feedback*, about

the current situation enables this (feedback) control to be dynamically exercised. Feedback is shown along the upward arrow in Figure 4. This aspect of the interactions is neglected in historical modeling, but missing or having the wrong feedback can cause accidents.

With the entire socio-technical system under consideration, hierarchical control is required for accident prevention. The higher controllers (e.g., regulators) specify the constraints for behavior (e.g., the scope of practice of frontline clinicians) in the lower level and make the boundary of safe operation visible. It enables the constraints for the entire system to be achieved through interactions of the system elements. Importantly, control and feedback interactions connect the hierarchical levels such that the behavior across the system is compatible. Treating accidents as a control problem generates a more detailed understanding and informs accident prevention more comprehensively.

While Rasmussen's model has enabled a more holistic view of accidents, the consideration is limited to system operations. Because having the wrong design is a prevalent cause of contemporary accidents as mentioned, an important aspect is still missing from Rasmussen's model.

2.1.2.2 Systems Theoretic Accident Model and Processes (STAMP)

STAMP is a more recent and advanced systemic model. Similar to other models based on systems theory, it provides a socio-technical perspective of accident causation and treats accident prevention as a control problem (Leveson, 2004). In addition, it characterizes accidents more extensively with systems and control theories and expands the consideration into system development.

Accidents are more extensively characterized as a control problem. In brief, to *control* is to impose constraints on the behavior of a component (Leveson, 2011a). For controls to be adequate, four conditions need to be met:

1) The controller must have one or more goals, which, for safety management, describe the hazardous state to avoid.
2) The controller must have a model of the process—an understanding of what is being controlled and what the current state is.
3) The controller must have an information source about the process state. The information (feedback) is used to update the controller's understanding stated in condition 2.
4) The controller must have a way to change the process state, so the process state advances towards the goal.

These conditions serve as the foundation on which safety constraints are derived for every controller—human or automated. When these conditions are not met, rendering control inadequate, an accident can occur.

System development must be considered in accident prevention. This is important not only because design problems have caused accidents but also the controllers responsible for system development are often different from those responsible for operations. For instance, what drugs frontline clinicians can prescribe depend upon the new drug approval by the Food and Drug Administration (FDA). The FDA's decision to approve drugs is not only based upon the information supplied in the new drug applications but also the recommendations from the FDA advisory committees, who are academically-affiliated researchers. These controllers do not completely overlap those who manage and provide care in the operational setting. Figure 5 shows the system involved in the development and approval of Vioxx (Rofecoxib), which caused increased risk of cardiac disease (Leveson et al., 2012). As shown, the decisions made during development have a profound impact on safety. Including this part of the system generates a more comprehensive understanding of accidents.

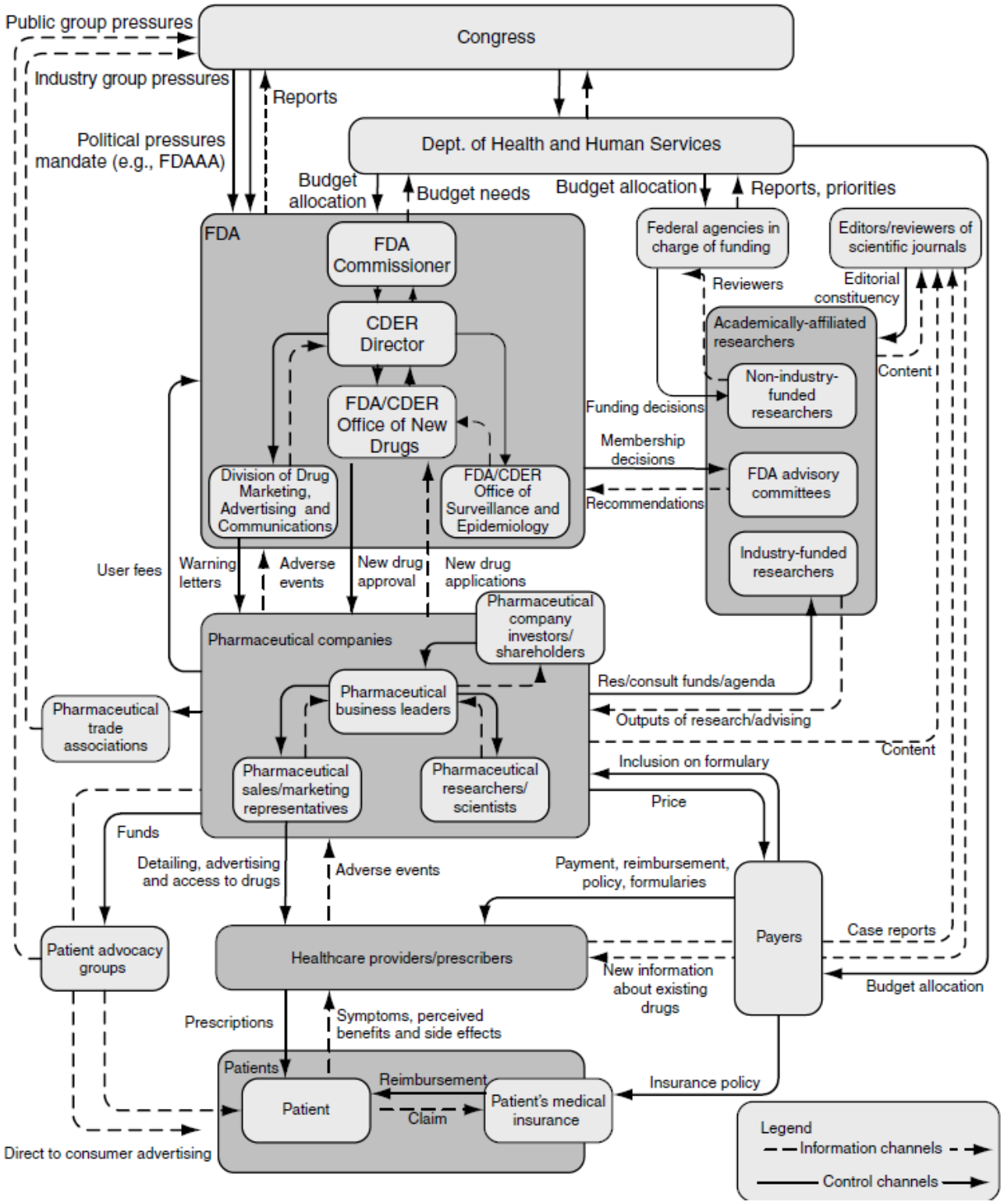


Figure 5 The system involved in Vioxx (Rofecoxib) development and prescription (Leveson et al., 2012)

Finally, STAMP shows that accident prevention cannot just focus on a component. In systems theory, *emergent properties* are those that "refer to the whole and are meaningless in terms of the parts which make up the whole" (Checkland and Scholes, 1999, p. 19). For instance, consciousness is an emergent property. Similarly, safety is an emergent property, and accident prevention is ineffective if it only focuses on a component. For instance, appraising a particular medical device as safe or not has

serious limitations because the appraisal neglects the context, e.g., whether it is used by people with the appropriate training or used for its designed purpose. To effectively prevent accidents, a holistic approach must be taken.

In summary, several modeling advances are brought about by STAMP. First, how accidents occur is described in detail with the conditions required for adequate control. Moreover, safety consideration is expanded to cover the development phase. Together with treating safety as an emergent property, STAMP further improves the understanding of accidents and safety management.

2.1.2.3 Implications for healthcare

Systemic models are more relevant to healthcare than the chain-of-event models. Care delivery is challenging not least because no two patients are identical. The need to deviate from even the best treatment guidelines is inevitable. The same challenge exists when managing healthcare organizations (Plsek and Wilson, 2001). Focusing on the people and their "errors" does not provide a sufficient understanding of accidents but often creates blame. Through the distinctive nonlinear modeling, systemic models focus on the behavior-generating mechanisms that stretch from the point of care to higher organizational and social levels. Therefore, systemic models enable more to be considered and thus learned from healthcare incidents.

2.2 Incident analysis techniques

Incident analysis techniques provide the procedures to identify the causal factors in an incident. For instance, a technique may specify the questions that should be answered or the criteria for an analysis to be complete. Because the techniques embody different accident causality models, the techniques place different emphases on work deviations, the context surrounding the behavior, etc. The choice of what technique to use affects what causal factors are identified.

Three incident analysis techniques are highlighted in this section: Root Cause Analysis (RCA), AcciMap, and Causal Analysis based on Systems Theory (CAST). RCA is based on the chain-of-events model. AcciMap and CAST are newer incident analysis techniques, and they are based on Rasmussen's model and STAMP, respectively. Their differences help illustrate the current challenges of learning effectively from incidents and introducing CAST into healthcare.

2.2.1 Root Cause Analysis (RCA)

RCA is commonly used in healthcare, but the guidelines vary. Authoritative guidelines have been published by some accreditation and regulatory bodies[†] (CMS, n.d.; NPSF, 2015; TJC, 2017a; VA, 2016). Of these guidelines, the NPSF version describes a two-step process: 1) identifying what happened through fact finding and flow diagramming and 2) developing causal statements. Specifically, causal statements are generated based on 75 "triggering questions" (on communication, training, fatigue/scheduling, etc.) and the optional use of cause and effect diagramming and the "Five Whys" technique. The causal statements also have to meet five rules (e.g., they 'clearly show the "cause and effect" relationship', and 'human errors must have a preceding cause'). In contrast, the TJC version describes an eight-step process, starting with exploring the events and culminating in establishing root causes and their interrelationships. Contributing process factors are identified by comparing the process between its designed state, the usual state, and the actual state in the incident. Additional contributing factors are probed from the angles of human factors, equipment, information, and environmental factors. Finally, the root causes should be identified by examining human resources,

[†] The inline reference provides the abbreviations of the organizations relevant to the current discussion: CMS, Centers for Medicare & Medicaid Services; NPSF, National Patient Safety Foundation; TJC, The Joint Commission; VA, U.S. Department of Veterans Affairs

information management, etc. While some aspects of the guidelines are similar, there are considerable differences on the definitions, analysis tasks, and completion criteria. Due to these differences, incidents are analyzed to different extent and the nature of the identified causal factors are also inconsistent, precluding further analysis or comparison in the aggregate.

More fundamentally, root causes do not produce sufficient safety learning. RCA embodies a linear view of accident causation, and its objective is to identify "the root cause (the fundamental reason which, if corrected, will prevent recurrence of these and similar occurrences…)" (Department of Energy, 1992, p. 1). In fact, the TJC (2017a) guidelines advise "prun[ing] the list of root causes" (p.79) and "[if] a team identifies more than four root causes, a number of the causes may be defined too specifically" (p.83). However, being able to find root causes is a fallacy. Finding root causes is psychologically appealing because humans naturally prefer certainty (Carroll, 1995). Furthermore, humans tend to overestimate the level of understanding of an accident, believing that the relevant causes have been found and there is enough knowledge to support the weighing of the different factors. Carroll has termed this phenomenon the "root cause seduction". Focusing on one or a small number of root causes does not prevent accidents.

From a practical standpoint, the analysis methods suggested for use in the guidelines are simplistic. "Five Whys" is a clear example. The method identifies the root cause by answering "why" five times, beginning with the observed error or event (Card, 2017; Leveson, 2011b). The primary problem with this procedure is that it restricts the inquiry to a linear trajectory and may omit important events. For instance, in the mentioned adverse drug event, the next question would explore "why the multidose insulin vial was placed next to heparin?", and this completely sidesteps the consideration of "why the clinician was confused between the insulin and heparin vials?" In addition, the method is incompatible with reality because the event chain can always be extended and additional causes found. By setting the number of "whys" to be independent of the problem on hand, it renders the endpoint for the analyses arbitrary.

Sociological reasons reinforce the arbitrariness of the analysis endpoints in any linear chain of events analysis. Empirically, analyses often end at points of convenience or with a root cause that fits the biased perception. Causes that are considered outside the boundary of the organization may be ignored, and attributing an accident to human error may be favorable when the truth is more "uncertain, complex, or embarrassing to the organization" (Leveson, 2011b, p. 38; Peerally et al., 2017; Percarpio et al., 2008). Also, declaring that the root cause has been found signals an incremental accomplishment, so attention can be focused on making the safety improvement rather than continuing the search. Emboldened by all these reasons, many organizations do not actually generate any meaningful, let alone comprehensive, findings.

RCA does not provide adequate guidance to understand human behavior. Human behavior is always shaped by the surrounding context (Leveson, 2011b; Rasmussen, 1997), but understanding "why" an unsafe human behavior occurred is a difficult undertaking due to the need to overcome inherent biases in human psychology: fundamental attribution error, the illusion of free will, the just world hypothesis, hindsight bias, etc. (Carroll, 1995; Reason et al., 2001). Dekker and Nyce (2012) have recognized the cultural-theological challenges as well. In the face of these challenges, the lack of guidance in RCA makes understanding human behavior particularly complicated (Percarpio et al., 2008; Senders, 2004). None of the associated techniques and aids provides an adequate framework of human decision making and human performance. Compounded by the lack of expert participation in healthcare, RCAs often lead to blame and ineffective safety interventions.

Notably, even recent improvements on RCA remain limited by the assumptions of linear causation. For instance, the London Protocol retains the Swiss Cheese model as its foundation (Taylor-Adams and Vincent, 2004). The methods it deploys (e.g., fishbone diagram) still restrict the inquiry of

causal factors to a linear trajectory. Inevitably, some causal factors (e.g., systemic factors, wrong or missing feedback) are missed due to this methodological flaw.

In summary, RCA leaves the analysis endpoint arbitrarily chosen and lacks sufficient guidance to elucidate the factors underlying human behavior. Variations also exist in its implementation in healthcare. Fundamentally, it embodies a linear view of accident causation and inherits the associated shortcomings. To effectively improve safety in healthcare, a more advanced incident analysis technique should be used.

2.2.2 AcciMap

AcciMap aids the identification and communication of causes based on Rasmussen's model. As mentioned, Rasmussen emphasized the need to consider the entire socio-technical system when analyzing accidents, especially the interactions across levels. AcciMap has thus been developed to capture the events involved in incidents (Svedung and Rasmussen, 2002) (Figure 6).

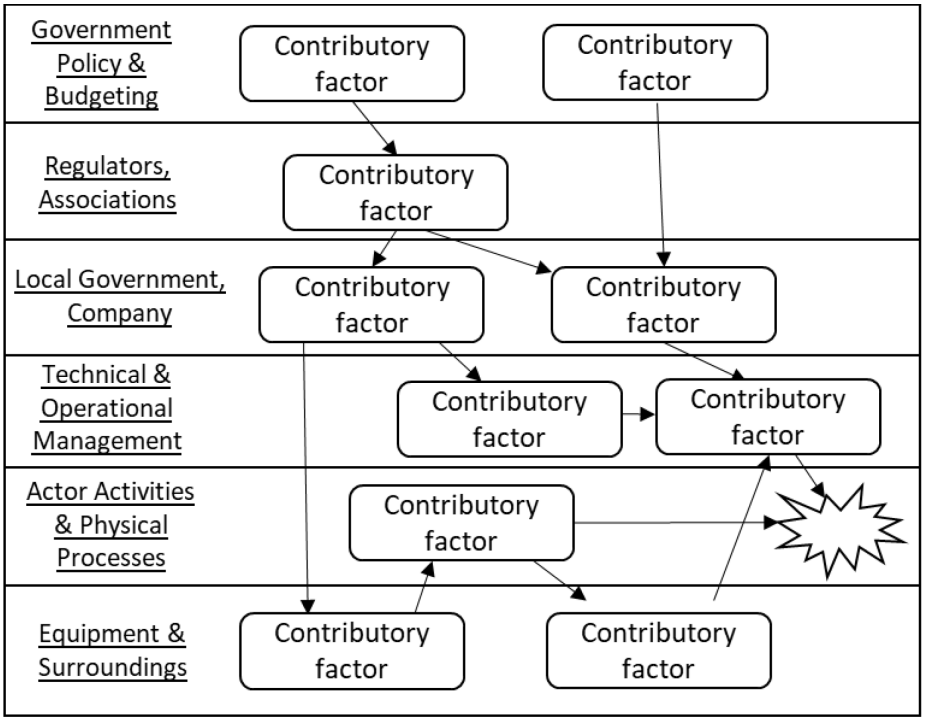


Figure 6 An illustration of Accimap. Adapted from Svedung and Rasmussen (2002).

The use of AcciMap still precludes the most important lessons to be learned from incidents. While AcciMap enables more causal factors at the management level and above to be explicitly considered and identified, its graphical layout includes only chains of events instead of close-loop control. This divergence from the original modeling of accident causation hampers causal factor identification using a systems perspective. Also, the lack of a structured process allows different analysts to identify very different causal factors for the same incident. The differences were observed in two AcciMap analyses of the South Korea Sewol Ferry accident, for example (Goncalves Filho et al., 2019). Empirically, learning and applying the technique was challenging when it was incorporated into a non-healthcare IRS in Australia (Goode et al., 2019, 2016). Finally, there is no differentiation between humans, machines, and social entities and no modeling of how humans behave in order to identify the reasons behind the events and factors. Learning with systemic incident analysis techniques has much room for improvement.

2.2.3 Causal Analysis based on Systems Theory (CAST)

CAST has been developed to provide a structured way to learn as much as possible from incidents. It is a structured process consisting of five steps (to be described in detail in Chapter 3). It is based on the STAMP model of accidents and includes the modeling of why the person or entity acted the way they did, not just a description of the behavior as in AcciMap and the RCA-related techniques. For example, simply saying that the clinician infused insulin instead of heparin is not helpful without understanding why she or he made that mistake, e.g., poor labelling, distraction or fatigue, inadequate training, incorrect pharmaceutical ordering, etc. While theoretically any of this information could be included in an RCA or AcciMap analysis, there are no procedures to guide the search for this information. CAST includes a structured process to assist in searching for this "why" information.

Emerging evidence has shown CAST to be more effective than other techniques. For instance, among four analyses of the South Korea Sewol Ferry accident, the two CAST-based ones had more causal factors that overlap than the two AcciMap-based analyses (Goncalves Filho et al., 2019). Moreover, the two CAST-based analyses had more safety interventions, and the safety interventions covered more levels of the socio-technical system.

The effectiveness of CAST has been demonstrated in healthcare as well. O'Neil (2014) analyzed a biopsy adverse event with CAST and found diverse causal factors covering the shortcomings of the electronic medical record, the technology limitation of biopsy pathway guidance, the unfamiliarity of providing short-stay care at the facility, etc. In contrast, an RCA performed by a hospital patient safety officer only stated the root causes to be a lack of communication, delayed assessment, and the act of silencing the alarm by the patient. The CAST analysis also had more diverse and effective safety interventions.

More recently, Canham et al. (2018) led a group of healthcare stakeholders in analyzing a medication error. The CAST analysis[‡] contained more thorough identification of causal factors, especially beyond those associated with the frontline doctor and nurses. In contrast, the official RCA focused on the frontline staff. Consequently, relatively weak, frontline-targeted safety interventions (e.g., personal reflection) were proposed in the RCA, whereas more effective ones (e.g., process redesign, change management) were proposed in the CAST. Wider CAST applications have the potential to substantially reduce incident recurrence in healthcare.

Despite the prospect, CAST adoption is not trivial. As mentioned in Chapter 1, knowledge and time constraints hinder CAST application, especially when expert guidance is not available at scale. For instance, some healthcare workers found the systems theory concepts and the graphical model difficult to grasp (Canham et al., 2018; Jun and Waterson, 2019). Also, while CAST application is not more time-consuming in safety-critical industries (Leveson, 2011b), healthcare staff are wary of the time it takes to learn the technique and to conduct the analysis. Further development is needed to facilitate CAST adoption in healthcare.

2.3 Redesigning IRSs

As described in Chapter 1, learning with the current healthcare IRSs is hampered by under-reporting, rarity of incident analyses, the superficial and blame-laden analysis output, nonexistent or ineffective safety intervention recommendations, and a lack of learning dissemination. Given the recognition of the flaws, there has been no shortage of ideas to improve IRSs. Some attempts to field redesigned systems have been made as well.

[‡] To be precise, it was a CAST-like analysis that was based on the same underlying accident causality model (STAMP); they utilized a safety control structure, and reported findings associated with flaws in the workers' understanding, controls, and feedback.

2.3.1 Ideas to redesign IRSs

Diverse ideas have been proposed to improve IRSs. On data collection, Pawlicki et al. (2017) suggested customizing submission forms to solicit targeted information based on the event type. Ford and Evans (2018) stated that a fundamental consideration should be "Might greater knowledge about this event help improve quality, safety, efficiency, or workflow?" and account for the ability to process the reports based on resource limitations. On report triaging, Scott et al. (2020) urged caution on basing the decision solely on harm. Because down-coding exists, some incidents that should be analyzed may be missed. Novel events should be analyzed, but their identification remains a challenge. On aggregate data analysis, Puthumana et al. (2017) suggested developing analyst-friendly tools, potentially using machine learning and natural language processing. Specifically, the tools should facilitate the understanding of trends and patterns. However, Scott et al. (2020) warned that the biases (e.g., reporting to apportion blame) pose a challenge for machine learning to directly analyze the reports. Other proposed ideas abound, and they cover the IRS functions quite comprehensively.

On the overall design and implementation, many experts recommend paying special attention to the safety culture to improve effectiveness (Carroll, 2018; Kaplan and Fastman, 2003; Leveson, 1995; Pawlicki et al., 2017). For instance, Carroll (2018) describes a "three lenses" approach to evaluating and optimizing the design of an IRS, covering strategic design (e.g., roles and responsibilities, rules and procedures), culture (e.g., habits, role models), and politics (e.g., power bases, coalitions). These ideas help improve IRS redesign as a whole.

While the proposed ideas are quite comprehensive when viewed together, a perspective is still missing: rarely are functional interdependencies considered in these ideas, except the one by Ford and Evans (2018) and the observation by Scott et al. (2020). To reiterate, tackling a problem by dissecting it into smaller problems and combining the solutions may not be effective, especially for problems in complex systems. The interactions between the parts must be considered in the solution process. More work needs to be done to improve IRS design, especially with a top-down approach (i.e., moving from the overall system to the individual functions, etc.) and building beneficial functional interdependencies.

2.3.2 The implementation of redesigned IRSs

Despite the abundance of ideas, relatively few recommendations have been adopted and fielded. Some work has been done to mitigate under-reporting, particularly by physicians. Turner et al. (2018) showed that offering $200 per reporting metric to about a thousand graduate medical trainees can increase their participation about 17 times or from less than 0.5% of the institutional total in the year prior to 7% during implementation. Moreover, the number of reports submitted by the trainees has sustained subsequently. While the incentive provided an apparent solution to under-reporting, it created a challenge for the processing and the resolution of the reports. This experiment demonstrates the very unintended consequence that Ford and Evans (2018) sought to guard against. It further shows that IRS redesign needs to be done holistically.

Similarly, Delio et al. (2019) have implemented a text-based reporting for physicians in an urban tertiary academic medical center and reported a 37-fold increase in physician participation. However, the implementation shifts the workload of reporting from physicians to safety analysts who manually enter the information provided by the physician. Moreover, the safety reports are free-text, which requires additional clarifications at times. This model may not be feasible in health systems where resource is lacking to accommodate the extra workload or where the model may be seen as a special treatment favoring physicians.

Outside healthcare, an IRS has been developed based on Rasmussen's accident model (Goode et al., 2017). Requirements for the IRS were first generated with the end users. The researchers then provided AcciMap training to the users and created software that accepts reports and produces

aggregate analysis output. In a 3-month national trial, the IRS received reports identifying causal factors across all system levels, which was an improvement to prior experience. However, quite some room for improvements remains. First, only a small number of causal factors was found for the higher system levels. Second, data collection is based on a taxonomy derived from a retrospective analysis of an accident rather than a proactive hazard analysis, which would be more comprehensive. Third, the report triaging function was not addressed in this IRS design. Recently, Goode et al. (2019) evaluated the IRS after 12 months of use. Most respondents did not have the resources to make use of the IRS nor found that the IRS brought value. The results suggest that designing IRSs that use systemic incident analysis tools requires further research.

In summary, fielding IRS improvements is challenging and more work remains. Effort to improve IRSs in healthcare focuses on individual IRS functions, and taking this approach can generate unintended consequences. In the IRS outside healthcare that incorporates a systemic incident analysis tool, report triaging and in-depth analyses are left to the local level, which is subject to resource and organizational limitations. Considering the interdependencies is crucial to improving IRS effectiveness, but it remains an area under-researched and untested.

Chapter 3. CAST: a more effective incident analysis technique

The methodological flaws hampering safety learning have been identified previously, so this chapter summarizes what is required in a more effective incident analysis technique. Afterwards, it focuses on CAST, which meets the requirements and enables learning from incidents effectively.

3.1 Requirements for a more effective incident analysis technique

A more effective incident analysis technique needs to (Leveson, 2019):

- *Help analysts avoid hindsight bias.* When an incident is examined after-the-fact, the behavior that contributed to the incident tends to be obvious to safety analysts, and the clues that the decision makers neglected or mistook become much clearer. However, the missed clues and the potential consequence of the behavior were less obvious to those involved as the incident unfolded. Hindsight bias creates blame and predisposes safety analysts to underestimating the challenge of preventing the same behavior from recurring. Effectively improving safety hinges on understanding why the behavior took place and why the clues were neglected or mistaken.
- *Account for the factors influencing human behavior.* Human behavior is influenced by the context (e.g., the information received, unspoken norms, physical and cultural environment) in which it occurs. Where human decisions or behavior contributed to an incident, identifying the underlying contextual factors is key to understanding the incident.
- *Create a blame-free understanding of the incident.* Blame motivates safety interventions that target the individual (e.g., termination, disciplinary action, retraining). These options ignore that others not involved are similarly prone to the unsafe decision or behavior. Besides, blame exacerbates the "second victim" phenomenon. In contrast, a blame-free understanding motivates more effective safety interventions. Illuminating the contextual factors also mitigates the psychological trauma. Lastly, a blame-free understanding is crucial to meeting contemporary expectations in healthcare (e.g., Standard LD.04.04.05 (TJC, 2018)).
- *Identify the causal factors comprehensively.* Superficial causes lead to superficial safety interventions. In the same vein, designing safety interventions without considering the causal factors comprehensively risks creating other unintended consequences.

Achieving these requirements is not trivial—historic incident analysis techniques have not adequately done so. Having a comprehensive accident causality model as the basis for the technique helps achieve these requirements.

3.2 CAST

3.2.1 Fulfilling the requirements

CAST has been designed specifically to fulfill these requirements (Leveson, 2019):

- To avoid hindsight bias, the technique incorporates a fundamental assumption that all human decision makers and operators try to do the right thing. This assumption aligns particularly well with the healthcare domain, where workers have an intrinsic motivation to deliver quality care and ease pain and suffering.
- Any decision or behavior that contributed to the incident does not happen by chance but can be explained. The investigation must try to understand why the decision or behavior seemed reasonable to the decision maker at the time of the incident. The underlying contextual factors, rather than the decision or behavior, are the emphasis.

- A blame-free understanding of the incident is created by adopting the principle that “blame is the enemy of safety”. The principle further builds on the mentioned assumption and the intrinsic motivation commonly found in healthcare. Moreover, the technique eschews blame at the practical level by avoiding blame-laden words such as “failed to” and “should have”. These words prejudge the decision or behavior and suppress further exploration. Instead, any commission or omission of behavior that contributed to the incident is described with “did” or “did not”. These words give a factual description without blame.
- Finally, instead of tracing a chain of events to find the “root cause”, the technique uses STAMP as the underlying accident causality model. Accidents are viewed as the result of inadequate control at all levels of the safety control structure. This holistic perspective enables analysts to generate more learning from each incident.

3.2.2 Performing a CAST analysis

CAST provides a methodical way to learn from an incident. As shown in Figure 7, performing a CAST analysis is a five-step process: 1) assemble basic information, 2) model safety control structure (SCS), 3) analyze the contribution of each component, 4) identify flaws in the overall control structure, and 5) create an improvement program. While the figure depicts the analysis as a series of steps, this journey of incremental learning is not strictly linear: revelations later in the analysis may revise some of the analysis decisions made early in the process (e.g., what is included in the SCS, the graphical model of the socio-technical system). This analysis process results in a set of comprehensive causal factors and effective safety intervention ideas.

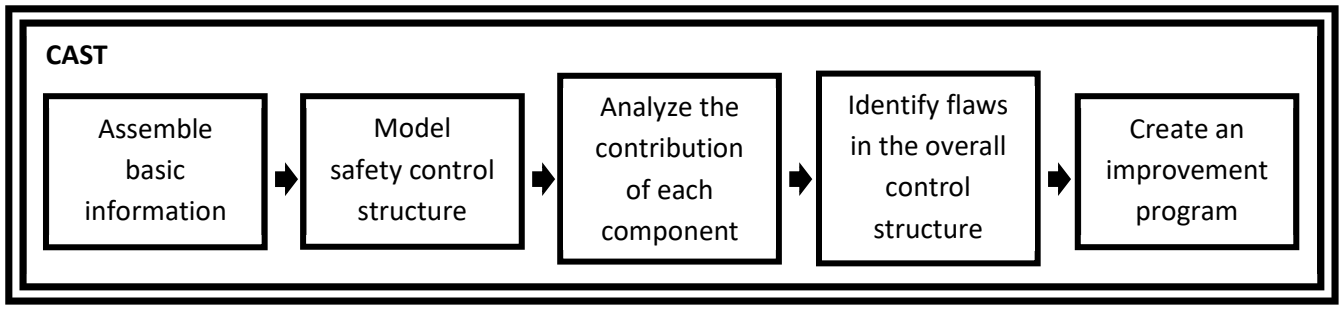


Figure 7 The five parts of a CAST analysis (adapted from (Leveson, 2019))

The analysis process is now described further and illustrated with the analysis of a radiation therapy (RT) incident. The incident is a freely available hypothetical case generally used to stimulate safety discussions among RT professionals (i.treatsafely, 2015). The analysis was conducted by the author and an expert clinical physicist. For brevity, only excerpts of the output from each step of the analysis are highlighted here. Some analysis tasks are elaborated in the next chapter with the CAST enhancements. The full analysis results are provided in Appendix B.

3.2.2.1 Step 1: Assembling basic information

In step 1, the basic information of the incident is gathered to inform the rest of the analysis. A list of proximal events is compiled. The purpose is not to specify the cause in a chain-like fashion but to elicit a starting set of investigation questions. The questions are not answered in step 1, so they do not need to be exhaustive. Step 1 includes a sub-analysis of the physical process in the incident. Attention is given to any failure only if it impacted safety. If applicable, the reasons why any equipment was missing, broken, or otherwise inadequate are identified, but the unsafe behavior and decision of any automated or human decision makers are not considered at this point.

The analyzed incident took place in the course of treating a 6-year-old patient with a right-thigh sarcoma. The treatment involved radiation delivery of 50 Gray over 25 fractions (treatment sessions). During chart rounds when the patient had already completed 15 fractions, the care team realized that the treatment plan was approved without leveraging the available magnetic resonance (MR) images and was based on computed tomography (CT) images alone. With the MR images fused to the CT images and re-contoured, the revised treatment plan revealed that the original target volume was 30% larger than necessary. The enlarged target volume resulted in an increased risk of growth delay and infertility.

Table 1 shows a set of proximal events and some preliminary investigation questions. Some questions cover the common practices of RT and provide background understanding for the author who does not have in-depth domain knowledge. Other questions seek to identify why a specific decision or behavior was made or omitted. These questions later help identify the contextual factors.

Table 1 The proximal events and preliminary investigation questions of the RT incident.

ID	Event	Question raised
1.	Primary radiation oncologist reviewed diagnostic MR images with radiologist.	-
2.	Primary radiation oncologist requested the MR images to be fused just prior to departing for a conference.	• Was the standard practice to fuse it for a sarcoma case? • Was the standard practice to fuse it before or after the review between the radiation oncologist and radiologist? • Why were the MR images not fused by the dosimetrist earlier? • Was the dosimetrist in the Radiation Oncology Department or Radiology? • What was the standard practice to communicate with/task the dosimetrist?
3.	MR images were not fused prior to the primary radiation oncologist departing for a conference.	• Why was a dosimetrist not available to fuse the MR image? • Why was the physician assigned the patient if he could not complete treatment planning before departing for a conference?
4.	Primary radiation oncologist completed the contouring on CT only and created an electronic note in *Treatment setup notes* to alert the covering radiation oncologist to review the MR images before approving the plan.	• Why was contouring done without the MR images being fused? • Was it a standard practice to split the contouring and treatment plan completion between different radiation oncologists? • What was the standard practice to communicate with/task the covering radiation oncologist? • What was the training on the use of electronic note and treatment plan review and approval? • Did the electronic note require acknowledgement?

		• Did the software selection process consider usability/discrepancy of usage?
5.	The dosimetrist completed the treatment plan and asked the covering radiation oncologist to review and approve it.	• Was the dosimetrist aware that the MR images needed to be fused?
6.	Covering radiation oncologist reviewed and approved the treatment plan without reviewing the MR images.	• Did the covering radiation oncologist receive the same training, if any, on the use of electronic note and treatment plan review and approval?
7.	Treatment delivery began for the patient.	-
8.	The case was scheduled to be discussed at previous chart rounds but the discussion was postponed due to lengthy discussions of other cases.	• Why was case review not done prior to treatment delivery? • Did the case get increasingly high priority to be reviewed as more treatment fractions were delivered? • Why was adequate time not budgeted for chart rounds?
9.	Chart round discussion identified that the MR images were not used in treatment planning	-
10.	The target volume was redrawn to complete the rest of the patient's treatment.	• Was it a standard practice to replan if a discrepancy was found in a treatment plan? • Was any medical intervention provided to address any actual or potential adverse effects from wrong dose?

From step 1, the cause of the incident is found to be more complex than an equipment problem. There was no physical failure associated with the devices that interacted with the patient. Specifically, the linear accelerator (linac) functioned as programmed. Also, the CT and MR machines performed as intended and acquired the respective images. The unsafe physical interaction involved the linac delivering radiation to an area larger than necessary, and it was a planning accuracy problem involving complex decision making. To sum up, there are no physical safety interventions that could readily address the incident.

3.2.2.2 Step 2: Modeling the SCS

In step 2, a graphical model is created to illustrate the control structure involved in the incident. An example SCS has been shown previously for the Vioxx incident (Figure 5). Symbols are used to depict control relationships in a control loop: boxes show the controller and the controlled process/object at the top and bottom, respectively. A control action is depicted with a downward arrow connecting the controller to the controlled process, and feedback is depicted with an upward arrow (Figure 8). For instance, while delivering RT, a therapist may stop the linac based on the displayed radiation output (monitor unit).

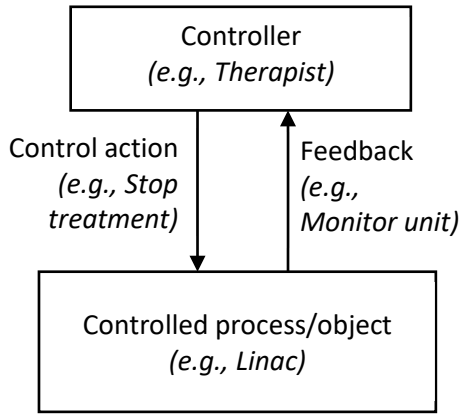


Figure 8 Graphical depiction of control relationships

A SCS comprises many control loops involving controllers who have safety responsibilities relevant to the incident. Controllers higher in the SCS have more general responsibilities. For instance, a hospital executive would be placed higher in the SCS for the more general responsibilities over various departments and services, whereas a pharmacy technician has very specialized responsibilities over medication preparation.

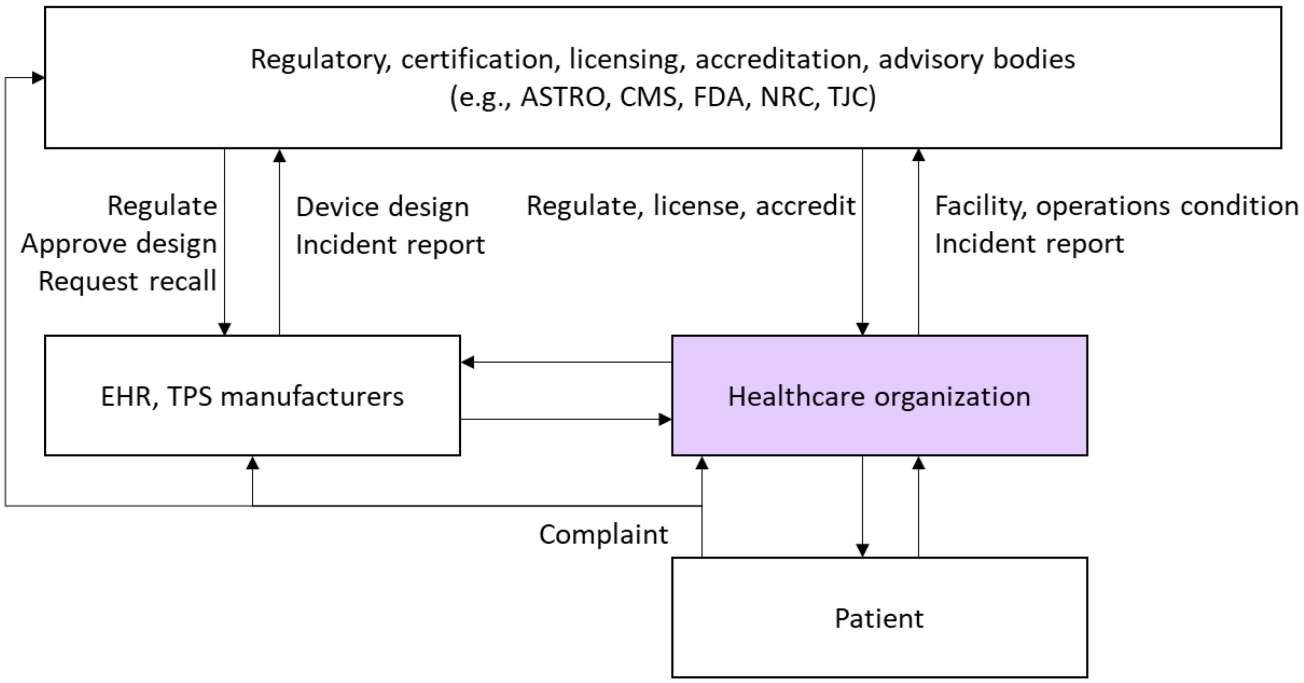


Figure 9 The SCS for the RT incident
(ASTRO = American Society for Radiation Oncology; CMS = Centers for Medicare & Medicaid Services; EHR = electronic health record; NRC = Nuclear Regulatory Commission; TJC = the Joint Commission; TPS = treatment planning system)

For the RT incident, the SCS extends beyond where direct patient care was provided (Figure 9). In addition to the healthcare organization where care delivery took place, the electronic health record (EHR) and treatment planning system (TPS) manufacturers and regulatory, certification, licensing, accreditation, advisory bodies (hereafter "regulatory and advisory bodies") are included as well.

Starting from the top, RT safety hinges on the controls imposed by the regulatory and advisory bodies on the manufacturers and healthcare organization. The regulatory and advisory bodies regulate, license, and accredit healthcare organizations, and they also approve software devices and can request recalls when products show unmitigated or newfound risk (FDA, 2020, 2005).

To perform their control functions, the regulatory and advisory bodies are informed by a variety of feedback. For instance, FDA approvals are predicated upon the submission of device information in the premarket notification, and recall decisions are triggered by incident reports through the postmarketing surveillance program. Similarly, the accreditation bodies make site visits to assess facility conditions and operational status. Patient complaints play a critical role as well.

Figure 9 provides a high-level model of the system that influences RT safety, and the other relevant interactions are captured by methodically expanding the components. For instance, the healthcare organization is handled as a "black box" with the details hidden in Figure 9, but the internal controllers, control actions, and feedback relevant to the incident are shown in Figure 10.

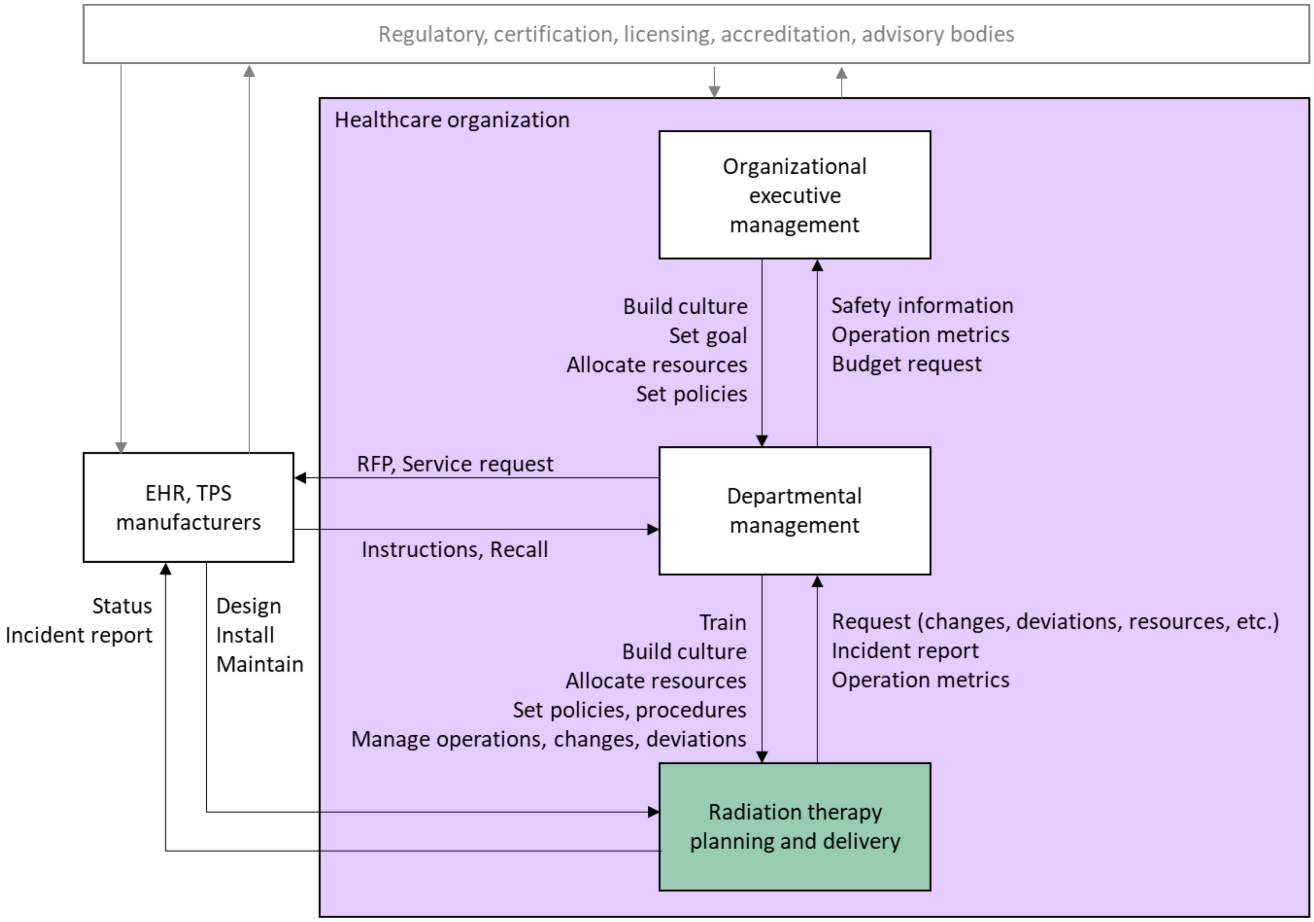


Figure 10 The part of the SCS showing the details of the healthcare organization (MR = magnetic resonance; RFP = request for proposal)

As shown in Figure 10, important strategic decisions are made by the organizational executive management. For instance, goals (e.g., patient volume) and policies (e.g., software procurement) are set. These decisions are informed by safety information and operation metrics from the departments.

At the departmental level, clinical and operational staff requires dynamic allocation by management because staffing needs vary based on the volume and complexity of the cases and the

technology used (Pawlicki et al., 2019). Detailed operation metrics provide a useful feedback to the departmental management in assessing the time pressure and adequacy of staffing.

The EHR, TPS manufacturers also interact with the departmental management to provide information that influences purchasing decisions, training, staffing, operational use, etc. In return, the manufacturers' actions are driven by requests for proposals (RFPs), service requests, etc. In addition, the manufacturers design, install, and maintain the TPS and EHR. These control actions are informed by status reports and incident reports whose level of detail, accuracy, and timeliness are important.

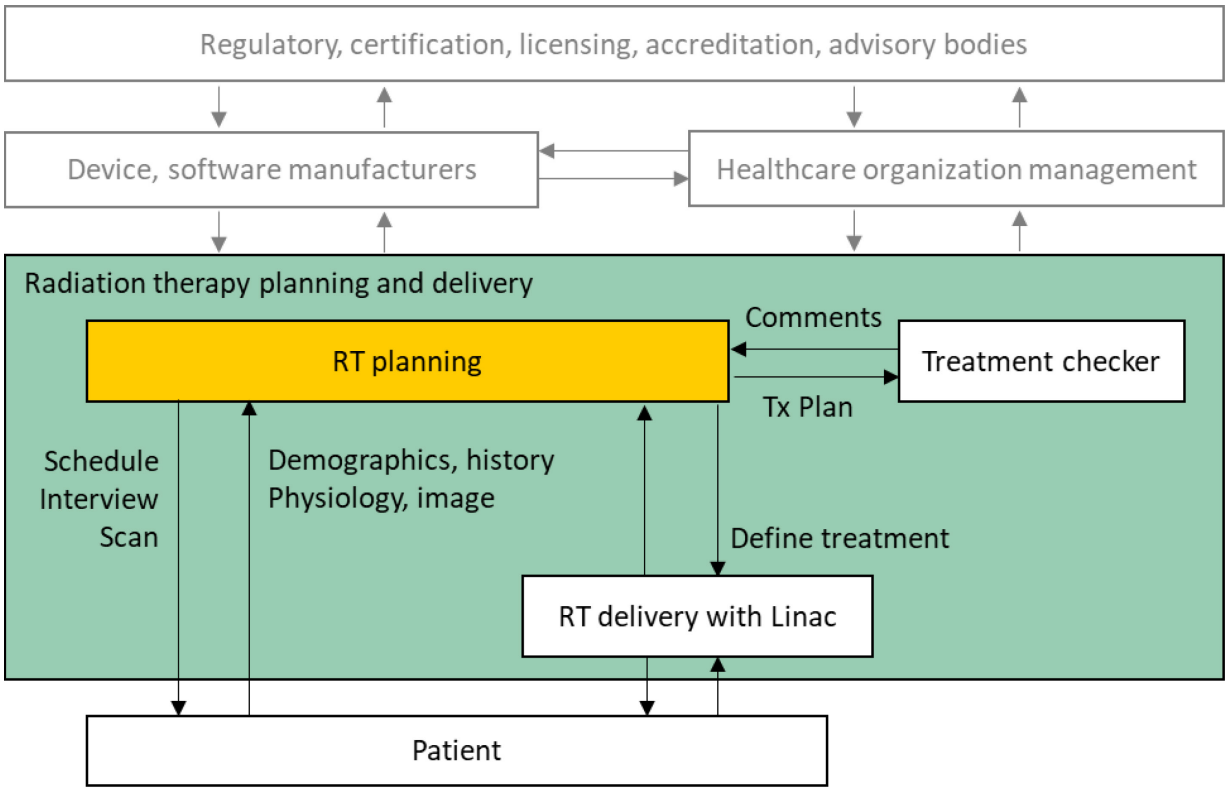


Figure 11 The part of the SCS showing the details of frontline RT planning and delivery. (Tx = treatment)

Figure 11 expands upon the details of frontline RT planning and delivery. The planning function is the focus for the incident and is modeled in more detail below. Meanwhile, Figure 11 shows an important interaction prior to RT delivery: treatment plans are independently reviewed by a treatment checker. This independent check usually takes place a day or just hours prior to the first treatment session, and the treatment checker examines the planned dose for the anatomical structures to treat and to avoid.

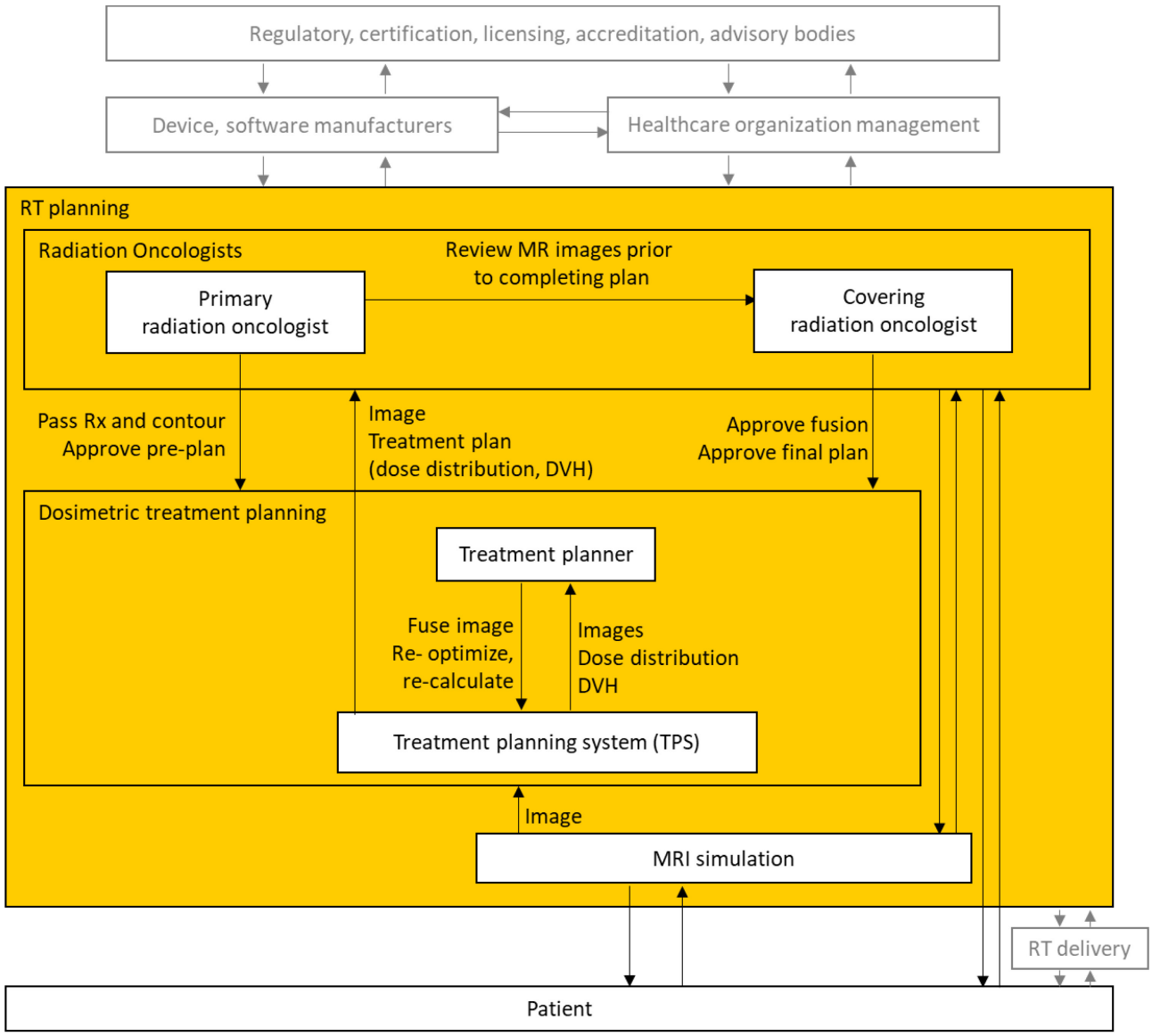


Figure 12 The part of the SCS showing the details of frontline RT planning (DVH = dose-volume histogram; MRI = magnetic resonance imaging; Rx = prescription)

The methodical expansion of relevant components culminates in Figure 12, which models RT planning in detail. In general, treatment planning involves iterative exchanges between a radiation oncologist and a treatment planner. The radiation oncologist specifies a simulation study, which may include a request for the treatment planner to fuse MR and CT images. With the images provided by the treatment planner, the radiation oncologist demarcates the tumor volume and organs at risk (OAR) on the images (the task is known as contouring). With contouring done, the physician prescribes "areas to be treated, dose, dose fractionation and treatment schedule" with a clinical treatment plan (Pawlicki et al., 2019b). The treatment planner then conducts dosimetric treatment planning to convert the clinical treatment plan into instructions that the treatment devices can actually use. Subsequently, the treatment planner provides the treatment plan to the radiation oncologist for review. The radiation oncologist may approve the plan or request further refinement to resolve any discrepancies with the prescription. Commonly, dosimetric treatment planning involves several iterations.

TPS is a key piece of technology used during dosimetric treatment planning. Modern TPSs have advanced functionalities that optimize the plan and calculate dose. Graphical displays of anatomy, dose

distribution and dose volume histogram (DVH) provide feedback to the treatment planner, so the need for further refinement can be appraised. Similarly, images and treatment plans are reviewed by radiation oncologists using the TPS.

Some interactions in the RT incident were different from the norm and are reflected in the SCS. The primary radiation oncologist was leaving for a conference, and the covering radiation oncologist eventually took over the case. Due to the involvement of two radiation oncologists, the control actions are distributed over two downward arrows, forming two control loops (Figure 12). In addition, the request to review MR images from the primary to the covering radiation oncologist is modeled with a horizontal arrow as well.

3.2.2.3 Step 3: Analyze the contribution of each component

In step 3, the decisions and behavior that contributed to the incident are identified for each controller. Then, the reasons for such decisions and behavior are established. To reiterate, the key is to understand why a decision or behavior seemed reasonable to the controller at the time it was made.

Each controller in the SCS is considered methodically, and starting at the bottom of the SCS has been found to be helpful (Leveson, 2019). For each controller, four aspects are examined:

- the responsibilities relevant to the incident
- the contribution: action, inaction, flawed decisions
- misunderstanding or flaws in the process model[§] underlying the contribution
- contextual factors that created the inaccuracies in the process model

The last two aspects are the key to understanding the incident and generating effective safety improvement. The flaws in the process models and the associated contextual factors can be probed with two questions (Leveson, 2011a, p. 362):

> *What information did the decision makers have or did they need related to the inadequate control actions?*
>
> *What other information could they have had that would have changed their behavior?*

Additional contextual factors may include human physiology, pressure (e.g., time), cultural norms etc.

For the RT incident, the treatment planner is the controller lowest in the SCS (Figure 12), so that person is the first controller of interest. Table 2 summarizes the analysis for the controller.

Table 2 Summary of the analysis of the treatment planner

Treatment Planner (Dosimetrist)
Responsibility relevant to this safety incident • Fusion and registration (primary)
Contribution to the hazardous state • Did not fuse MR image to CT for contouring
Process model flaw • Did not know the need to fuse the MR image
Contextual/process model factors • The original request to start the treatment planning process did not include the fusion order. • The physician subsequently called but did not reach the dosimetrist to request fusion.

[§] A model of the process being controlled, e.g., how the process works and what the current state is (Leveson, 2019).

- The electronic note in the TPS (for the covering radiation oncologist) requesting MR fusion was never read.
- The TPS did not require MR image fusion for sarcoma patient before contouring or other treatment planning activities could be performed.
- The treatment plan did receive final approval

The dosimetrist was responsible for image fusion but did not carry out the task. It turned out that the person did not know that image fusion was needed. This process model flaw can be explained by the interactions associated with the treatment planner depicted in the SCS (Figure 12). As a brief reminder, the treatment planner, in general, receives control inputs from the radiation oncologist. Specifically, what needs to be accomplished for treatment planning is described in the prescriptions and contouring requests. Also, the treatment planner's work is done using the TPS, which provides feedback on how well the plan meets the prescription (e.g., dose distribution), etc. In the incident, the process model flaw was first created by the interactions with the primary radiation oncologist. The original prescription and contouring request was issued to shorten the time to treatment plan review and did not include the fusion order. Subsequently, the primary radiation oncologist did call to request the MR image to be fused but did not reach the dosimetrist. It was the end of the work day, and there was no dosimetrist available to perform the task. Ultimately, the dosimetrist did not actually get an active request for MR image fusion.

Furthermore, there was no cause for the dosimetrist to suspect image fusion was needed based on the interactions with the covering radiation oncologist and the TPS. While the primary radiation oncologist added an electronic note to ask the covering radiation oncologist to review the MR image and request fusion, the note was not read. Therefore, the covering radiation oncologist never asked the dosimetrist for image fusion either. In addition, the TPS did not require fusion or provide any alert before contouring or other planning activities could be performed. Finally, the treatment plan did receive approval from the covering radiation oncologist, which would have eliminated any doubt by the dosimetrist on whether image fusion was needed. As shown, the dosimetrist did not “fail”. Instead, the omission can be explained by the contextual factors.

For brevity, the analysis of the departmental management is now discussed (Table 3), skipping the results for the other frontline controllers. (See Appendix B for full analysis results.)

Table 3 Summary of the component analysis of the departmental management

Departmental Management

Responsibilities relevant to this safety incident

- Share concerns with the vendors and work with them to improve products
- Establish management of change requirements for evaluating all changes for their impact on safety, including changes in the safety control structure
- Provide physical and personnel resources for safety-related activities. Provide adequate resources for personnel, equipment, and time for commissioning

Contribution to the hazardous state

- Selected and implemented TPS and EHR with which use discrepancies occurred
- Did not set and train staff on the procedure to coordinate treatment planning tasks
- Did not staff dosimetrist to fuse MR image when primary oncologist called

- Did not allocate sufficient staff time for chart rounds (or having enough staff to complete chart rounds on schedule)

Process model flaws

- Regarded the electronic note a minor feature of the information systems
- Considered staff experienced with care coordination
- Considered staffing and work hour arrangements adequate

Contextual/process model factors

- The general practice of procurement requirement specification did not include the level of detail pertaining to electronic note
- Few alternative information systems
- More major features in the information systems took up training time
- Opinion can differ on the need of MR image fusion for particular sarcoma cases. In general, clinician autonomy is highly valued.
- Many care coordination tasks routinely take place without complication, creating a false sense of security
- Information of safety events involving TPS and EHR would not typically get reported
- Chart round delays are not uncommon across organizations
- The case volume in the department may have prevented chart rounds to be extended, but the case volume target is typically set at the institutional level

Unanswered questions

- Was there a previous incident report on task coordination, or TPS use discrepancy?
- Was a request submitted to organizational executives to budget for dosimetrist overtime work and increased capacity for chart rounds?

The departmental management contributed to the incident by selecting and implementing the TPS and EHR with which the use discrepancies occurred. The underlying process model flaw was that electronic note was considered a minor feature of the information systems. The misunderstanding arose because the electronic note feature was not scrutinized in the procurement process. The procurement process, including the generation of RFPs, in healthcare is not budgeted for the level of time, staffing, (systems engineering) expertise that engineering/defense industries have. Moreover, the alternatives for information systems were few thus the department would not have much bargaining power for customization even if the necessary design analysis was done. When the implementation took place, more major features in the information systems also took up training time. In addition, an alert was not required for missing MR image fusion for sarcoma cases in TPS and EHR. The opinion can differ on the need for image fusion because it may not be indicated or bring value for particular cases. In general, clinician autonomy is highly valued.

The management also contributed to the incident by not setting (and training) staff on the procedure to coordinate treatment planning tasks, with or without the use of TPS and EHR. A process model flaw was that the staff was believed to be experienced with care coordination. This false sense of security was developed from the fact that many care coordination tasks routinely take place without complication. Furthermore, the impression was not corrected with incident reports. Information of incidents involving TPS and EHR would not typically get reported because the users may not consider these events reportable. While accreditation standards (e.g., APEx) stipulate the need for safety event

reporting within the healthcare organization, they do not have the specifics covering information system incidents.

A third contribution by the departmental management was not staffing a dosimetrist to fuse MR image when primary oncologist called to request it and not allocating sufficient staff time for chart rounds. The flawed process model was considering staffing and work hour arrangements adequate. Chart round delays are not uncommon across organizations. Furthermore, the case volume target is set at the institutional level, so the departmental management could not improve the situation on its own.

As described, the flawed process model of the departmental management resulted from the interactions with the organizational executives, accreditation bodies, frontline staff, and EHS and TPS manufacturers. This is representative of the results for mid-level controllers: the contextual factors arose from the interactions with higher-, lower-, and same-level controllers. It further shows that accident causation cannot be adequately described with a linear depiction. Instead, taking a systems perspective enables the causal factors to be more comprehensively identified.

Due to the limitations of analyzing a hypothetical case, two specific questions could not be answered: Was there a previous incident report on task coordination, or TPS use discrepancy? Was a request submitted to the organizational executives to budget for dosimetrist overtime work and increased capacity for chart rounds? Knowing the answers to these questions would have further informed the search for contextual factors and the area of exploration for the other controllers.

Ultimately, identifying the contextual factors helps avoid blame. Taken at face value, the decisions and behavior of the controllers would have seemed culpable. For instance, conventional analyses would state that the dosimetrist “failed” to fuse the MR images, the primary radiation oncologist “should have” planned an accurate treatment, and even the departmental management “failed” to procure well designed TPS and EHR and staff adequately. However, the reasons for these decisions and behavior became much clearer after the contextual factors were identified, e.g., the request for MR image fusion actually never reached the dosimetrist. The deeper understanding makes explicit the challenges of care delivery and reinforces the fact that healthcare workers really are motivated to deliver quality care.

3.2.2.4 Step 4: Identify flaws in the overall control structure

To identify the systemic causal factors in step 4, a change of perspective is used. While the focus is on the individual controllers in step 3, a more expansive look over the entire system is taken here: the previously identified contextual factors may collectively display a pattern or they may give clues to the more fundamental conditions that spurred their development. While this is the least structured part of CAST, some potential systemic factors have been identifies that might be considered (Leveson, 2019, p. 77):

- Communication and coordination
- The safety information system
- Safety culture
- Design of the safety management system
- Changes and dynamics over time
- Internal and external economic and related factors

For the RT incident, the contextual factors identified for all the controllers were examined collectively, and communication and coordination stood out as a salient systemic factor. For instance, it affected at least the treatment planner (e.g., the request for MR image fusion never reached the person), primary and covering radiation oncologists (e.g., the request to review MR images from the former

never reached the latter). This systemic factor was pervasive and actually extended beyond the stated examples (also impacting the manufacturers and the regulatory and advisory bodies, for instance).

Ultimately, three systemic factors were identified: communication and coordination, safety information system, and economics. Interested readers are referred to Appendix B for details. Instead of elaborating on communication and coordination, economics is described here to show the diversity of the findings. In addition, while a potential systemic factor, changes and dynamics, could not be confirmed due to information limitation, it is described to illustrate the process of exploration.

Economics

In the conventional fee-for-service payment model, quality and safety activities are not directly reimbursed. Training (e.g., on the use of TPS), reporting safety incidents (and participating in their analyses), supporting the development of consensus guidelines, or evaluating software options for procurement and the practicality of a workflow do not carry financial incentives. Yet, these activities were obviously inadequate in this incident. The lack of financial incentives may have compressed the time that staff member could contribute to these activities, enabling the incident to take place.

Changes and dynamics

It could not be determined whether changes and dynamics contributed to the incident. Given more information, exploration would have been made into the following areas:

Staff, software, policy, and procedure: Were the staff (both frontline staff and management) new hires or did they just return from an extended leave of absence? Similarly, was there implementation of new software (e.g., the TPS), or procedures pertaining to treatment planning? Were there any changes to billing or personnel policies? If any of these conditions applied, the staff may not have been ready to perform the job functions and the changes may not have been well managed. The process to develop and implement these changes should be examined. For instance, was the change accurately communicated? Was training provided and adequate? Was safety, proficiency, and practicality assessed? Were lessons learned shared and the software, policy, and procedure refined?

Patient volume: Was there an abrupt increase in patient volume? As mentioned, the staffing decision tends to be made at the organizational level (i.e., not at the departmental level) and takes time before adjustments can be effectively made. If patient volume increases in a relatively short period of time, it could strain the care team, impacting the abilities for dosimetrists to fuse images and radiation oncologists to fully specify and review treatment plans, discuss cases at chart rounds without delay, etc. If applicable, the process to control the patient volume (e.g., referrals and scheduling) should be examined.

3.2.2.5 Step 5: Creating an improvement program

In Step 5, recommendations are created to address the identified causal factors: the contextual factors and the systemic factors. Different safety interventions may be needed at different system levels. A process to generate design ideas is introduced in Section 4.2.3 in the next chapter. A highlight of the results are provided below.

To recapitulate, the RT incident involved the omission of MR image fusion, and many factors (identified in steps 3 and 4) helped cause the incident. For instance, the original request to start the treatment planning process did not include the fusion order and the TPS did not require MR image fusion for a sarcoma patient before other contouring or treatment planning activities could be

performed. Moreover, there were three systemic factors: communication and coordination, safety information system, and economics.

In response, about 40 safety intervention options were generated, and they encompass practice change, technology, safety information, communication, care coordination, change management, role and responsibility and management (Appendix B).

For example, to completely eliminate any potential for omitting MR image fusion where indicated, a fundamental system redesign can be made. MRI-only RT planning is an emerging practice that can eliminate the need for image fusion in treatment planning (Korsholm et al., 2014; Schmidt and Payne, 2015). Moreover, it also eliminates other errors associated with the fusion between MR and CT images and the radiation exposure from CT imaging. However, the technique is still under active research, and implementation requires substantial capital investment and system changes. It is unlikely to be feasible in the near term.

A combination of other safety interventions can also reduce the likelihood of fusion omission by addressing the contextual factors. For instance, the EHR, TPS can be configured or redesigned to provide error message and restrict plan finalization when there is a deviation from normative practices (e.g., MR image fusion for sarcoma patients). The prescription template can be modified to require justification if MR image fusion is to be omitted for sarcoma patients. The policy can be changed to allow the omission only for patient-based reasons (i.e., to shorten the time to plan review would *not* be eligible), and monitored with regular peer review of the justifications by the safety committee.

In a broader sense, communication and care coordination need to be improved. An operational study can be conducted to identify the communication means that are used for task requests and their merits and vulnerabilities. A set of agreed and acceptable communication means can then be set. If the electronic note feature in the TPS has a role, the software should be configured or redesigned to require acknowledgement and automatic re-prompting (if the note is not read and acknowledged within a certain timeframe).

Management and regulatory changes can create a safer care delivery environment for frontline staff. The departmental management can allocate resources and make procurement decision based on a safety analysis that comprehensively accounts for unsafe interactions, and this should be supported by executive actions (e.g., allocating resources, setting patient volume goals). Regulatory and other advisory bodies can expand the quality and safety activities required for licensing and accreditation. Organizational executive can also provide financial incentive, time allocation for staff's contribution to quality and safety activities, and make promotion considerations based on such.

As the examples have shown, a diverse set of options to improve safety can be generated by following the CAST process. Different objectives are targeted by different safety interventions. Some specifically prevent MR image fusion omission while others more broadly enhance staff interactions and the care delivery environment. They also differ in their ability to eliminate a particular hazard or just reduce the likelihood for its occurrence. Different stakeholders are involved in their implementation. They enable a comprehensive approach to improving safety.

3.2.2.6 Summary

In summary, the five steps of CAST provide a methodical procedure to identifying causal factors comprehensively and to address them effectively. Step 1 captures mostly the "what" aspect of an incident, but a snippet of the "why" aspect is also provided at the level of the physical process. Step 2 yields a graphical model that illustrates the controls around the system. Step 3 identifies the flawed process models and contextual factors that led to the unsafe behavior or decisions of each controller. Step 4 reveals the systemic factors that impacted much of the system. Lastly, step 5 addresses the findings to improve system safety.

Healthcare incidents are non-trivial. In the RT incident, an omission by a frontline staff was connected to many different decisions both within and outside the healthcare organization—even regulators and accreditation bodies that are not involved in direct care delivery. CAST enables this deeper understanding of an incident to be generated. In turn, a more effective and comprehensive approach to improving safety is also made possible.

Chapter 4. CAST enhancements

While CAST enables learning from incidents effectively, its application in healthcare is not trivial. To recapitulate, the following challenges exist:

- Time pressure with incident analyses and safety interventions
  - Many clinicians take on additional responsibilities as safety analysts, and the time spent on analysis often competes with patient care.
  - Human lives depend on the care being provided, and the care often has a strict therapeutic window and cannot be interrupted.
- Lack of the relevant knowledge
  - The safety analysts often have limited knowledge of systems engineering or systems theory.
  - Terminology differences between the fields have hampered idea cross-pollination.

Given the challenges, some healthcare staff have found the CAST concepts (e.g., SCS) difficult to grasp and are wary of the time it takes to learn the technique and to conduct the analysis (Canham et al., 2018; Jun and Waterson, 2019).

For CAST to gain widespread use in healthcare, it must be tailored to the requirements and limitations of the environment in which it is to be used. Methodological refinement, reference materials, templates, and training were developed to render CAST more practical for use in the healthcare setting. They are described in this chapter. They were also evaluated in the field, and the evaluation is described in the next chapter.

4.1 Enhancing learnability and the use of CAST in healthcare

Seven specific enhancements were made: a generic SCS, a list of reference controller responsibilities, a graphical safety intervention design process, templates, and a training program, which includes cases illustrating sample systemic factors and a reference CAST analysis.

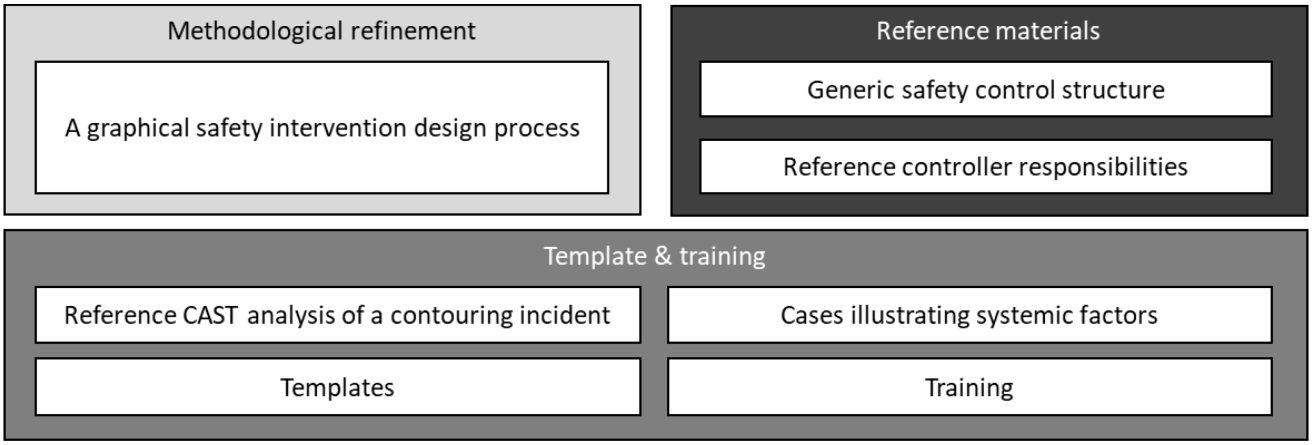


Figure 13 *The enhancements to facilitate CAST application in healthcare*

The generic SCS comprehensively models the interactions to deliver RT. It comprises multiple parts showing the details from frontline care delivery to regulatory decision making. When a CAST analysis is conducted, the generic SCS enables the relevant parts to be changed instead of creating the entire SCS from a blank slate in step 2.

The responsibilities of the controllers in the generic SCS are compiled into a reference document. The information facilitates the selection of the relevant controllers when creating the SCS and the identification of the behavior that contributed to the incident when each controller is examined (step 3). Together with the generic SCS, this information is especially useful for the safety analysts unfamiliar with the particular medical specialty (e.g., when the analysis is conducted by analysts from the institutional level rather than those in the radiation oncology department.)

For step 5, the graphical safety intervention design process separates the overall design task into a set of smaller tasks and represents them in a graphical format. It fosters the consideration of interactions in the system and enables more design options to be generated for selection. This framework aims at assisting safety analysts without extensive engineering expertise.

The templates keep the working information organized. They also provide a just-in-time refresher of some CAST concepts, capitalizing on the occasion where there is the greatest motivation to learn. Some automation is available as well.

The cases illustrating sample systemic factors and the reference CAST analysis are key content of the training program. They provide examples of systemic factors and how to perform a CAST analysis.

The broader training program comprises videos and tutorial sessions. The videos describe the concepts required to conduct a CAST analysis. The videos are short and enable information to be communicated consistently. They also create learning autonomy, reducing the duration of the tutorial sessions and aiding scheduling and coordination. In tandem, the tutorial sessions incorporate demonstrations and exercises. They enable safety analysts to receive individualized assessment and real-time feedback.

4.2 Detailed descriptions of the CAST enhancements

The description covers not only what each enhancement is but also demonstrates the use with examples from analyzing the RT incident introduced in Chapter 3. The process of development is also described where relevant. While the methodological refinement is applicable to healthcare broadly, the reference and training materials are either only applicable to radiation oncology or may be less relatable to the practitioners from other specialties. Additional developments for other specialties are left for future work. Such developments can further facilitate CAST application in other medical specialties.

4.2.1 Generic safety control structure

The generic SCS is more complete than is needed to analyze a particular incident. The benefit is that it will be easier to select the relevant control loops from a premade model than to create a new one from a blank slate for each analysis, especially for novices.

The generic SCS has 39 controllers and several hundred control actions and feedback. It spans eight parts:

- Overall system
- Healthcare organization
- RT planning and delivery
- RT planning
- CT simulation
- MRI simulation
- RT delivery (linac)

- RT delivery (brachytherapy)

The various parts model the interactions in the SCS at different levels of detail and are color-coded to show the connection (Figure 14). For instance, the healthcare organization is abstracted as a component in the overall system, but more of its internal interactions can be modeled.

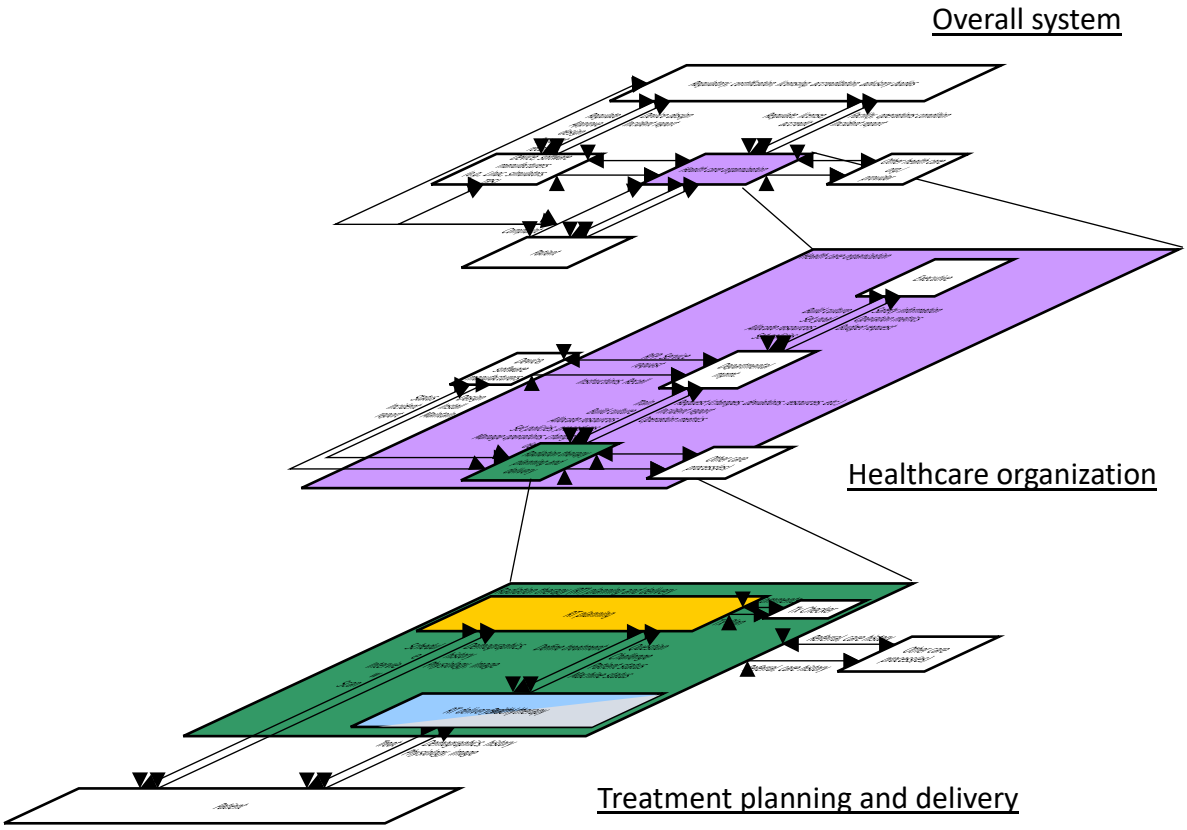


Figure 14 The first three parts shown as projections to illustrate their relationships

The first four parts have been described previously in Section 3.2.2.2 as part of the SCS of the RT incident. These parts will be revisited shortly when the use of the generic SCS is demonstrated. Meanwhile, the part on RT delivery (linac) is described to provide another example, whereas Appendix C documents all eight parts in full.

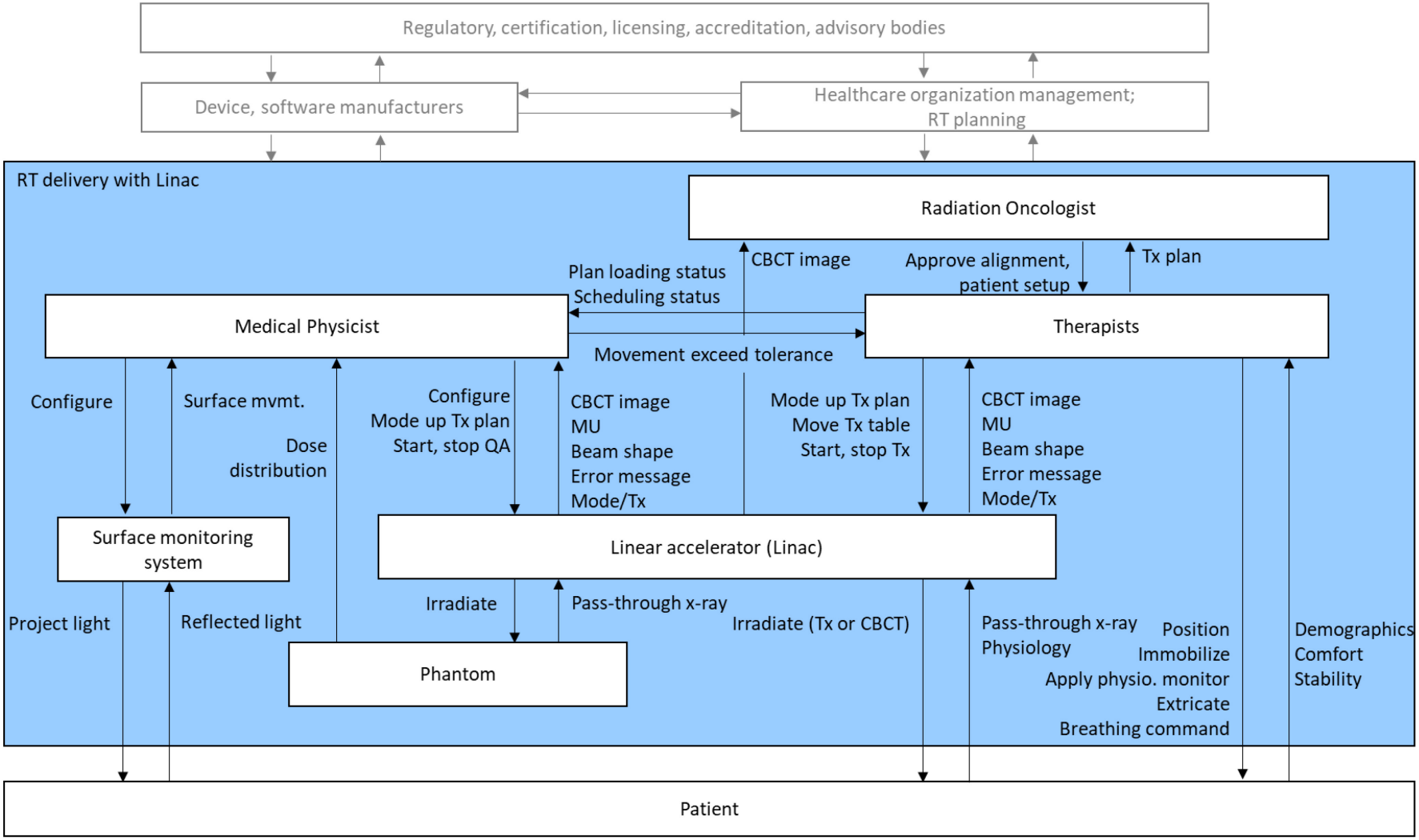


Figure 15 The part of the SCS showing the details of RT delivery with linac (CBCT = cone beam computed tomography; MU = monitor unit; mvmt. = movement; QA = quality assurance; Tx = treatment)

Figure 15 emphasizes the part of the SCS directly delivering RT with the linac, which is staff-intensive. Therapists, medical physicists, and radiation oncologists are commonly involved. Prior to treatment, the therapists have the important control action of replicating the patient positioning from the simulation session. For image-guided radiation therapy (IGRT), imaging (e.g., cone beam CT) provided by the linac is used as feedback to assist with alignment. The radiation oncologist then approves the alignment if the images are consistent with the treatment plan.

To start treatment, the therapists configure and operate the linac while monitoring the output (e.g., monitor unit, shape), machine status, etc. For treatments requiring extra precision, the medical physicist operates a surface monitoring system, which provides feedback on the extent of surface movement. If movement tolerance is exceeded, the medical physicist coordinates with the therapists to stop the treatment and realign the patient.

With automation embedded, the linac is also an important controller. It delivers radiation based on the programmed spatial-temporal trajectory. The intensity and beam shape are also modulated in the newest devices. Some linacs even have automation to trigger the starting and stopping of the radiation beam using feedback of physiology information (e.g., respiratory motion) (Freislederer et al., 2015).

For long-term maintenance, the medical physicists provide quality assurance by testing the different functionalities of the linac using phantoms, which provide feedback of dose distribution. Configuration are changed in response to the results.

4.2.1.1 Examples from analyzing the RT incident

With the generic SCS, creating a SCS for the RT incident is straightforward:

1. Using the basic incident information gathered in step 1 of the analysis and the reference controller responsibilities (described in the next section), the relevant controllers are identified.
2. A review of the generic SCS shows that the first four figures (the overall system, the healthcare organization, treatment planning and delivery, and treatment planning) contain the relevant interactions.
3. The first three figures can be incorporated with few modifications (Figure 9 to Figure 11). One modification, for instance, is changing a controller from the generic designation, “Device, software manufacturers” to its identity specific to the incident, “EHR, TPS manufacturers”. These modifications require little time.
4. The part of the generic SCS focusing on treatment planning (Figure 16) goes through more elaborate modifications to capture the unique aspects of the incident (Figure 17). An additional controller, the covering radiation oncologist, was involved and needs to be added. Moreover, the interaction between the primary and covering radiation oncologists are captured with a new arrow and label. Lastly, some of the original control actions (e.g., approve fusion) and feedback are also rearranged given the delegation of responsibilities.

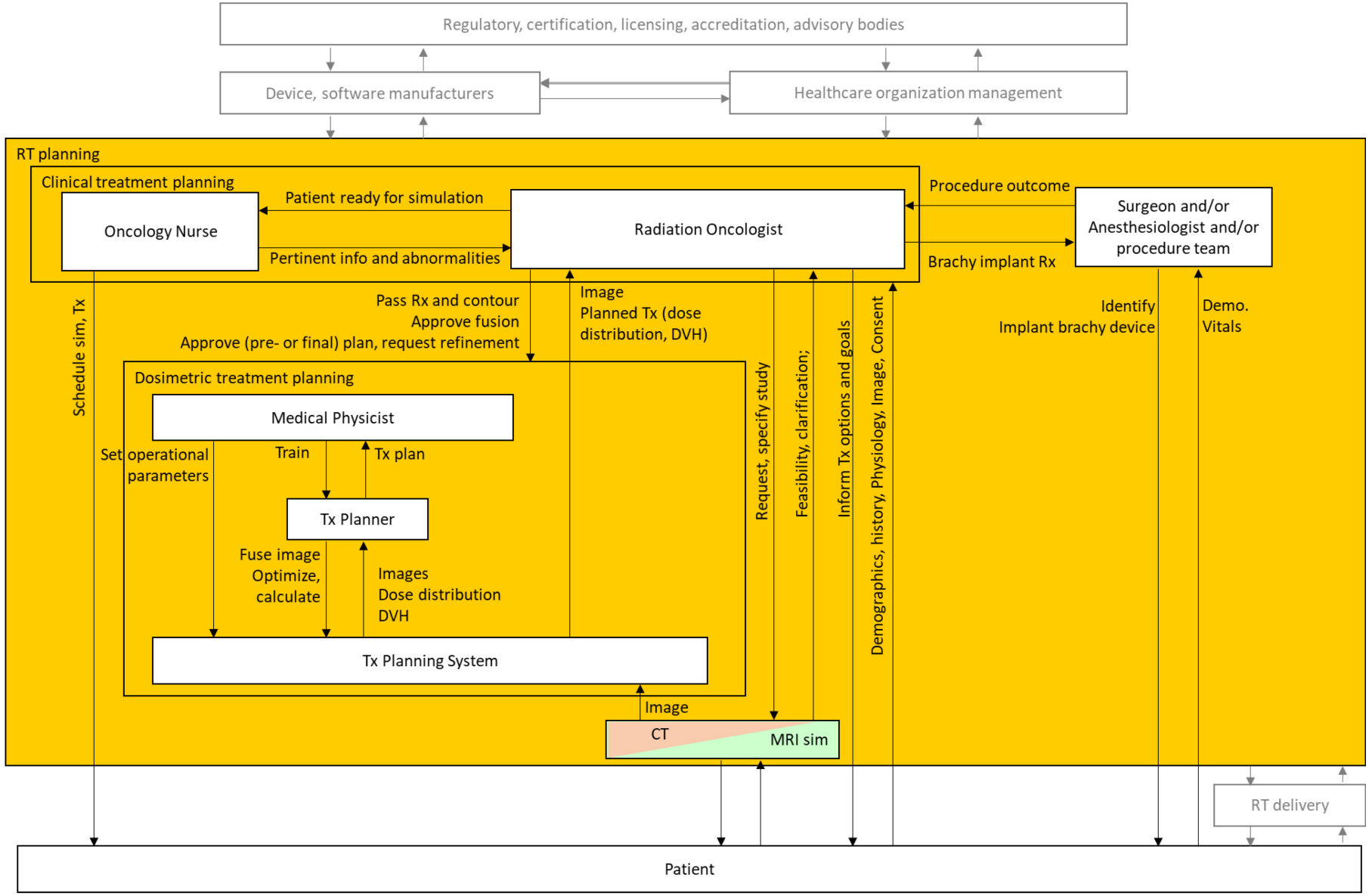


Figure 16 The details of RT Planning from the generic SCS. This figure subsequently went through more elaborate modifications to generate part of the SCS used in the RT incident analysis.
(CT = computed tomography; DVH = dose-volume histogram; MRI = magnetic resonance imaging; Rx = prescription)

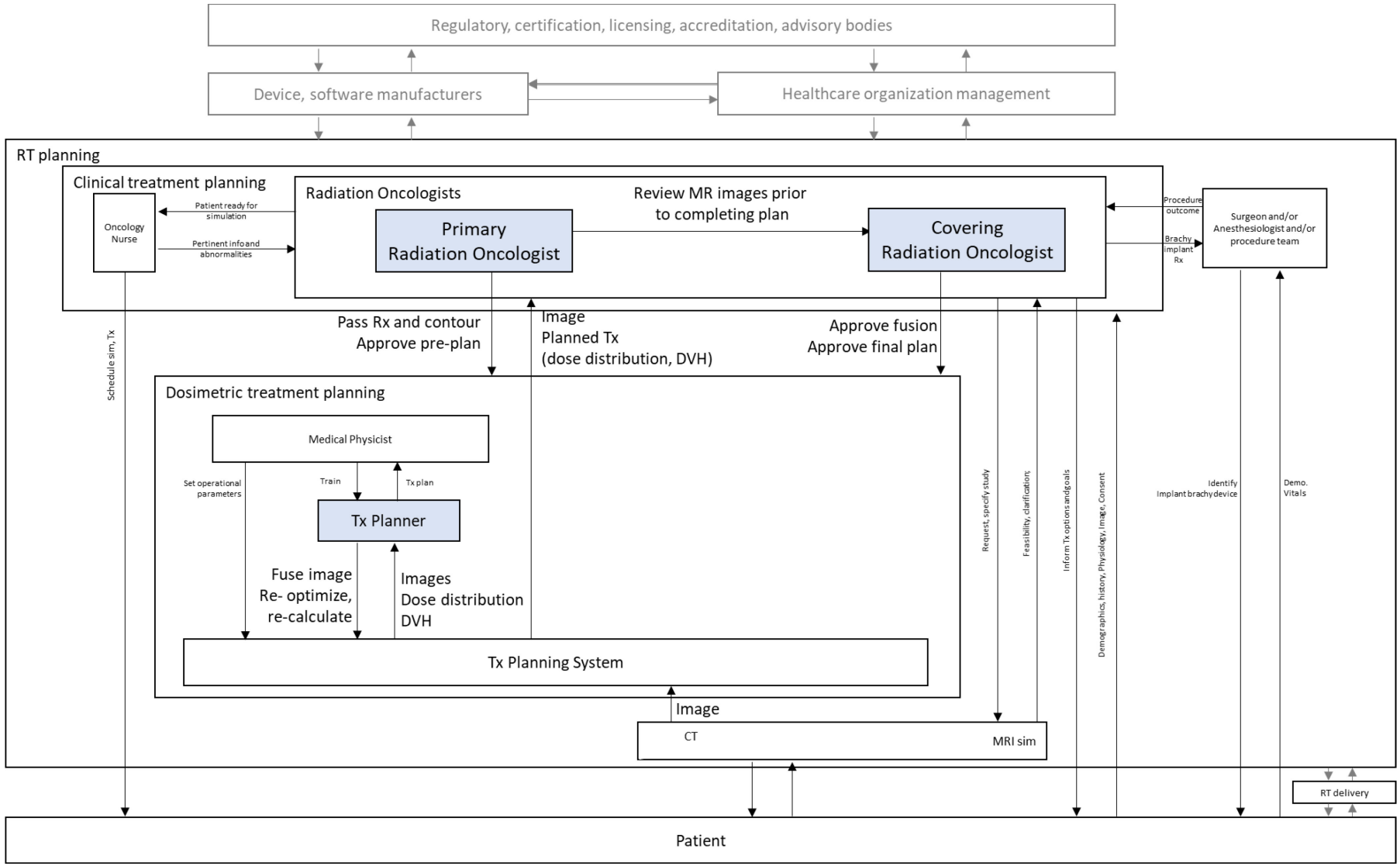


Figure 17 The part of SCS showing the details of RT Planning created from modifying the generic SCS. A working draft with the controllers known to be relevant being highlighted and others de-emphasized with reduced font size.

Notably, before the analysis is complete, the SCS should be considered a draft, and the apparently irrelevant controllers and interactions should be retained temporarily. To focus attention, the safety analyst can highlight the controllers known to be relevant and de-emphasize the other controllers and interactions with a reduced font size. For instance, because RT was delivered with the linac (as compared to brachytherapy), the Surgeon, Anesthesiologist and procedure team were not involved. Instead of their immediate removal from Figure 17, they are retained temporarily in case of later revelation of their relevance. These controllers and interactions are eventually removed at the completion of the analysis to produce a more concise figure (Figure 12).

4.2.1.2 Process of development

The generic SCS can be developed by:

1. *Setting the scope of the model.* The scope should provide a wide coverage of the system of interest because it is impossible to know beforehand what parts of the system an incident may concern.
2. *Gathering system information.* This is relatively easy for developers who are familiar with the system. Otherwise, bibliographic research, an orientation program, in-person observation, and domain expert inputs can be leveraged, as in this study.
3. *Creating the model.* Leveson and Thomas (2018) provide a detail description of the process, which can be summarized as 1) the creation of a highly abstracted SCS, identifying the obvious controller and control actions and 2) iterative refinement to expand the previously abstracted controllers and processes to explicate the more detailed interactions.
4. *Updating based on use experience and system changes.* Actual use of the generic SCS may reveal a lack of necessary detail in certain parts of the system. Revisions are also needed as the system changes over time.

4.2.2 Reference controller responsibilities

The responsibilities were compiled for the controllers ranging from frontline clinicians to the regulatory and advisory bodies. Appendix D documents them in full. As an example, treatment planners are commonly responsible for:

- Fusion and registration (primary)
- Contouring/segmentation
- Dose-volume constraints
- Dose calculation
- Review of final treatment plan (compared to physician request)
- Patient positioning (supervisory or advisory) and image acquisition
- Treatment delivery (advisory)

Also, the responsibilities for the regulatory and advisory bodies are to:

- Protect the health and safety of the public
- Set regulations, standards and policies that identify organizational outcomes that hospitals must achieve
- License specialized devices for use
- Ensure timely access to all safe/effective medical devices
- Inform the public of safety concerns related to medical devices in a timely manner.

4.2.2.1 Examples from analyzing the RT incident

The use of the reference to support creating SCSs has been described in the last section. The use to identify a controller's contribution to an incident is now shown:

1. For each controller of interest, the list of reference responsibilities is reviewed against the basic incident information generated in step 1 to derive the responsibility relevant to the incident. For instance, MR image fusion is an important aspect of the RT incident, so the treatment planner's responsibility for fusion and registration is relevant to the incident.
2. The commission or omission of an action, derived from the relevant responsibilities, is then identified as the controller's contribution. In the RT incident, the dosimetrist contributed by omitting MR image fusion, as mentioned.

4.2.2.2 Process of development

The information can be compiled from the system information gathered to create the generic SCS.

4.2.3 A graphical safety intervention design process

Once the causal factors are understood, recommendations for changes to the system must be created. Some practitioners in healthcare consider this task more difficult than identifying the causal factors, and the safety interventions proposed are often ineffective (Card et al., 2012; Kellogg et al., 2017; Wu et al., 2008). A graphical design process was created to help tackle the challenge. The process has three steps: 1) creating new ways to improve the system design, 2) tracing the design recommendations to the SCS, and 3) detailing the design recommendations (safety intervention options).

4.2.3.1 Creating new ways to improve the system design

The CAST analysis gives a clear description of what the safety interventions need to achieve. The causal factors can be described in terms of new design recommendations. In general, these new design recommendations should have the following characteristics:

- They should allow flexibility in implementation. For example,

  The covering radiation oncologist must confirm with the primary radiation oncologist the need to review MR images prior to treatment plan approval

  allows more flexibility than:

  The covering radiation oncologist must <u>email</u> the primary radiation oncologist to confirm the need to review MR image prior to treatment plan approval.

- They should be enforceable. For example, the design recommendation above:

  The covering radiation oncologist must confirm with the primary radiation oncologist the need to review MR images prior to treatment plan approval

  is more enforceable than:

  The covering radiation oncologist must handle the need to review MR image prior to treatment plan approval

  because "handle" is ambiguous and can be interpreted in ways that may not solve the specific problem.

- They should describe only one change at a time to provide traceability, which aids subsequent implementation verification. The requirement:

  The covering radiation oncologist must confirm with the primary radiation oncologist the need to review MR images prior to treatment plan approval and must ensure the case is discussed at chart rounds prior to treatment start

  states more than one objective, as there is a second recommendation pertaining to case discussion.

4.2.3.1.1 Examples from analyzing the RT incident

From Section 3.2.2.3, some causal factors were:

- Treatment planner did not know the need to fuse the MR image because the original request by the radiation oncologist was issued without the fusion order.
- As the radiation oncologist subsequently called to request MR image fusion, the person did not reach the treatment planner.
- The TPS did not require MR image fusion for sarcoma patient before other contouring or treatment planning activities could be performed.

Ultimately, the treatment planner did not fuse MR image when indicated. Therefore, some new design recommendations (DRs) can be defined as:

DR-1. Treatment planner must fuse MR image when indicated.

DR-2. Treatment planner must know definitively the need for MR image fusion at the start of treatment planning.

DR-3. A task request directed to the treatment planner must be re-conveyed unless it is acknowledged within a business day.

DR-4. Treatment planning team members must be informed of any deviation from normative practices.

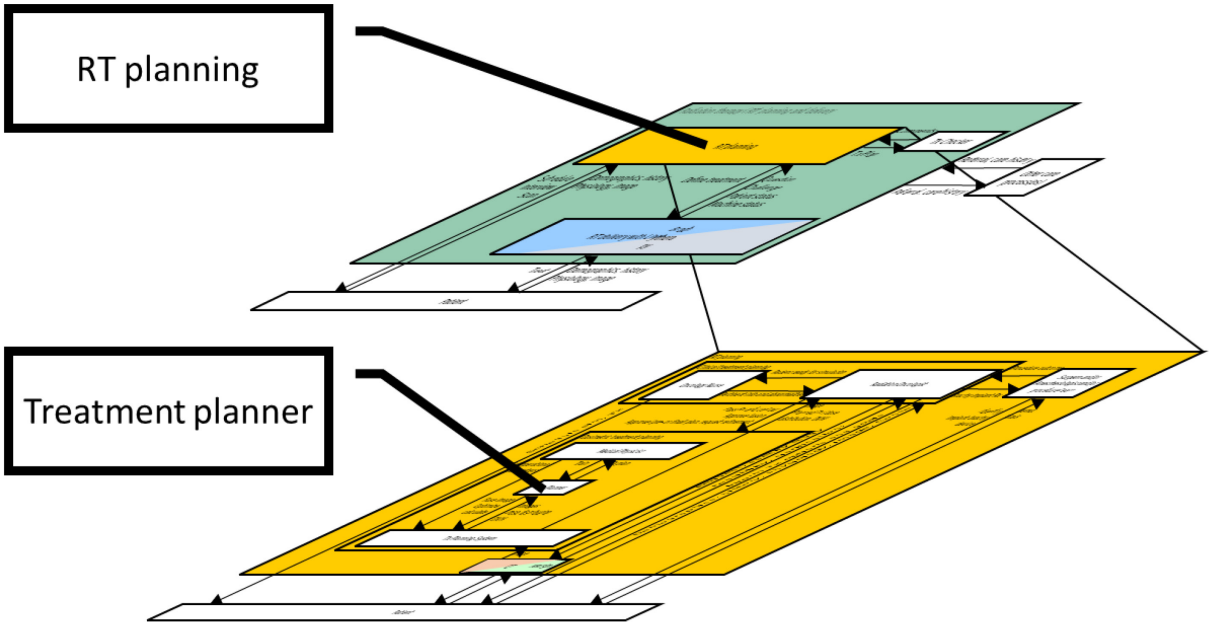


Figure 18 The relative levels of abstraction between the treatment planner and RT planning

The mentioned design recommendations target the treatment planner near the bottom of the SCS, and RT planning is a higher-level abstraction that includes the treatment planner (Figure 18). Another design recommendation can be defined for RT planning:

DR-5. RT planning must incorporate clearly defined soft tissue boundaries when indicated.

In this design recommendation, the focus is not on MR image fusion alone but the merits of incorporating MR image into treatment planning, which is to provide clearly defined soft tissue boundaries for contouring.

4.2.3.2 Tracing design recommendations to the safety control structure

The design recommendations can be traced to the SCS for visualization. This task shows the parts of the system that are targeted by the design recommendations.

4.2.3.2.1 Examples from analyzing the RT incident

Figure 19 shows the mapping for the first four design recommendation. DR-1 addresses the control action of the treatment planner, so it is mapped to the downward arrow. DR-2 addresses the process model of the treatment planner, so it was mapped to the controller. DR-3 addresses the control inputs from the higher-level controllers, so it is mapped to the relevant downward arrows. Lastly, DR-4 is mapped to the upward arrows from the TPS because the TPS provides feedback to the treatment planning team members. DR-4 is also mapped to the downward arrows from the radiation oncologists due to their evaluative responsibilities, and it is mapped to the horizontal arrow between the primary and covering radiation oncologists. Notably, when this is done, a previously missing (now shown as a dash line) horizontal arrow from the covering to the primary radiation oncologist is identified.

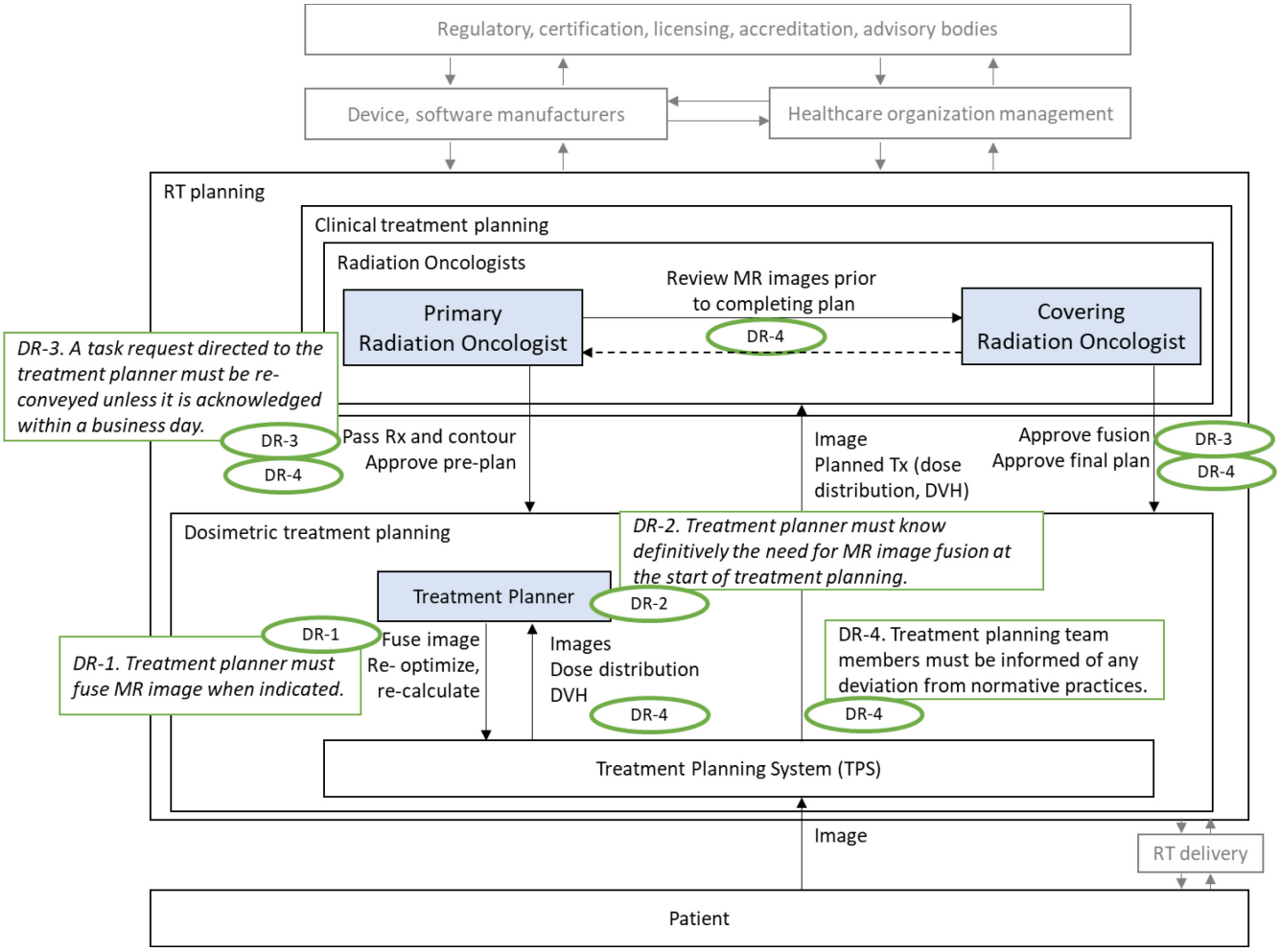


Figure 19 Mapping of design recommendations (DR-1 to DR-4) to the SCS

The fifth design recommendation is mapped to the part of the SCS showing the details of RT planning and delivery (Figure 20). Because DR-5 targets the feedback used by RT planning when defining treatment, it is mapped to the upward arrow.

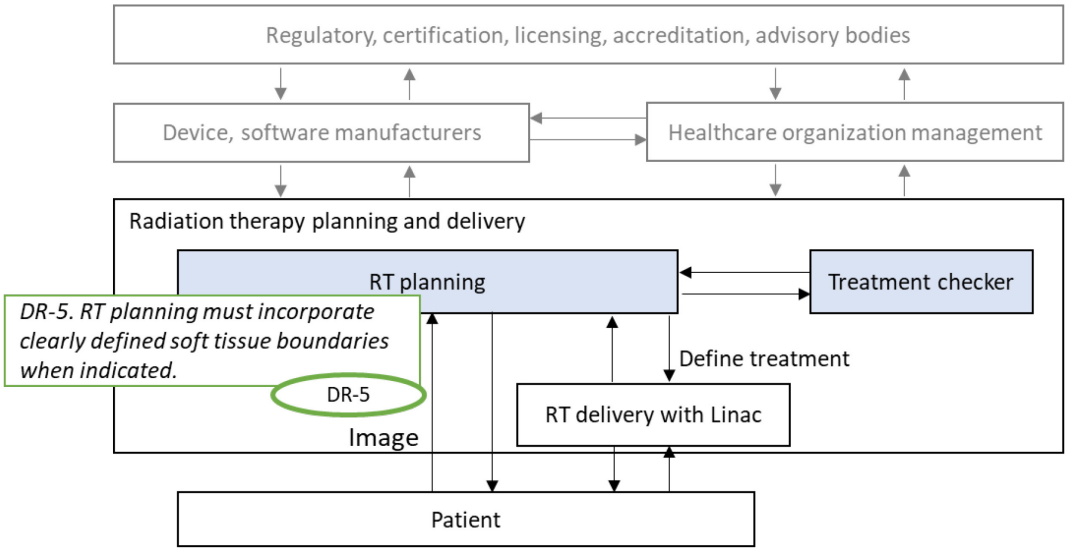


Figure 20 Mapping of a higher-level design recommendation (DR-5) to the SCS

4.2.3.3 Detailing the design recommendations

Until now, the design recommendations have been defined to allow flexibility in implementation. They are now are refined to identify the implementation details for selection and implementation. This is done by selecting the interaction(s) of opportunity and specifying the means of implementation.

An *interaction of opportunity* is an interaction that can be added, modified, or even deleted (unintended consequences should be assessed for selection) in the system to prevent a causal factor identified by CAST. The categories of interactions the safety analysts can use are the same as the generic options in a proactive STPA analysis (Leveson and Thomas, 2018, fig. G-2). STPA is a proactive analysis that identifies all potential causal scenarios. Those causal scenarios must then be eliminated from the system design. CAST is a reactive process that identifies only the scenario that must be eliminated to prevent that specific scenario. But the general ways to prevent scenarios are the same in both.

Three primary categories are:

- Control action and feedback, which have been described before.
- *Process input* is the raw material, information, etc. that feeds the process and is transformed. For instance, electricity is an indispensable input to a linac.

The selection or addition of interaction(s) of opportunity can be done as follows:

- If the design recommendation addresses a control action or feedback, the control action or feedback should, naturally, be considered.
- If the design recommendation addresses a process model, there are more options to consider. A process model is informed by multiple sources of information:
    - Feedback. Feedback helps detect if the intended change has resulted from a control action or if adjustment is needed to correct deviation from the target state. For example, a serum titer can be obtained as a feedback to assess immunity. Simply getting vaccinated may not provide enough assurance and result in a flawed process model. This concept is also analogous to applying the plan-do-study-act (PDSA) approach to quality improvement in healthcare (Leis and Shojania, 2017).

- Control inputs from higher levels and coordination and communication from peer controllers. The consideration should not be limited to the control inputs and communication in the closest hierarchical levels but even at the highest level.
- A signal giving advance notice of impending changes to the process state. For example, pre-hospital notification of a mass casualty incident can improve the configuration and staffing of the emergency department, leading to the ability to care for more patients.

In short, feedback, control inputs, and information sources that provide advance notice of impending changes should be considered if the design recommendation addresses a process model.

A *means of implementation* describes the format, method, or other characteristics of how the design recommendation can be operationalized. For instance, a physical control action (e.g., moving a patient) can be performed manually, mechanically (e.g., with a traditional stretcher), electromechanically (with a powered stretcher), etc. Different means also exist for intangible interactions (e.g., those at the organizational level). For instance, safety information may be passed from frontline staff to management using an incident report, but direct observation of patient care, morbidity and mortality conferences, etc. are also feasible alternatives/complements.

Specifying the means of implementation is inherently an expression of creativity. What is feasible depends on what interaction is being considered. If the safety analyst is absolutely at a loss, a literature search may give further inspiration. The Agency for Healthcare Research and Quality has published some evidence-based safety practices (Hall et al., 2020; Shekelle et al., 2013; Shojania et al., 2001) that may be relevant.

4.2.3.3.1 Examples from analyzing the RT incident

For DR-5 (i.e., “RT planning must incorporate clearly defined soft tissue boundaries when indicated”), the design recommendation addresses the feedback, so it was mapped to the upward arrow (Figure 21). The same feedback is intuitively the interaction of opportunity. To consistently meet DR-5, MR images can be used to simplify the current practice of using *both* MR and CT images. Not only does MRI-only RT planning prevent inadvertent image fusion omission, it also eliminates other errors associated with image fusion (Korsholm et al., 2014; Schmidt and Payne, 2015).

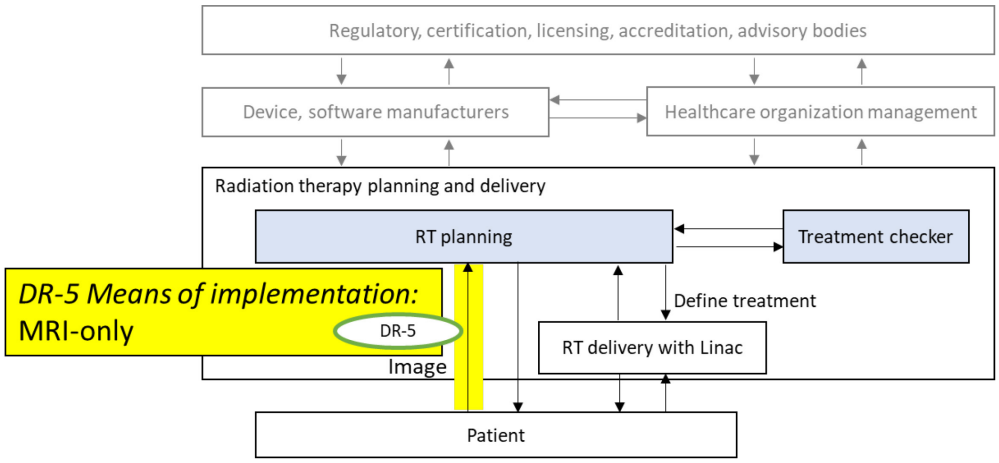


Figure 21 Safety intervention to address DR-5 with image use, achieving hazard elimination. Highlighted feedback is the interaction of opportunity.

In this example, hazard elimination is achieved by simplifying the feedback when the system is considered at a higher abstraction level. Safety interventions targeting a higher hierarchical level can eliminate a whole class of flawed interactions at a lower hierarchical level.

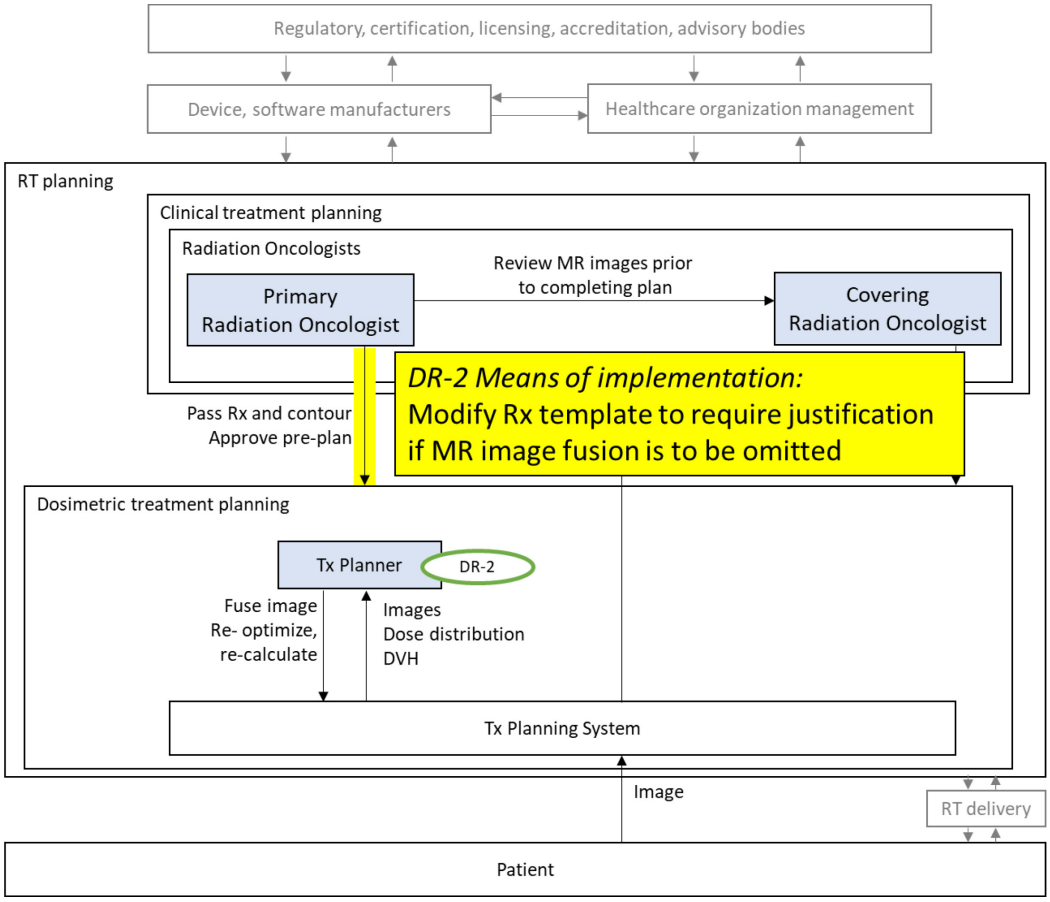


Figure 22 One safety intervention option to address DR-2 with a prescription template modification. The highlighted control input is the interaction of opportunity.

Next, DR-2 (i.e., “Treatment planner must know definitively the need for MR image fusion at the start of treatment planning”) addresses the process model of the treatment planner, so it is mapped to the controller (Figure 22). As mentioned, if the design recommendation addresses a process model, feedback, control inputs from higher controllers, communication from peers, and information sources that provide advance notice of impending changes can be considered as the interaction of opportunity. In this case, the primary radiation oncologist’s control input, “Pass prescription and contour”, which is the downward arrow directly above where DR-2 is mapped, is an interaction of opportunity. The means of implementing DR-2 is to modify the prescription template to require justification if MR image fusion is to be omitted.

Other safety intervention options exist for DR-2 (Table 4). Options 2 and 3 comprise training and policy/procedure modifications and are created by using the control actions of the departmental management as the interaction of opportunity.

Table 4 Some safety intervention options for DR-2

Safety intervention options	**Details**
Option 1	• *Interaction of opportunity:* Primary radiation oncologist's control action, "Pass prescription and contour" • *Means of implementation:* Modify prescription template to require justification if MR image fusion is to be omitted
Option 2	• *Interaction of opportunity:* Departmental management's control action, "Train" *Means of implementation:* o Orientation training for new oncologists should cover ▪ the need to specify MR image fusion in the prescription ▪ acceptable justifications for omitting MR image fusion ▪ the need to justify MR image fusion omission in the prescription o Orientation training for new dosimetrists should cover ▪ acceptable justifications for omitting MR image fusion ▪ the need to seek clarification for MR image fusion if the information is missing from the prescription ▪ that an incident report should also be filed to pursue further improvement
Option 3	• *Interaction of opportunity:* Departmental management's control action, "Set policies, procedures" • *Means of implementation:* Modify departmental procedure to require the need for MR image fusion to be specified in a prescription and allow MR image fusion omission only for patient-based reasons

Even though options 2 and 3 are more easily implemented, administrative interventions are generally deemed to be relatively weak. Nonetheless, the options can be augmented to improve their effectiveness. The options rely on the control actions of the departmental management, but the departmental management does not necessarily have a good understanding of whether the actions are effective—assuming the actions to be effective only to be informed otherwise by an incident report would be regrettable. A new feedback, MR fusion audit, can be added for the departmental management (Figure 23). Operationally, the safety committee would audit the prescriptions every month for whether the justification for MR fusion omission is consistent with the policy and whether the training is effective.

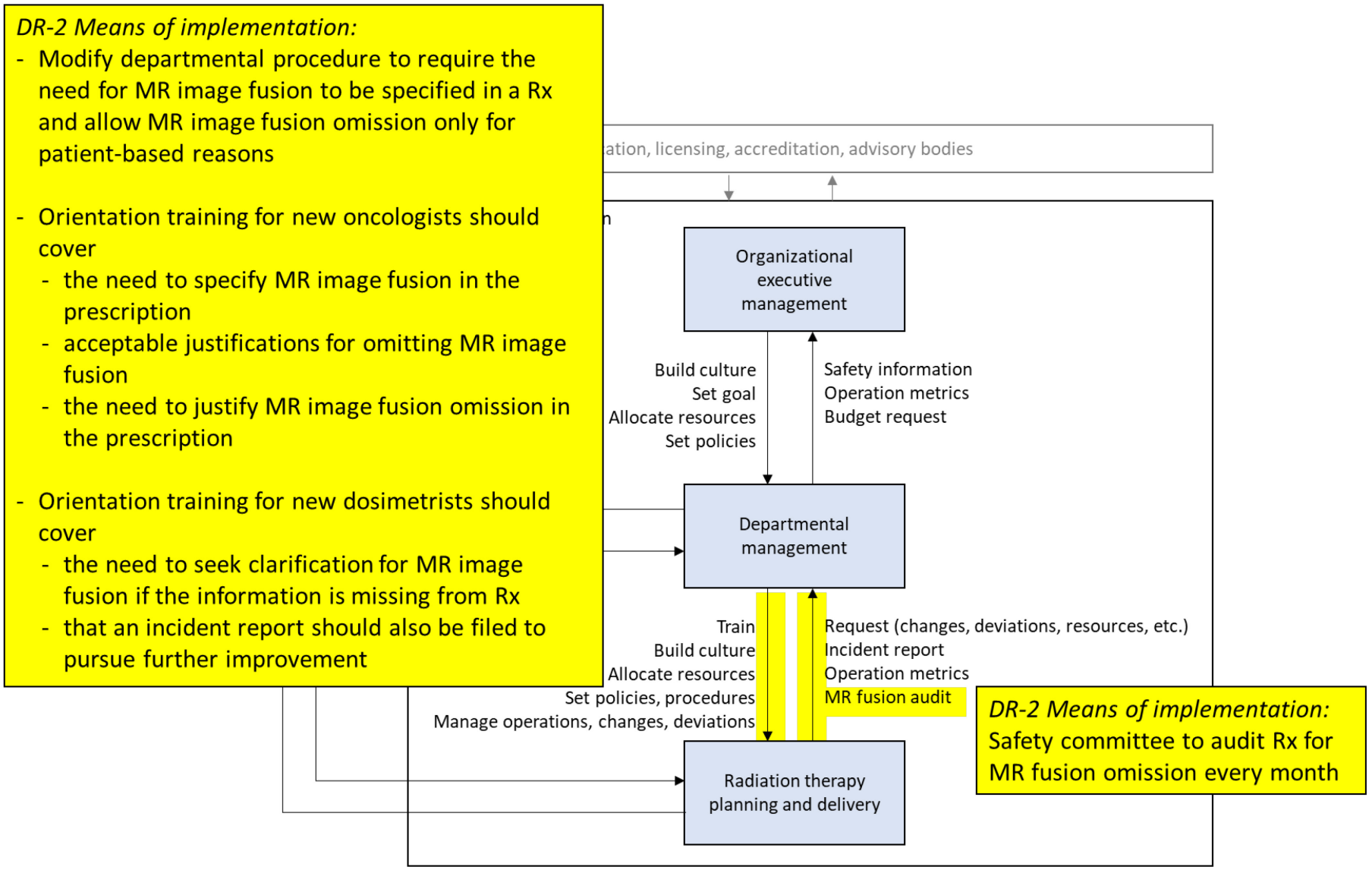


Figure 23 Safety intervention ideas to address C-SC-1 with audit, training, and policy and procedure

In this example, the effectiveness of the safety interventions is increased by ensuring that close-loop control is in place. By inspecting the relevant control loop(s) and ensuring that control actions are paired with feedback (i.e., paired arrows), a better design can be generated. This is the merit of using a graphical design process with the SCS.

4.2.3.4 Summary

This graphical design process has three steps: 1) creating new ways to improve the system design, 2) tracing the design recommendations to the SCS, and 3) detailing the safety intervention options. The process has several strengths. First, instead of brainstorming for safety intervention ideas as in the conventional approaches (e.g., TJC, 2017a), the SCS provides a contextualized canvas—a set of controllers, control actions, and feedback tailored to the system of interest—for design conceptualization. Second, the hierarchical layout of the figures enables the focal point to be drawn from the component level to higher levels, facilitating hazard elimination. Third, the control-theoretic foundation of the SCS assists in designing more effective safety interventions. Fourth, using the graphical approach reduces the cognitive effort of processing information (Nemeth, 2004; Norman, 2011). Lastly, the incremental steps disentangle the non-trivial task of safety intervention design into a group of smaller tasks.

4.2.4 Templates

Seven templates were developed to organize the vast quantity of information. Specifically, one template each was built for parts 1-4 and two templates were built for step 5, where safety intervention design is done using both textual and graphical information. One additional template was built to report the analysis output.

Several features are built into each template. A “hint text” describes the subtasks and reference materials relevant to the part of the analysis. The template layout (e.g., text boxes, lists, tabs) helps organize the working information. The template for step 3 is shown below while Appendix E displays the full set of templates.

4.2.4.1 Examples from analyzing the RT incident

The template for component analysis (step 3) facilitates the generation of investigation questions and the transition of the analysis from one controller to the next. The template comprises five tabs, and the first one (Figure 24) includes the hint text, which provides the instructions and reviews how to generate investigation questions.

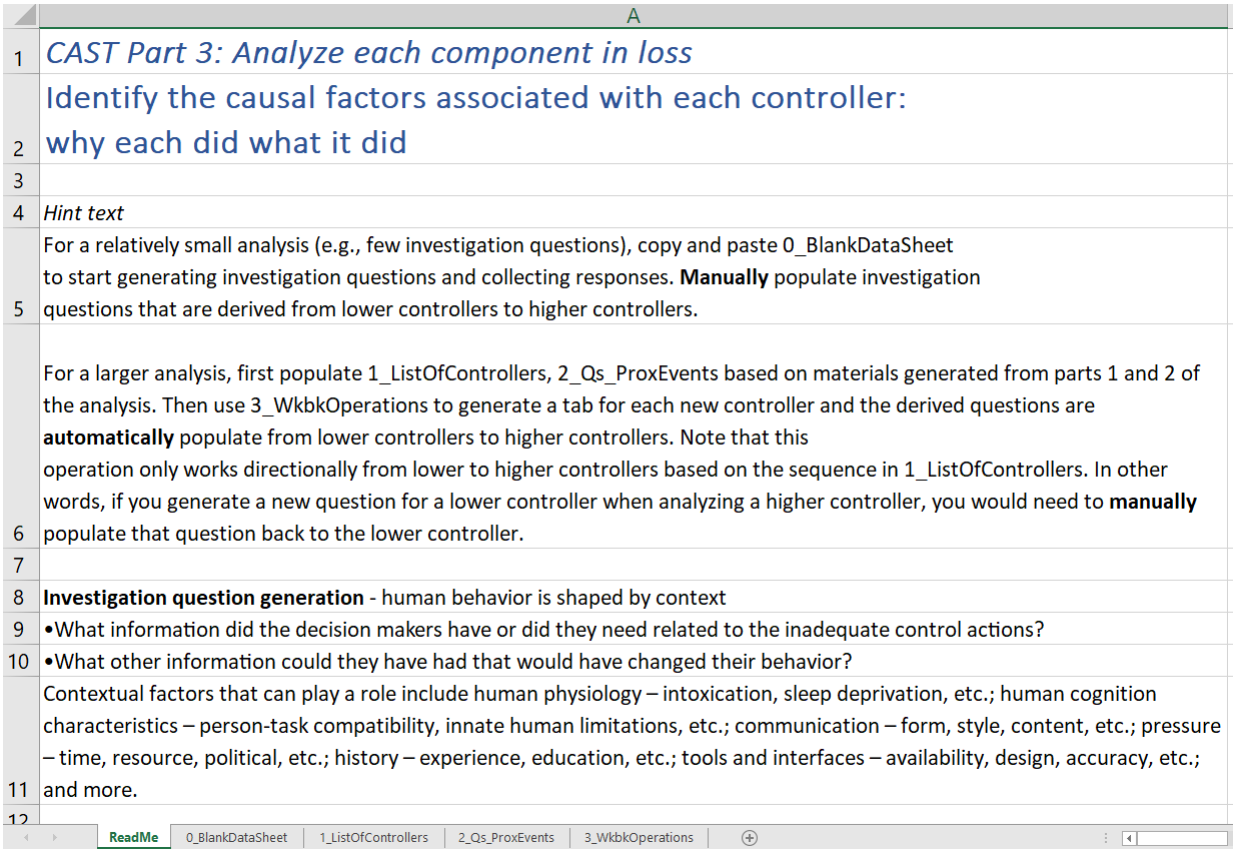


Figure 24 First section of the step 3 template

The next tab is a blank data sheet for use in an analysis with just a small number of controllers to analyze. A copy of the data sheet is used for each controller. In columns A to D (Table 5), the controller of interest, the responsibilities relevant to the incident, the specific contribution to the incident are identified—in ways described in previous sections. Columns E to I (Table 6) record the actual investigation questions, the findings, and any additional investigation questions targeting another controller based on the findings. An excerpt of the data related to the treatment planner in the RT incident is shown below.

Table 5 Columns A to D of the blank data sheet in step 3 template with example data entries

Controller	Responsibilities relevant to this safety incident	Given the responsibilities in this safety incident, is there any new interaction (control action, information source or feedback) for the controller beyond what is captured in the safety control structure?	Contribution to the hazardous state (identified by answering "what was the responsibility and whether it was fulfilled; what action or lack thereof led to the responsibility not being fulfilled?")
Tx planner (dosimetrist)	*Fusion and registration (primary)*	*No*	*Did not fuse MR image to CT for contouring*

Table 6 Columns E to I of the blank data sheet in step 3 template with example data entries

Question	Response/finding		Additional question for other controllers	Relevant controller
What was the dosimetrist's understanding of the contemporaneous treatment planning process state?	…		*Why did the Tx Checker miss that the MR image was not fused for the sarcoma patient even though it was a norm?*	*Tx Checker*

The third to fifth tabs provide extra functionalities for analyses of a broader scope (with more controllers of interest). The findings from analyzing one controller often prompt further questions targeting other controllers. These questions can be missed if they are dropped or not propagated appropriately, e.g., from manual copy and paste. Manual propagation also takes time. The extra functionalities automatically collate the relevant investigation questions for each new controller of interest. To support these functionalities, the third tab captures the list of the controllers of interest. The information is used to populate pull-down menus (e.g., so an investigation question could be tagged to a controller of interest) and enables an algorithm to collate and propagate investigation questions.

The fourth tab records the set of preliminary investigation questions from step 1, which are tagged with the associated controllers and propagated at the initialization of data sheets.

Lastly, the fifth tab provides the interface to generate data sheets with the algorithm. These functionalities help prevent investigation questions from being inadvertently dropped and eliminate the need for manually copying and pasting.

4.2.5 Cases illustrating systemic factors

Seven incidents were compiled to illustrate a sample of systemic factors, including:

- Communication and Coordination
- Incident Reporting System
- Changes and Dynamics
- Safety Culture
- Care Provision in a Training Setting
- Economics
- Environment

A commentary was provided for each systemic factor-incident pair. These materials form part of the training content. The materials showcasing communication and coordination flaws are shown as an example below. The complete set of materials is documented in Appendix F.

Systemic Factor 1: Communication and Coordination

Information shaping the process model of a component also shapes the behavior. Therefore, communication is crucial—it conveys not only the decisions from controllers at higher hierarchical levels to those below but also the status of the components or processes being controlled in return. Similarly, information sharing harmonizes decision making for controllers at the same hierarchical

level. This is especially important when identical control actions may be performed by multiple controllers or when control actions have direct dependencies.

The Safety Challenges of Supervision and Night Coverage in Academic Residency (Raffel, 2019)

A 64-year-old man complained of shortness of breath and was hospitalized. Oxygen was administered to maintain adequate oxygen saturation. The patient had bilateral pleural effusions and pulmonary emboli and was recently diagnosed with metastatic cholangiocarcinoma.

One night, the patient became acutely short of breath with altered mental status. The intern night float was paged to assess the patient by the bedside nurse. The intern reviewed the patient's clinical history, recent labs, and imaging from the electronic medical record. The signout received from the patient's primary team identified the patient as a full code. However, a contingency plan was not provided and the overall goal of care could not be determined. The intern ordered some imaging for chest and head, laboratory tests, and an electrocardiogram.

The patient's condition further deteriorated and had a decreasing blood pressure. The intern attempted to activate the rapid response team to escalate oxygen therapy with high flow nasal cannula. However, her attempt was in vain as she had an incorrect paging number. Eventually, the intern asked the nurse to page the team, and they arrived.

The intern also paged the overseeing senior resident for assistance but, again, had the wrong pager number. Leaving the bedside environment to look for the resident was deemed infeasible due to the patient's unstable condition. Having toiled for an hour at the bedside, the intern caught sight of another senior resident who was passing by and requested his help.

The senior resident reviewed the laboratory test results, paged the ICU fellow and suggested the intern to call the patient's family. They notified the family of the critical condition and inquired what resuscitative measures (e.g., intubation and use of a ventilator) they would prefer. After an in-depth discussion, the family decided to abstain from drastic measures, consented to a "Do-Not-Resuscitate" and "Do-Not-Intubate" order and elected for comfort care. The intern then provided symptom and air hunger management with morphine drip until the patient passed away a few hours later.

Systemic factor illustration

Providing night coverage is challenging—the amount of resources reduces yet patient condition can deteriorate precipitously as during daytime. In this challenging context, the full functioning of a system is crucial. Quality patient care requires adequate communication and coordination.

In the designed setup (Figure 25), patient care is provided first and foremost by the bedside nurse and the intern night float. To augment the intern's ability to handle emergent situations, a senior resident, a rapid response team and an attending physician add not only hands to execute multiple tasks at once but also experience and knowledge in clinical decision making.

To render the system fully functional, different information needs to be exchanged. As night coverage begins, the patient's primary care team signs out the patient to the intern with comprehensive information: a description of the patient's health problem, information about the situation, consideration of available options and the action that is deemed desirable. The intern and the bedside nurse discuss the patient condition so treatment orders can be issued. If the patient deteriorates and care needs to be escalated, the intern communicates the patient condition to the senior resident and the attending to request assistance. In turn, the intern may receive additional treatment decisions. Similarly, assistance request is sent to the rapid response team. From a strategic perspective, management defines the criteria and means of communications to facilitate the frontline activities. Lastly, the clinicians discuss care options with the patient (or the family, if

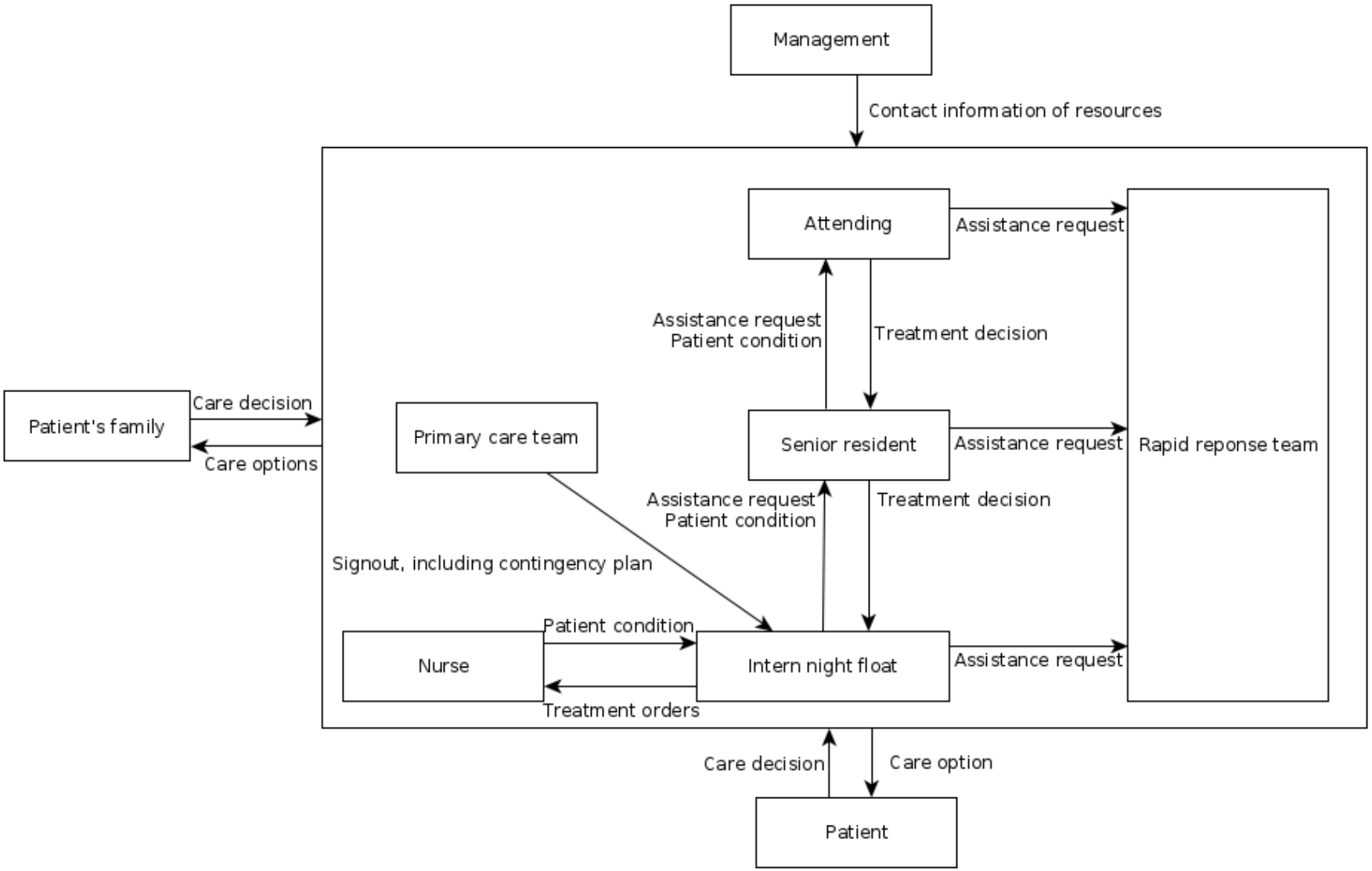


Figure 25 Communication network as intended to provide night coverage in academic residency

applicable) in a prospective and recurrent fashion as the disease progresses so patient-centered care decisions can be made.

As this incident unfolded, however, the system did not function as designed. Figure 26 shows the communication network in actuality. Due to chance encounter, new components were involved, whereas other communication links were missing, and still some other links were flawed.

Starting with the frontline, the primary care team did not provide a contingency plan in the signout to the intern, and the care goal desired by the patient could not be determined. The code status, as documented, was inaccurate—the patient's family already requested comfort care should he deteriorate. When attempting to request assistance from the rapid response team and the senior resident, the intern used the wrong pager number hence could not reach the parties as intended. Had the overseeing senior resident was contacted, perhaps he/she would have been cognizant of the appropriate code status of the patient, thus eliminating the need to put the patient's family through an emotionally traumatizing episode, questioning their earlier care decision. It is unclear if the ICU fellow was successfully contacted and provided any advice. Also, it is unclear why the senior resident did not suggest contacting the attending physician. Ultimately, the maximum amount of system knowledge was not brought to bear when a patient's life was at stake.

The communication problem extended beyond the frontline. The intern did not receive accurate pager information from management as part of the orientation—it was the intern's first rotation at the hospital, and she was providing last-minute coverage for another intern.

In summary, flawed communication and coordination affected many components in the system and prevented the best care to be delivered.

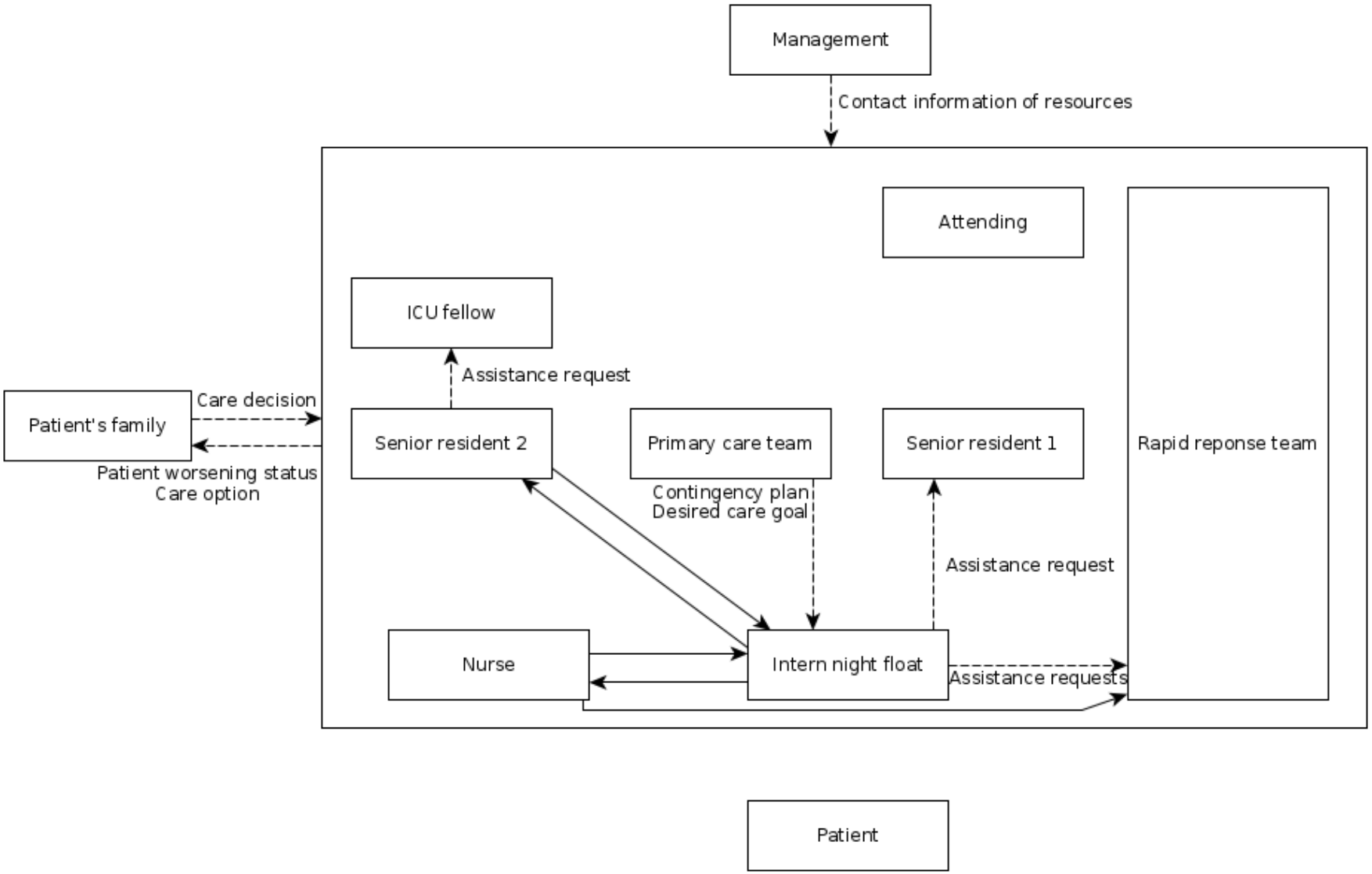


Figure 26 Actual communication network with many links missing. Senior resident 2 and ICU fellow constituted new components that were not in the original setup. Dash and dotted lines indicate the flawed communication

4.2.6 Reference CAST analysis

The analysis of the RT incident is the reference CAST analysis. It forms part of the training content. Similar to its use in this dissertation, it helps demonstrate the concepts and the tasks to conduct a CAST analysis.

4.2.7 Training program

Complementing the mentioned enhancements, training enables their use to be more effective. The aim of the training program is to equip safety analysts in healthcare to apply CAST at the entry level. The associated learning objectives are for safety analysts to:

- model the care system with a SCS and navigate within the model during the process of inquiry
- generate comprehensive investigation questions
- identify the process model flaws, contextual factors, and systemic flaws that contributed to the incident
- design effective safety interventions

To achieve the aim and objectives, the training program covers different categories of knowledge (Krathwohl, 2002): factual, conceptual, and procedural. The factual and conceptual knowledge includes two selected STAMP principles, SCS, simple model of human controller (France, 2017; Leveson and Thomas, 2018; Thomas, 2019), and safety constraint. The concept of a SCS further covers more elementary concepts: control loop, controller, controlled process, control action and feedback. In tandem, the procedural knowledge includes the subtasks in steps 1-5 of the analysis. An emphasis is placed on how to use the CAST enhancements. Figure 27 depicts the content in a concept diagram.

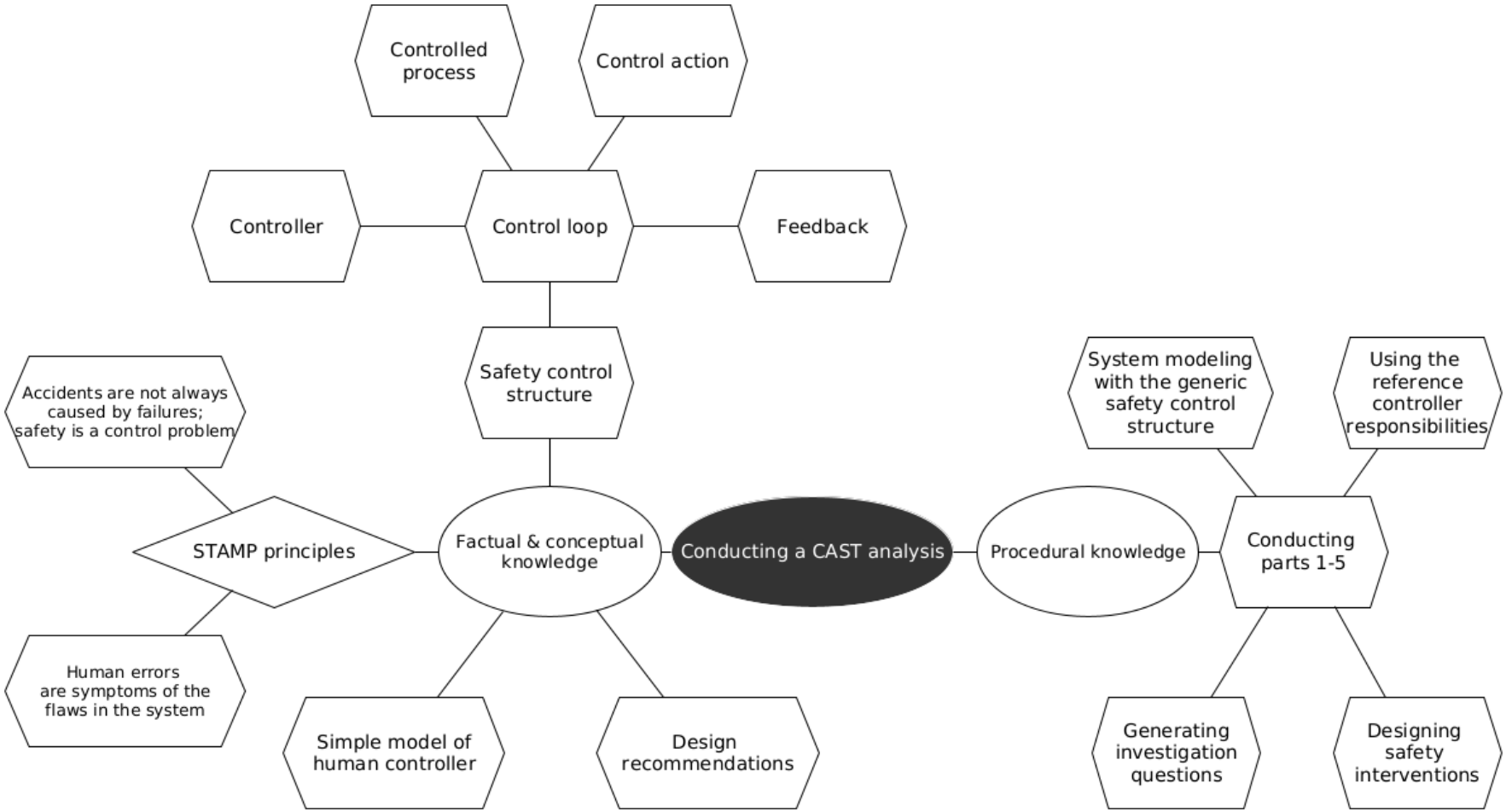


Figure 27 Concept diagram of the training program. The black oval states the learning aim; the white ovals state the broad categories of knowledge; the diamond states a subgroup; and the hexagons state the content items.

The curriculum is delivered with videos and tutorial sessions. Ten videos, each ranging from two to four minutes in length, provide a conceptual discussion of the content items. The key messages and length of each training video are described in Table 7. The examples illustrating the key messages are drawn from RT to make them more relatable.

Table 7 Key messages and length of training videos

Video title	Key messages	Length
Analyzing adverse events with CAST—A 2-minute conceptual overview	• Decisions far from the frontline contribute to an adverse event but they are often neglected; learning about these obscure causal factors is crucial to improving safety • CAST can be used to identify causal factors comprehensively and to design effective safety interventions • Adverse events are not always caused by failures; safety should be viewed as a control problem • Human errors are symptoms of the flaws in the system	2 minutes 20 seconds
Control loops—Modeling how we achieve goals safely	• Achieving goals safely requires matching actions to the situation—the premise of close-loop control • The formatting of a control loop: controller, controlled process/object, control action, feedback • Many interactions are not unidirectional; close-loop control enables us to adapt to changing conditions and has great safety implications	2 minutes 7 seconds
Safety control structure—Modeling how a safe system works	• SCS models a system and includes various components with safety responsibilities • SCS can be constructed with a set of control loops; the control loops are positioned based on systems and control theories	3 minutes 9 seconds
A simple model of human controllers	• The decision to take a control action is informed by a set of beliefs—process models of automation, controlled process, other controllers, and environment. • The process models are not static but updated as the situation changes; the sensory feedback and received inputs produces the process model updates	2 minutes 7 seconds
CAST: a 30,000-foot view	• CAST is a 5-step process • High-level descriptions of the subtasks and purposes of each part	2 minutes 34 seconds
CAST Step 1—Assemble basic information	• In step 1, the analyst produces a brief incident description, a list of proximal events—to generate a partial set of “why”	3 minutes 25 seconds

	questions, and examines the causal factors at the physical level • The crucial need to use impartial language • How the causal factors are determined at the physical level	
CAST Step 2—Model safety control structure	• A generic SCS has been created for use • In step 2, the analyst selects the controllers of interest from the generic SCS, modifies and creates additional loops as needed	3 minutes 58 seconds
CAST Step 3—Analyze each component	• In step 3, the analyst generates and answers investigation questions methodically for all the controllers involved • The analysis starts at the bottom of the SCS and moves to higher controllers	2 minutes 1 second
CAST Step 4—Identify systemic factors	• Define systemic factors • Highlight a few common systemic factors: communication and coordination, incident reporting system, safety culture	2 minutes 58 seconds
CAST Step 5—Create improvement program	• Having many safety intervention options is desirable • In step 5, the analyst defines design recommendations, maps them to the SCS, and specifies the detail of safety intervention options	2 minutes 49 seconds

Tutorial sessions provide an opportunity for the safety analysts to reinforce the factual and conceptual knowledge described in the videos and build experience executing the analysis tasks. The tutorial sessions bifurcate into two tracks: a more elaborate track for the lead analyst and a more condensed track for the rest of the analysis team.

The lead analyst track comprises two 1-hour sessions. The first session starts by reinforcing the knowledge of a control loop. This is achieved with incrementally more challenging exercises, starting with basic recall of terminology then concept applications. The session then transitions into practicing the subtasks in steps 1-2 through an abbreviated analysis of the contouring incident.

The second session starts by reinforcing the fundamental knowledge of the simple model of human controllers. Further practice is included for the subtasks in steps 3-5. Table 8 and Table 9 show the content in each tutorial session, which also carries a 10-minute buffer.

Table 8 Content and time allotted in Session 1 for the lead analyst

Content	**Time**
Fundamentals—building a control loop	10 minutes
CAST Step 1—Assemble basic information • Generating a list of “why” questions when documenting the proximal events • *(Focus)* Analyzing causal factors at the physical level	20 minutes
CAST Step 2—Model safety control structure • Create control structure from the generic safety control structure	20 minutes

Table 9 Content and time allotted in Session 2 for the lead analyst

Content	Time
Fundamentals—the simple model of human controllers	10 minutes

CAST Step 3—Analyze each component
• Practice generating investigation questions
  ▪ for frontline controllers
  ▪ for higher controllers
	10 minutes

CAST Step 4—Identify systemic factors • Identify systemic factor ▪ (Focus) communication flaws	10 minutes
CAST Step 5—Create improvement program • Defining design recommendations • Mapping design recommendations to SCS • Select the interaction of opportunity • Specifying the means of implementation	20 minutes

The condensed track for the rest of the analysis team comprises two 30-minute sessions. The track focuses on the fundamentals because the lead analyst is anticipated to supply some of the procedural knowledge in an analysis. With this in mind, the content and the amount of time allotted to the fundamentals are unchanged from the lead analyst track, whereas the procedural knowledge content is scaled back. Table 10 and Table 11 show the content in the tutorial sessions, each carrying a 5-minute buffer, in the condensed track.

Table 10 Content and time allotted in Session 1 for the rest of the analysis team

Content	Time
Fundamentals—building a control loop	10 minutes
CAST Step 1—Assemble basic information • Generating a list of “why” questions when documenting the proximal events	5 minutes
CAST Step 2—Model safety control structure • Create control structure from the generic safety control structure	10 minutes

Table 11 Content and time allotted in Session 2 for the rest of the analysis team

Content	Time
Fundamentals—the simple model of human controllers	10 minutes
CAST Step 3—Analyze each component • Practice generating investigation questions	10 minutes
CAST Step 5—Create improvement program • Defining design recommendations • Mapping design recommendations to SCS • Select the interaction of opportunity	5 minutes

- Specifying the means of implementation

In summary, a compact training program was developed. It incorporates both videos and tutorial sessions to equip safety analysts to apply CAST at the entry level. The videos enable the concepts to be communicated in a consistent and relatable way, facilitating learning autonomy. They also shorten the duration of the tutorial sessions, making scheduling and coordination less challenging. In tandem, the tutorial sessions enable the safety analysts to receive individualized assessment and real-time feedback, which aid mental representation construction and refinement.

4.3 Summary

Seven specific enhancements were made to facilitate CAST application in healthcare. They encompass methodological refinement, reference materials, templates and training. The generic SCS facilitates step 2 of the analysis. The list of reference controller responsibilities support SCS construction in step 2 and the identification of individual contribution in step 3. The graphical safety intervention design process helps conceptualize effective safety interventions in step 5. The cases illustrating sample systemic factors—similar to what could be identified in step 4—and the reference CAST analysis provide key content for the training program. Lastly, the templates help organize the information used for each step of the analysis and help communicate the overall results.

Chapter 5. CAST trial implementation and evaluation

The enhancements were developed on a theoretical foundation and with an iterative, participatory process with expert inputs. Their efficacy needs to be tested in practice. This chapter discusses the trial implementation, evaluation framework, and results.

The design of the trial implementation and evaluation followed the guidance for complex interventions in healthcare (Craig et al., 2008). A case study with a quasi-experimental approach (Shadish et al., 2002) was used because a multi-site randomized experiment with control was not feasible, partly due to the same time constraint in healthcare that hinders CAST adoption. In this quasi-experiment (Figure 28), one treatment (the implementation of CAST enhancements) was provided to one group (the safety team at a radiation oncology department). A pretest and different posttests were conducted through surveys and a CAST analysis independently conducted by the safety team.

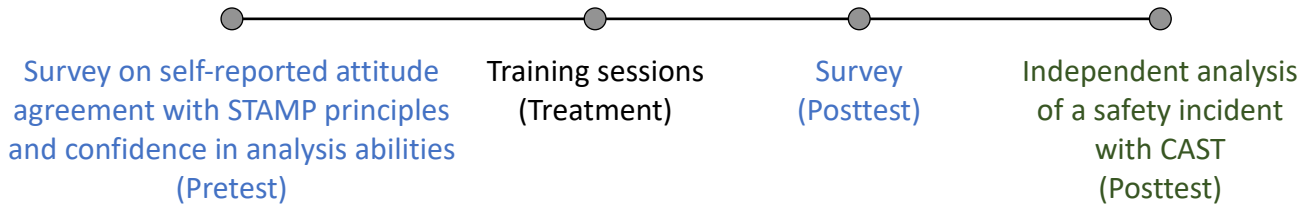


Figure 28 A timeline of key events in the trial implementation and evaluation

5.1 Trial implementation

5.1.1 Context

The trial took place in an academic radiation oncology department at a nonprofit State hospital. The radiation oncology department provides advanced RT to the full range of malignant and benign disease. The department provides clinical services to over 5000 new patients each year, engages in research, and hosts residency programs in both radiation oncology and medical physics.

Specifically, the trial involved the entire safety team in the department. The safety team comprises six members (a dosimetrist, a patient services supervisor, two medical physicists, and two radiation therapists) and represents about 8% of the department staff. Each member has been analyzing incidents for an average of 9.7 years (range: 5-20 years). A medical physicist serves as the lead for the team. The team reports to the departmental quality committee and the chair of the department. Prior to the training program, none of the participants was aware of CAST.

5.1.2 Training

As mentioned in Chapter 4, the learning objectives of the training program are for safety analysts to:

- model the care system with a SCS and navigate within the model during the process of inquiry
- generate comprehensive investigation questions
- identify the process model flaws, contextual factors, and systemic flaws that contributed to the incident
- design effective safety interventions

The training program was implemented in a virtual learning environment. This format differed from the in-person training originally planned and was used due to the policies on visitors and remote work during the COVID-19 pandemic. Prior to each tutorial session, the relevant training videos and templates were shared with the participants. The tutorial session then took place over video conferencing.

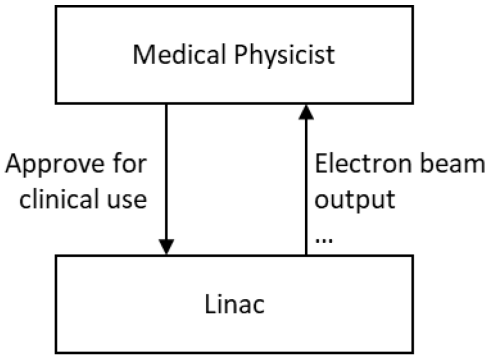


Figure 29 A control loop describing the linac performance test created by the training participants

In the first sessions for the lead analyst and the rest of the safety team, the participants developed the ability to perform steps 1 and 2 of CAST. Their understanding of the terminology was reinforced. Also, they succeeded in generating the "why" questions as they organized the proximal events in step 1. The lead analyst also became familiar with analyzing the causal factors at the physical level. For step 2, they practiced modeling an aspect of the linac performance test in a control loop (Figure 29) and were later able to create a SCS for the RT incident. They selected the relevant parts from the generic SCS and identified the controllers of interest. They also edited and created the control loops using the steps as described in Section 4.2.1.1.

One of the participants remarked that SCSs should not be made too broad (by including components external to the healthcare organization) because analyzing external components "felt like placing the blame elsewhere". In short, the participant still perceived that blame would be embedded in the analysis results. This remark provided insights on how the training materials can be improved. Even though the training materials had covered the features in CAST to prevent blame, the remark showed that the ability to produce a blame-free analysis had not been internalized at the time of the first training sessions. Up until then, no results from a CAST analysis had been presented. The participants were unable to see firsthand the ability to produce a blame-free analysis. In response to the participant's concern, the blame-free property of CAST was reiterated. In addition, it was explained that thoroughly identifying the causal factors associated with all the relevant components—including those external to the healthcare organization—is one of the ways how CAST leads to a blame-free analysis. Identifying the contributions that the external components made does not change the fact that the internal components contributed to the incident as well. As the healthcare sector increasingly embraces a systemic view of incidents, this sharing of the findings and suggestions is anticipated to be more common and can serve as a sign of taking the fair share of responsibility.

In the second sessions for both tracks, the participants were able to formulate comprehensive investigation questions for the RT incident. The lead safety analyst became familiar with identifying systemic factors. All the participants also practiced generating safety intervention ideas.

In summary, all but the lead analyst in the study team achieved the learning objectives with one hour of tutorial (two hours for the lead analyst). The remark from a participant around analysis scoping and blame provided insights on how the training materials can be improved. Overcoming cultural

barriers (e.g., the hesitation to explore causal factors external to the healthcare organization) was also important.

5.2 Evaluation

CAST application was evaluated outside the training setting. Both qualitative and quantitative approaches were used for triangulation. This was consistent with other quality improvement research in healthcare (Berg et al., 2018).

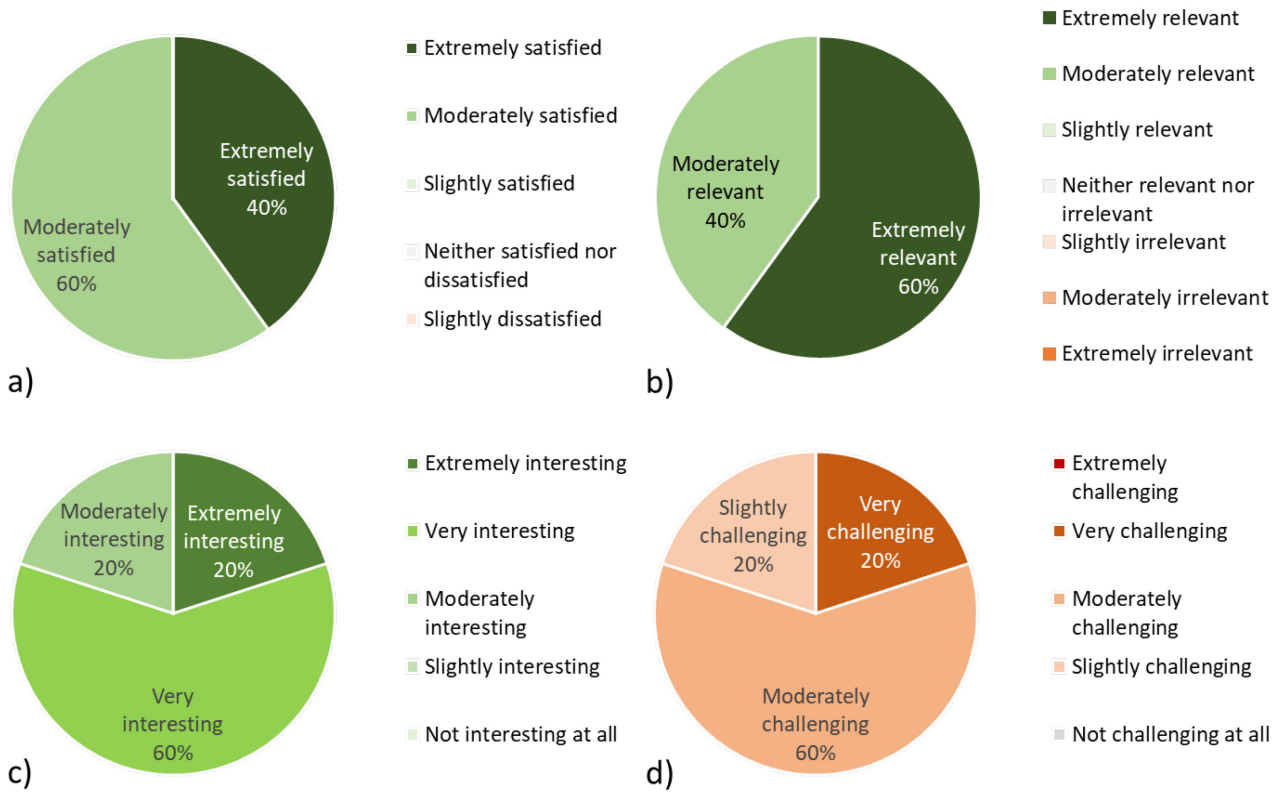


Figure 30 Overall feedback on the training program (n=5)

Overall, the training program received positive feedback from the participants (Figure 30). When surveyed, 60% of the respondents was moderately satisfied with the training program, and the remainder was extremely satisfied (panel a). All of the respondents found the exercises either moderately relevant or extremely relevant (panel b). The program was also considered at least moderately interesting, while most respondents found it very or extremely interesting (panel c). On the other hand, one respondent found the program very challenging while most of them found it slightly or moderately challenging (panel d).

The following sections provide a detailed evaluation using the team's CAST analysis of a safety incident and self-reported confidence in analysis abilities and attitude agreement with STAMP principles.

5.2.1 Independent analysis of a safety incident with CAST

A CAST analysis produced by the safety team provided qualitative data for evaluation. The analysis output was assessed from the following perspectives:

- the contextual factors identified at the physical level

- the breadth and depth of the SCS constructed for the analysis
- the contextual factors identified for individual controllers
- the systemic factors identified
- the safety interventions proposed

These perspectives were used in previous assessments of in-depth incident analyses (Canham et al., 2018; Goncalves Filho et al., 2019; Kellogg et al., 2017; Salmon et al., 2017; Underwood et al., 2016).

In addition to assessing the findings based on theoretical grounds, an empirical comparison was made, first, against the original incident analysis based on a linear view of accident causation. The original analysis was conducted in accordance with the incident response procedure by the safety staff on site. This enabled an assessment of whether the CAST analysis produced additional safety learning. Notably, because by the two analyses were conducted by different safety teams, neither was influenced by the practice effect (Shadish et al., 2002) that may be present otherwise.

Additional empirical comparisons were made with the published experiences of introducing CAST to novices: Canham et al. (2018) analyzed a medication error with a group of healthcare stakeholders; six aviation safety analysts-in-training also analyzed a railway accident (Underwood et al., 2016). Only high-level comparisons were made because the incidents were different. Nonetheless, the comparisons shed light on how CAST analysis outputs differ based on the analysis settings. As shown in Table 12, the analysis in Canham et al. (2018) took place over two workshops lasting five hours in total, and each included an introduction to STAMP. The healthcare stakeholders were divided into groups, and they were coached by chartered Human Factors and Ergonomics (HFE) specialists. The analyses in Underwood et al. (2016) were conducted in 1.75 hours by six trainees. They were enrolled in a six-week training course and received 2.75 hours of training on accident theory and application of STAMP. The CAST analyses were performed individually but the trainees received ongoing guidance by the safety researchers with a background in HFE. In this study, all but one analyst received only one and a half hours of training, and the lead analyst was trained for just an *extra* hour. The safety team also had only one hour to conduct the analysis and was not coached by someone with an advanced degree in safety science.

Table 12 Analysis settings in this study, Canham et al. (2018), and Underwood et al. (2016)

Setting details	**This study**	**Canham et al. (2018)**	**Underwood et al. (2016)**
Training & analysis time	*Training* Team members 1.5 h (incl. 30 min video) Lead 2.5 h (incl. 30 min video) *Analysis* 1 h	*Training & analysis* 5 h with two STAMP introduction sessions of unspecified duration	*Training* Part of a 6-week course for aviation accident investigators; 2.75 h on accident analysis theory and STAMP *Analysis* 1 hr 45 min
Team/individual analysis	Team	Team	Individual
Coaching during training	Without guidance by an expert with an advanced degree in safety science	Coached by chartered Human Factors and Ergonomics (HFE) specialists	Received ongoing guidance by the safety researchers with a background in HFE

5.2.1.1 Results and discussion

The analyzed incident occurred when treating a breast cancer patient with external beam at one of the satellite facilities. A positioning discrepancy resulted in a single-fraction treatment variance, and an additional fraction was required. The information below is extracted from the CAST analysis output[**], and an assessment is also provided. Appendix G documents the analysis in full.

The incident was described as follows:

> This was the 2nd fraction of a breast treatment that was simple tangent fields only. The [RT therapists (RTTs)] performed a timeout with patient. They loaded [the reference surface] belonging to the patient [into the surface monitoring system]. Then they positioned the patient using [the system], took a billing capture, and checked for elbow clearance [with regards to the rotation of the linac gantry]. The RTTs then left the room [and] performed pre-treatment timeout at console. [RTT A] was the driving therapist and beamed on. After treating the medial [treatment field], [RTT A] noticed the longitudinal [patient position] was different than acquired, but [the displacement was less than the threshold that required action]. The RTTs discussed the finding and thought that possibly the breast board was indexed incorrectly. They checked [the breast board and it] was okay. They then checked that the incline was correctly set, which [it] was. [RTT A] proceeded with lateral treatment field. [After the treatment, both] RTTs helped the patient off the table and escorted her out of the room.
>
> [RTT A] noticed that the [the *boost* reference surface in the surface monitoring software] was open, then both RTTs discussed that finding and realized that the longitudinal [patient position] was in fact different because the incorrect [reference surface] was used for positioning the patient. After looking at [the surface monitoring system], they both realized that [the *boost* reference surface] is loaded first when loading the patient on the [the surface monitoring system].
>
> [RTT A] entered the event into [the IRS] and informed the physicist and the manager. The physicist contacted another physicist responsible for radiation safety to explain the event and determine if it was a reportable misadministration. It was determined that this fraction did not deviate by the amount that would make it a reportable event, so this is not a state-reportable event. The radiation safety physicist confirmed this analysis with the organization's radiation safety officer. The physician was informed of this single fraction treatment variance, and she decided to add another fraction of tangential whole-breast treatment. She determined that the variance did not result in a deviation that would be detrimental to the patient's course of therapy after adding that additional fraction.

[**] Modifications were made to re-format and to anonymize the content. Additional background information, derived from Hoisak et al. (2020), was inserted for readers outside radiation oncology.

5.2.1.1.1 Safety control structure

To analyze the incident, the safety team modeled the system using two parts of the generic SCS (Figure 31 and Figure 32). The part focusing on the healthcare organization (Figure 31) is broadly similar to its original form in the generic SCS. The safety team removed the control loops involving the organizational executive management and other care processes. The information label “request for proposal (RFP)” between the departmental management and the device, software manufacturers was also removed.

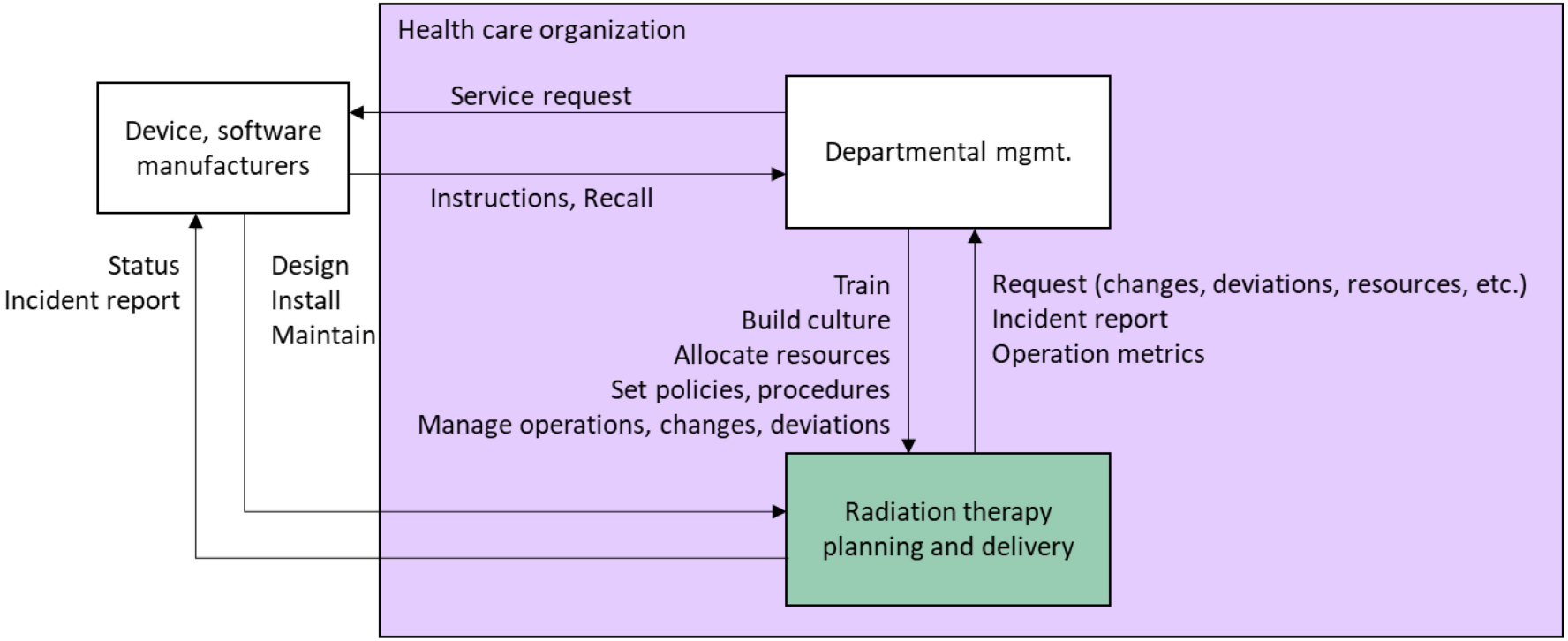


Figure 31 The part of the SCS showing the details of the healthcare organization

The part of the SCS showing the details of RT delivery with linac (Figure 32) went through more extensive modifications. Besides eliminating control loops (e.g., the one involving the phantom), control actions (e.g., “apply physiological monitor” by the therapists), and feedback (e.g., “CBCT image” to the radiation oncologist), the safety team also changed some control actions and feedback (e.g., “setup or movement exceeds tolerance” from therapists to the medical physicist, and “suggestions to mitigate” vice versa). A new control loop was created between the therapists and the surface monitoring system with the control actions “choose surface” and “start monitoring” and feedback “notify RTT of patient position”.

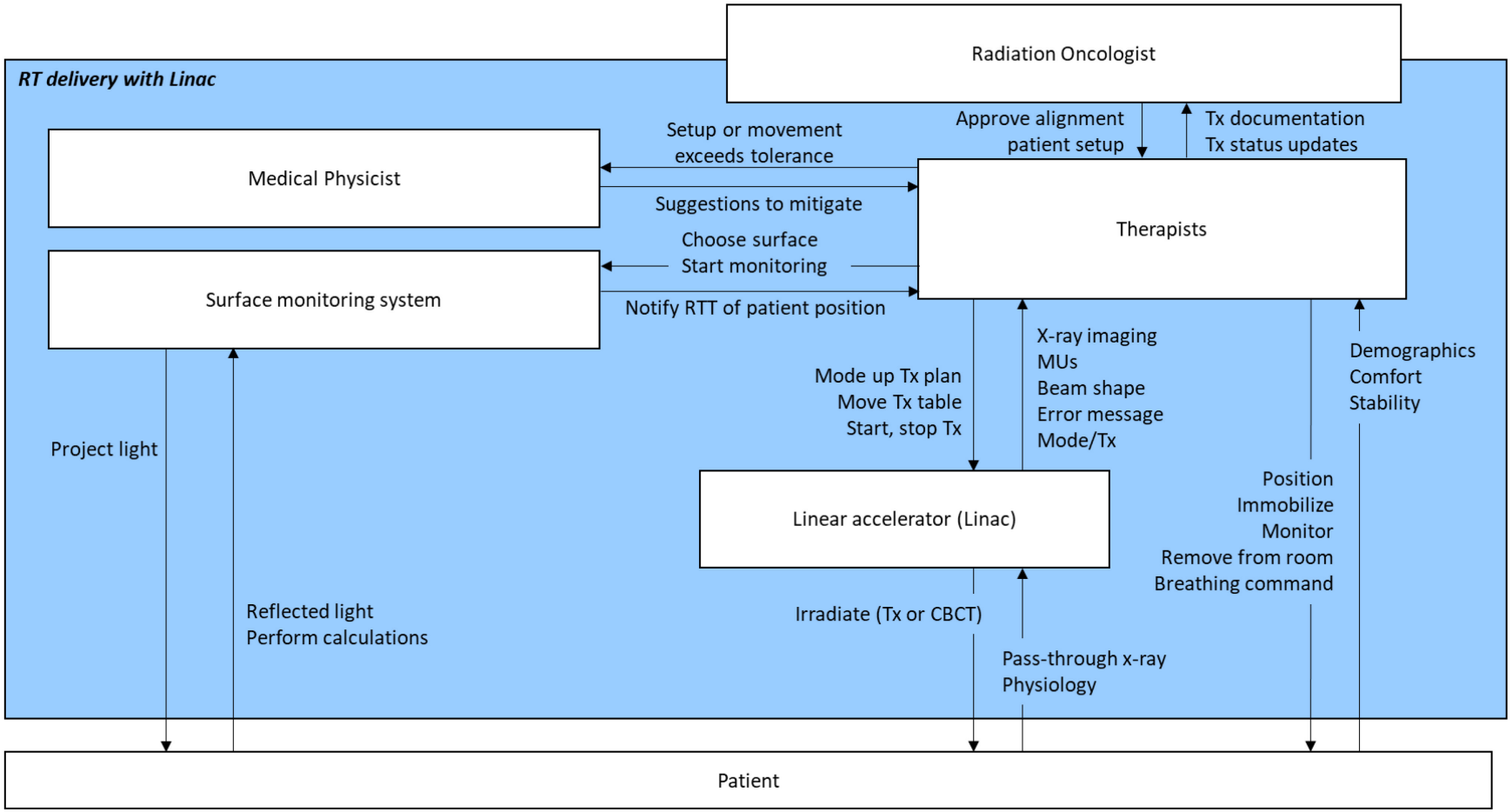


Figure 32 The part of the SCS showing the details of RT delivery (linac)

The breadth of the SCS was not limited to the healthcare organization where the incident occurred: Figure 31 includes the devices, software—the surface monitoring system and linac—manufacturers. The depth was not limited to the frontline (the staff delivering RT): Figure 31 also includes the departmental management. However, the SCS excluded the regulatory and advisory bodies and the organizational executive management.

The breadth and depth of the SCS shed light on the training effectiveness. During training, a participant remarked that SCSs should not include components external to the healthcare organization because the team has no authority over external components. The participant surmised that the effort spent analyzing the components would not produce meaningful changes. In response to the remark, it was pointed out that restricting the SCS to within the healthcare organization may leave some investigation questions unanswerable, and some causal factors, especially those associated with higher-level controllers, may be missed. The participant was coached later in training to include components external to the healthcare organization when constructing SCSs. The breadth of the SCS actually used in the independent analysis suggests that the coaching during training successfully convinced the participants on the merits of taking a relatively broad view of the system. However, the SCS still did not include any components above the departmental management. This limited the scope of the inquiry and, as will be shown below, left some potential contextual factors unexplored.

In comparison to the published experiences of introducing CAST to novices, the SCS used by Canham et al. (2018) also did not cover any regulatory or advisory bodies. In contrast, some of the aviation safety analysts did include the regulatory component in their SCS (Underwood et al., 2016). In both prior works, more time was allotted for the analysis. It remains unclear if barriers, cultural or otherwise, prevent healthcare analysts from examining the regulatory and advisory bodies for their contribution or if additional time would permit the system to be modeled more extensively.

Lastly, some technical critique can be made on the details of the SCS. Most of the modifications were consistent with the customs of depicting control loops and constructing SCSs. However, three discrepancies were noted:

- The part of the generic SCS focusing on RT planning and delivery was not included, and this omission created a disconnect between the two parts of the SCS (Figure 31 and Figure 32). One way to visualize the problem is the mismatch between the color-coding of the diagrams (i.e., Figure 32 has a blue background instead of dark green, as in the bottom box of Figure 31). One way to rectify the situation is to amend the bottom box in Figure 31 from “Radiation therapy planning and delivery” to “RT delivery with Linac” to preserve continuity. Better still, the treatment planner, modeled in the part of the SCS focusing on RT planning and delivery, was actually analyzed in step 3, so the part of the SCS should have been included to capture the associated interactions.
- In the part of the SCS showing the details of RT delivery with linac, “perform calculations” was inadvertently added to the feedback from the patient to the surface monitoring system. This calculation is internal to the surface monitoring system, and its results are not provided by the patient.
- The control action to “monitor” the patient by the therapists was unnecessarily added. The task is already symbolized by the feedback arrow (while additional aspects of patient state/information, if applicable, could have been appropriately added).

These discrepancies were minor and did not substantially weaken the CAST analysis. Nonetheless, future training should cover similar misconceptions to enhance learner proficiency.

In summary, the safety team succeeded in constructing a SCS independently for the incident. Most of the modifications by the safety team were technically sound. This accomplishment contrasted with past report of healthcare workers having concerns about the amount of time and expertise to apply

the modeling technique effectively (Jun and Waterson, 2019) and suggests that the task can be feasibly executed within the constraints.

5.2.1.1.2 Contextual factors for individual controllers

The safety team selected four controllers for examination: the RTTs, the treatment planner, the departmental management, and the manufacturers. Some associated contextual factors were identified.

For the RTTs, while they "felt that something wasn't quite right with the setup," they verified that the breast board index and incline were correct and acceptable, and this supported their decision to continue treatment. Another contextual factor was that the surface monitoring system indicated the patient position to be within tolerance. In fact, the RTTs knew that, should a positioning discrepancy reach the action threshold, the surface monitoring system would switch off the beam of the linac. This feature may have created a false sense of security: while some interoperability exists between the surface monitoring system and the linac, the devices are not further designed to verify the consistency between the linac treatment plan and the surface model used by the surface monitoring system. The surface model for the boost (with an isocenter different from that in the primary) treatment also loads by default. These contextual factors explained the RTTs' behavior and illustrated the connections to the other parts of the system.

The treatment planner, a dosimetrist, was another frontline staff examined. The dosimetrist worked at the main campus but was assigned to provide permanent coverage to the satellite facility remotely after the local dosimetrist retired two months prior. The dosimetrist used the procedures from the main campus for this case, and the differences contributed to the incident: different isocenters were used for the primary and the boost treatments at the main campus, whereas the same isocenter was typically used at the satellite facility; the treatments were also planned simultaneously at the main campus thus the boost reference surface was available to be loaded. A process model flaw was that the person thought the procedure differences were due to billing requirements but not anything that had safety implications. Another key contextual factor was that the frontline staff, in general, were not familiar with a software update related to inactivating surfaces that were not being used in the surface monitoring system.

For the departmental management, the identified contribution mostly concerned the lack of a robust procedure to troubleshoot positioning discrepancy. Similar incidents had occurred at the main campus, and they were caught prior to treatment with radiographic imaging. However, radiographic imaging was not incorporated in procedures. A contextual factor was that it was best to minimize radiation dose to the patient, especially for simple tangent cases. In the same vein, the use of field light would have revealed the setup deviation, but its routine use was not advisable exactly due to the advent of surface monitoring systems.

Lastly, the involvement of the manufacturers was described. The presence of some but not full interoperability (e.g., inability to check the consistency of the treatment plan and the surface model as mentioned) contributed to the incident. However, no clear contextual factor was identified. It was recognized that the appropriate training on the surface monitoring system software update was available.

In brief, some contextual factors were identified for the four selected controllers. A richer set of contextual factors was identified for the frontline staff, which helped prevent blame. In contrast, the contextual factors were less comprehensive for the higher-level controllers. For instance, beyond the procedure aspect, two contributions by the departmental management comprised 1) assigning a main campus dosimetrist to cover a satellite facility when there were differences in the treatment planning procedures and 2) not adequately training frontline staff on the software update with the surface monitoring system, but the contextual factors associated with these contributions were not identified. Similarly, the contextual factors underlying the contributions of the manufacturers remain unclear.

The relatively few contextual factors identified for the higher-level controllers arose at least in part from not including additional controllers higher in the SCS. As can be seen from the generic SCS (Figure 47), the departmental management and the manufacturers receive control inputs from the organizational executive management and the regulatory and advisory bodies, for example. These control inputs likely played a role in the decision making. For example, the assignment of a main campus dosimetrist to cover satellite facility may have been due to budgetary interactions with the organizational executive management and/or external payers. Likewise, the regulatory/advisory guidelines (or lack thereof) on harmonizing procedures between facilities especially where staff provide cross coverage are relevant as well. For the contributions by the manufacturers, the FDA clearance of the devices could have been explored as a contextual factor as well. Not including additional controllers higher in the SCS relinquished the opportunity to identify additional contextual factors.

Nonetheless, the safety team identified more contextual factors than other novices. As reported by Canham et al. (2018), previous participants in healthcare were able to identify the contextual factors (in the form of feedback flaws) for frontline components. However, no specific contextual factor was identified at the hospital level or above. Similarly, in the study by Underwood et al. (2016), the novices focused on the frontline staff and did not identify any contributing factors for company management, for instance. While more contextual factors could have been explored in this study, the safety team succeeded in identifying some for the departmental management. The diverse contextual factors for frontline staff also helped safety intervention design and blame avoidance.

5.2.1.1.3 Systemic factors

The safety team identified the inadequate sharing of safety information as a systemic factor that precipitated the incident. Similar incidents had occurred across different sites in the enterprise, but the information was not widely discussed. Concurrently, frontline workers lacked clear guidelines to troubleshoot processes adequately when potential issues were identified.

This systemic factor was legitimately identified as it impacted at least the departmental management and the frontline components. However, at least one more systemic factor—change management—was apparent in this incident but not discussed by the safety team. Specifically, at least two key changes occurred, and their management was flawed. First, there was the retirement of a dosimetrist at the satellite site, and the covering dosimetrist used incompatible treatment planning procedures from the main campus. Second, there was a software update related to inactivating surface models, but the frontline staff were not familiar with the update. This apparent systemic factor deserved to be further explored and addressed if verified.

In the published experiences of introducing CAST to novices, systemic factor identification focused on 1) coordination and communication and 2) changes and dynamics, based on an earlier version of the analysis process. In the previous study in healthcare, some communication flaws were identified for two controllers, but a specific discussion of coordination and communication as a systemic factor was not provided (Canham et al., 2018). Similarly, Underwood et al. (2016) did not report any specific systemic factors identified by the trainees; in fact, only half of them reached the final stage of exploring system changes over time. Identifying systemic factors is the least structured part of the analysis (Leveson, 2019). Instead of taking a checklist approach of examining preconceived systemic factors, it requires a more thoughtful consideration of the relationships between contextual factors and controllers—something that the current version of the analysis process emphasizes. Taken together, the safety team accomplished a non-trivial task by identifying a systemic factor.

Did the CAST analysis generate additional safety learning? The original incident analysis identified the causes as a sequence of events: the boost reference surface was inadvertently loaded into the surface monitoring system, so the longitudinal patient position was different than acquired, so the

treatment variance occurred. The original analysis did note that the breast board index and incline were verified by the RTTs and the default loading of the boost reference surface contributed to the incident. In this sense, there was no overt blame for the RTTs, but the search for causes did not go beyond them either. In other words, the contributions by the treatment planner, departmental management, and the manufacturers were not described. More importantly, the actions of the RTTs were the focus instead of the factors underlying the actions. In addition, no systemic factors were identified. All in all, the CAST analysis provided a more comprehensive understanding of the incident.

5.2.1.1.4 Safety interventions proposed

The following safety interventions were proposed in the CAST analysis:

1. To mitigate treatment deviation, ensure that either only the current treatment surface is imported in the [surface monitoring] system or the surface(s) not being used are deactivated.
2. Immediately, either plan and [treat] these cases the [local] way or educate the clinic (and update the [standard operating procedure]) to plan and treat these cases the [way it is done at the main campus].
3. The vendor ([surface monitoring system]) should be notified of this type of incident to understand whether or not future features of their software can mitigate it.
4. Standardizing the planning and treatment procedures for these cases will be necessary for the start-up of our new [satellite facility—different from where the incident occurred].
5. Information on near misses such as this one generates value and leads to safety improvement. Staff are encouraged to continue the input of near misses in the quality systems.

These interventions were assessed for effectiveness based on the organizational levels they target and their characteristics. Proposed intervention 1 appears to target frontline staff: an emphasis is made for RTTs to ensure that the relevant surface is imported for each treatment or that the irrelevant surface models are deactivated. The intervention can prevent the recurrence of the exact same incident, but its effect relies on human actions, so it only achieves hazard reduction at best. Nonetheless, it is an intervention that the healthcare organization can implement without external assistance.

Proposed intervention 2 tasks the departmental management to implement an improved administrative control on the isocenter and sequence of boost treatment planning. Application of the procedures still relies on human actions thus, again, it only achieves hazard reduction. However, the process modifications being put in place have the potential to be more effective than proposed intervention 1.

Proposed intervention 3 creates the possibility of achieving hazard elimination for the specific incident. To this end, it is crucial to have a built-in device mechanism to verify the consistency between the treatment plan used by the linac and the surface model used by the surface monitoring system. However, it is not an intervention that can be implemented by the healthcare organization alone and requires the cooperation of the linac and surface monitoring system manufacturers.

Proposed intervention 4 targets the departmental management and, as an administrative control, carries the potential for hazard reduction. Notably, improving change management enhances safety beyond the specific incident. This demonstrates the merit of using an incident to better understand the flaws at the higher levels of the system.

Proposed intervention 5, another administrative control, targets primarily frontline staff and seeks to reinforce reporting. Because reporting necessarily only occurs after an incident has happened, the safety intervention only qualifies for damage reduction—assuming that a timely response takes place. Yet, in the long run, reporting can catalyze improved system design with the potential for hazard elimination—assuming the report is processed effectively as demonstrated above. Therefore,

reinforcing the value of reporting and communicating its impact can combat under-reporting and improve system safety beyond the specific incident.

The following was recommended in the original incident analysis:

- Be mindful of which surface model is selected in surface monitoring system
- A second RTT to double check the surface model selection in the surface monitoring system and planned vs actual couch parameters.
- Verify light field on patient
- Verify the planned vs. actual couch parameters prior to treatment
- Require the treatment planner to use the same isocenter for both the boost and primary treatment plans unless physically impossible or significantly dosimetrically detrimental.
- Require the therapy form to clearly indicate whether the boost treatment has a different isocenter or not
- Deactivate the boost surface model for primary treatment

All the recommendations in the original incident analysis target frontline staff and contain an implicit assumption that the frontline staff were not being mindful enough. The recommendations rely on human actions and cannot eliminate the hazard causing this incident. They may not improve system safety more broadly either. In contrast, interventions 3-5 proposed in the CAST analysis target system components above the frontline and have the potential to achieve hazard elimination or more broadly improve system safety. These differences further support that the CAST analysis is value-adding.

In summary, five safety interventions were proposed by the safety team. They target different aspects of the system ranging from frontline staff to the departmental management and the vendor. If implemented, they have the potential for hazard elimination, hazard reduction, and damage reduction. Moreover, the proposed interventions are more far-reaching than the initial improvement recommendations from the satellite facility, showing the value of the CAST analysis.

5.2.1.1.5 Overall assessment, achievements, and challenges

Before the overall assessment is described, recall the five perspectives of interest:

- the contextual factors identified at the physical level
- the breadth and depth of the SCS constructed for the analysis
- the contextual factors identified for individual controllers
- the systemic factors identified
- the safety interventions proposed.

All but one have been appraised in detail: the contextual factors at the physical level is what remains. The analysis did not explicitly discuss the physical level beyond the verification of the index and incline of the breast board. Thus, it could only be surmised that no physical failure (involving the breast board or otherwise) occurred. It remains unclear if any physical controls could have prevented the incident and if so, the contextual factors for their absence.

For the overall assessment, a set of criteria proposed by Jacobsson et al. (2012) was used covering analysis scope and quality (Table 13). Adaptations were made because the original criteria were devised with a linear view of accident causation. The scope dimension assesses whether an analysis only targets the frontline staff, equipment, or comprehensively addresses additional (e.g., organizational) aspects. The quality dimension assesses whether the findings only cover the events superficially or if they elucidate the underlying causal factors. The nature and the implication of the recommendations are assessed as well.

Table 13 Assessment dimensions and rating levels; adapted from Jacobsson et al. (2012)

Dimension	2 (Poor)	4 (Fair)	7 (Good)	10 (Excellent)
Scope	Only dealt with "operator error" and "technical failure"	Dealt with technical aspects broadly + some organizational aspects.	Technical + organizational aspects reasonably covered	"All" aspects covered
Quality	Analysis shallow. Stopping at what happened, normally operator error or technical failure. Very local view. Recommendations are only to prevent exactly the same incident to happen at the same place.	Analysis somewhat deeper than for 2 (poor), including some contextual factors. Mostly rather local view.	Analysis deep into unsafe contributions of each controller and also underlying contextual factors. Analysis covers design, procedures, training, etc. Recommendations cover many controllers lower in the SCS.	Analysis deep into unsafe contributions of each controller, various underlying contextual factors, and systemic factors. Analysis covers broad design, procedures and safety management system. Recommendations span the entire system

Based on the assessment criteria, the analysis was "fair". In terms of scope, the analysis covered both the frontline and some organizational aspects of the incident. Had the regulatory and accreditation bodies been included and examined, the analysis would have qualified as "good" (or better). In terms of quality, the analysis contained the contextual factors for the frontline staff and the departmental management, a systemic factor, and safety interventions that went beyond the frontline and had the potential for hazard elimination and the prevention of dissimilar incidents. Therefore, the analysis was at least "fair" in the quality dimension as well. Had more diverse contextual factors been found for the controllers (especially the manufacturers), the analysis would have qualified as a "good" assessment in this dimension.

Reflecting on the experience, one safety analyst lauded the experience as "high yield" and proposed that the department further provide opportunities for residents and all staff to analyze different incidents with this technique on a quarterly or semi-annual basis.

Looking ahead, the safety team has the potential to further improve its CAST proficiency over time. As discussed, the safety team produced a fair CAST analysis and met the expectation for an entry-level performance. Given additional experience and training, the safety team should be able to produce more elaborate analyses at the expert level—those exemplified by the reference analysis of the contouring incident (Appendix B) and previous work by Balgos (2012); Leveson et al. (2016); O'Neil (2014); Samost (2015), etc.

Despite the potential, the actual ability to produce an expert-level analysis may be hindered by time. While the time required for each analysis task reduces as expertise is developed, the overall amount of time it takes to produce an expert-level analysis may still exceed the time allotment. A reason is that an expert-level analysis comprises a much larger scope with more controllers. Examining the higher controllers may also take more time because the associated behavior, process model flaws and contextual factors may be more obscure. Indeed, the time dedicated to each in-depth incident

analysis in healthcare (e.g., 28 person-hour on average (Blanchfield et al., 2018)) is substantially less than that in other safety-critical industries (e.g., 13 months on average for aviation investigations (Fielding et al., 2010)). Additional work should be done to increase the time allotment for in-depth incident analysis in healthcare.

5.2.2 Self-reported attitude agreement with STAMP principles and confidence in analysis abilities

Besides gauging the technical knowhow, evaluating the affective response to the implementation was also important. Self-reported attitude agreement with STAMP principles and level of confidence in analysis abilities provided additional data for evaluation. A one-group pretest-posttest design (Shadish et al., 2002) was operationalized with an anonymous online survey through Qualtrics (Provo, UT). The pretest was administered prior to the training sessions whereas the posttest was conducted right after—before the safety team undertook the CAST analysis independently. At each time point, the safety analysts were asked to rate their attitude agreement and confidence. Appendix H documents the survey questionnaires.

The agreement with the safety principles embedded in STAMP was assessed with ten statements. The statements were adapted from Leveson's (2011, chap. 2) comparison between the assumptions embedded in traditional safety practices and those that are more suitable for contemporary complex systems. These paired statements cover five aspects:

- the relationship between blame and safety improvement
- the propensity for accidents to occur
- the role of operators in accidents
- the nature of the accident causation process
- the relationship between safety and reliability

For instance, two opposing views of the relationship between blame and safety improvement are

> *"Assigning blame is necessary to learn from and prevent accidents or incidents"*

and

> *"Blame is the enemy of safety. Focus should be on understanding how the system behavior as a whole contributed to the loss and not on who or what to blame for it"*.

In turn, the questionnaire solicited responses with a 5-point Likert scale ranging from "strongly disagree" to "strongly agree". This approach was used previously to assess paradigm change in other educational programs (e.g., Fang et al. (2004); Piasentin and Roberts (2018)). For each pair of the statements, reverse coding was applied to the responses associated with the traditional safety paradigm. This treatment followed the practice by Piasentin and Roberts (2018) and enabled the compiled results to reflect participants' agreement with STAMP principles. A pretest-posttest comparison was then made on the proportion of the responses in each agreement category.

Similarly, the participants were asked to rate their confidence with a 5-point Likert scale ranging from "not confident at all" to "very confident" in the abilities:

- to identify causal factors that eschew blame
- to identify comprehensive causal factors
- to design effective safety interventions.

Soliciting a confidence rating was previously used by Duncan (2018), and Brubacher et al. (2019) for RCA training programs and by Brown et al. (2020) when evaluating the efficacy of a communication training program for medical physicists. The three Likert items were combined into a composite Likert-scale score for each respondent.

Unlike some previous studies (Brown et al., 2020; Brubacher et al., 2019), paired t-test was not used in this analysis to analyze the self-reported confidence data. The small sample size, especially

with one nonresponse in the posttest, nullified the assumption of normally distributed measurements requisite for paired t-test (Peat and Barton, 2014). Instead, Wilcoxon matched-pairs signed rank test (MacFarland and Yates, 2016) was performed using R (R Version 4.0.4, Vienna, Austria: R Foundation for Statistical Computing). The data were also analyzed without statistical testing to provide a more detailed perspective.

5.2.2.1 Results and discussion

For both sets of metrics, the unit of analysis was the safety team that received the training. All six participants completed the pretest survey, but one participant did not complete the posttest survey, giving a response rate of 83%. Three reminders were sent after the training session, including one by a departmental leader.

5.2.2.1.1 Attitude agreement with STAMP principles

Prior to the training, the overall agreement with STAMP principles was equivocal (Figure 33). Of the five principles, two were largely aligned with the respondents' attitude. Nearly all the responses were in agreement that blame is the enemy of safety and human error is only a symptom of systemic flaws. Half of the responses showed agreement that systems tend to migrate towards states of higher risk. In contrast, half of the responses showed disagreement that reliability is not safety, and most of the responses showed disagreement that accidents are complex and non-linear. Interestingly, an appreciable proportion of responses showed ambivalence on the propensity for accidents to occur and the nature of the accident causation process.

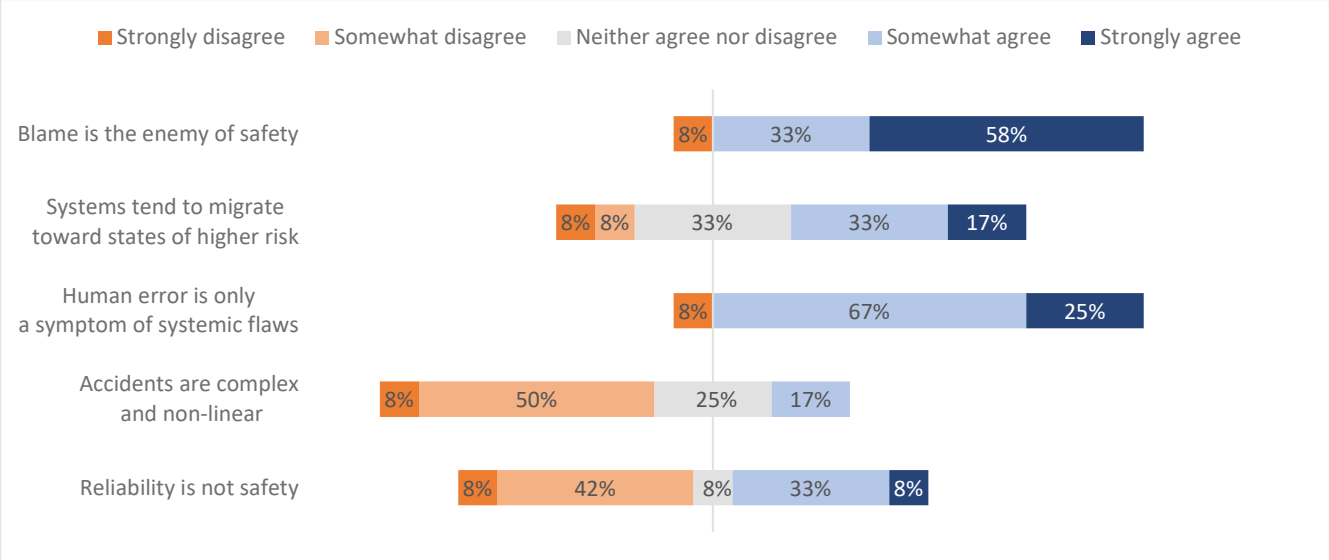


Figure 33 Attitude agreement with STAMP principles prior to training (n=6)

After the training, agreement increased with three of the five STAMP principles (Figure 34). The largest increase occurred around the nature of the accident causation process: the proportion of responses agreeing that accidents are complex and non-linear grew by 53 percentage points. The next largest increase (30 percentage points) occurred around the principle that systems tend to migrate toward states of higher risk. All respondents now agreed that blame is the enemy of safety.

Notably, increase in agreement did not occur with all of the STAMP principles. There was a one percent point decrease around the principle that reliability is not safety. More importantly, there was a net shift of responses into the *strongly disagree* category (apparently from the *somewhat disagree* and *neither agree nor disagree* categories), and the responses in the category increased by 22 percentage

points. Also, agreement with the principle that human error is only a symptom of systemic flaws decreased by 12 percentage points as a new ambivalent response was recorded.

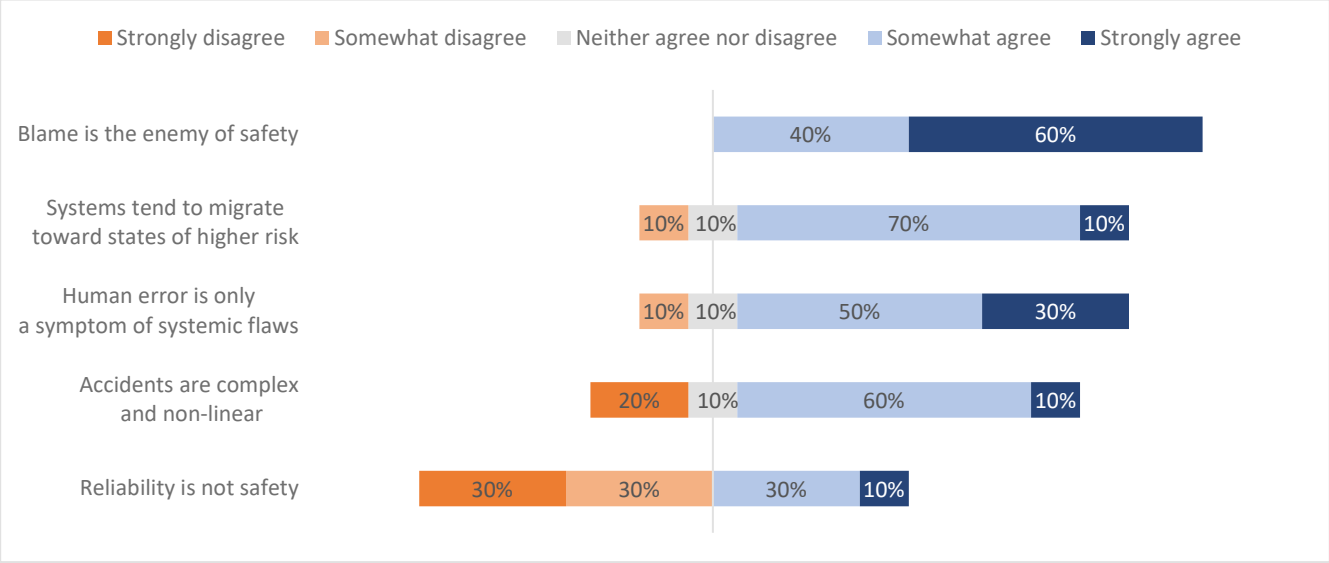


Figure 34 Attitude agreement with STAMP principles after training (n=5)

Examining the training program in combination with the attitude agreement results provided some additional insights. The training program was designed to equip safety analysts to apply CAST, which elucidates the complex and non-linear nature of accident causation in a given incident. The large increase in attitude agreement in this aspect suggests that the demonstrations and examples incorporated into the training were able to illustrate this principle, and the exercises enabled the principle to be internalized.

Interestingly, it remains unclear what increased the agreement with the principle that systems tend to migrate toward states of higher risk. Because of the time constraint imposed on the training program, the principle was not explicitly covered. Potentially, the principle became obvious to the safety analysts given the explicit modeling of the higher-level controllers in the SCS and the methodical examination of their roles in the analysis process. After all, the higher-level controllers play an important role in the migration toward states of higher risk (Leveson, 2004). Future studies can explore the relationship between curriculum arrangement and the attitude agreement with the principle—if another curriculum arrangement can be even more effective.

Broadly speaking, the agreement with the principle that reliability is not safety remained the same. This may have occurred because the principle was not elaborated on and argued for beyond its initial assertion in the conceptual overview video. The results suggest that the lack of additional coverage may have polarized some participants who were originally skeptical or unsure of the principle. As a principle central to STAMP, it should receive a more thorough treatment in future training.

Some mixed results concerned the principle that human error is only a symptom of systemic flaws. While the agreement slightly decreased after the training and an ambivalent response arose, it also appeared that the *strongly disagree* response in the pretest was “softened” to a *somewhat disagree* response after the training. The reduced agreement at the aggregate level suggests that the principle also received insufficient coverage beyond the conceptual overview video. However, the elimination of a *strongly disagree* response suggests that the training program made an impact on the strongest skeptic

of the principle. As with the previous principle, more explicit reinforcement of the principle is likely beneficial in future training.

The data had to be viewed with the incomplete response rate in mind. With an incomplete response rate, nonresponse bias can be introduced. As one participant did not respond, a conservative test was performed by removing the responses in the least agreement with STAMP in the *pretest* (i.e., increasing the proportion of responses in agreement even before training). Under this adverse scenario, an increase in agreement persisted for the principles that accidents are complex and non-linear (by 50 percentage points) and that systems tend to migrate toward states of higher risk (by 20 percentage points). In other words, the increase in agreement with these principles was robust even when potential nonresponse bias was accounted for.

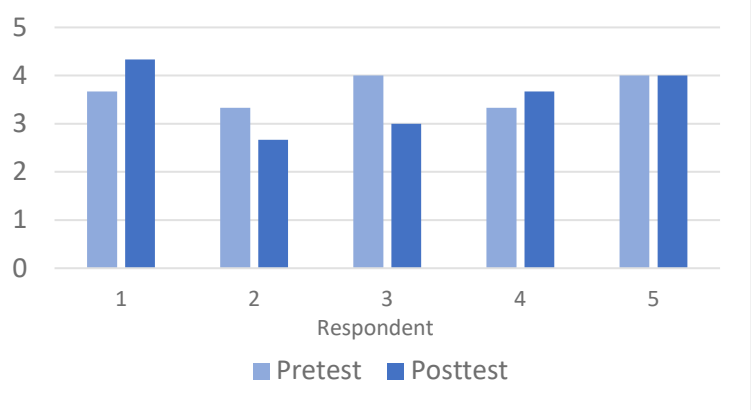
Another noteworthy consideration concerned the attitude agreement at baseline. The participants mostly agreed, even before the training, with the principles that blame is the enemy of safety and human error is only a symptom of systemic flaws. This was beneficial to CAST implementation: insights conflicting with one's pre-existing mental models can otherwise undermine the adoption of even the best innovations (Senge, 2006). However, the high degree of agreement at baseline also limited the potential increase that the survey responses could have measured. Future studies should investigate the attitude changes in these aspects with a different instrument and/or with cohorts having a lower degree of agreement at baseline.

In summary, agreement with STAMP safety principles broadly increased after training. This suggests a paradigm change may have occurred and the participants embraced the systems safety thinking. Reviewing the more granular data further provided insights on the refinement to be made to the training program. The principles that 1) reliability is not safety and 2) human error is only a symptom of systemic flaws should be elaborated and reinforced. Future research can explore whether explicit coverage of the principle that systems tend to migrate toward states of higher risk is more effective, as with the use of a different measurement instrument and cohort.

5.2.2.1.2 Confidence in analysis abilities

The composite Likert-scale scores were equivocal. The overall confidence increased for two respondents while it decreased for two others; the reported values for a fifth respondent were constant (Figure 35). The median value remained the same, but the interquartile range was wider in the posttest data.

Figure 35 Paired Likert scores of self-reported confidence in analysis abilities before and after training



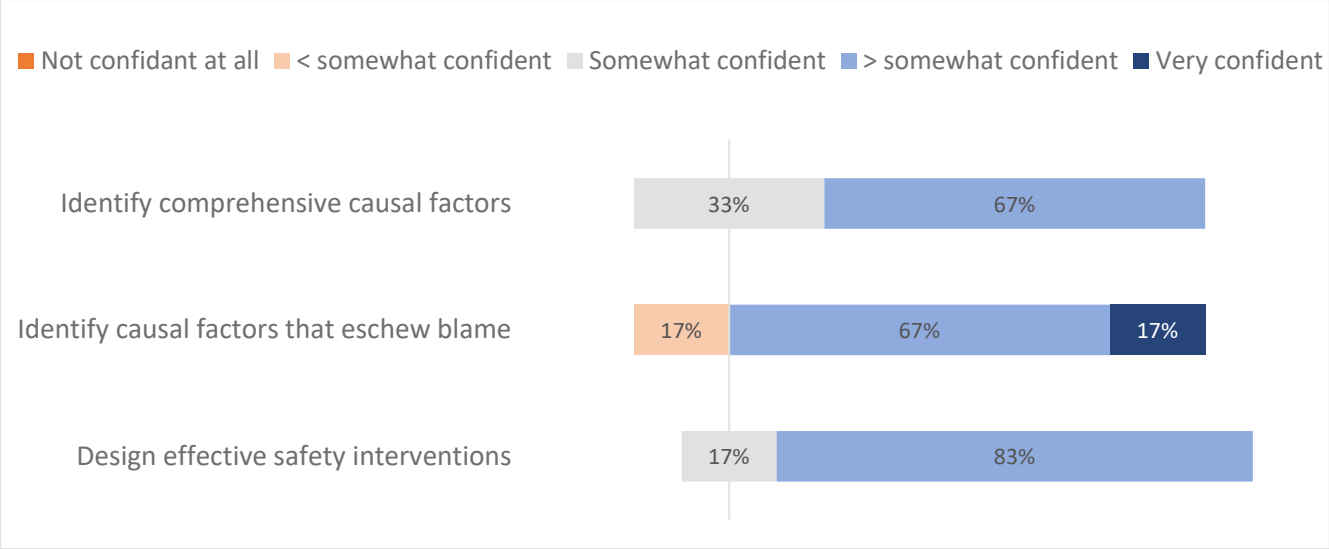


Figure 36 Confidence in analysis abilities prior to training (n=6)

The data were further examined at a more detailed level. Prior to the training, most of the participants were *more than somewhat confident* in their analysis abilities (Figure 36). Comparing between the three abilities, the one to identify causal factors that eschew blame had the most diverse responses, with one participant being *less than somewhat confident* while another being *very confident*. With two participants reported being only *somewhat confident*, the ability to identify comprehensive causal factors seemed to have the largest room for increase.

After the training, the reported confidence had mixed adjustments (Figure 37). For the ability to identify comprehensive causal factors, 40% of the respondents now reported being *very confident* whereas none did prior to the training. On the other hand, there was a more gradated response in the ability to identify causal factors that eschew blame. While the proportions of respondents at the extremes remained roughly the same, there was a net shift of responses into the *somewhat confident* category (apparently from the *more than somewhat confident* category), and it now accounted for 40% of the respondents. Similarly, on the ability to design effective safety interventions, there was a net shift of responses from the *more than somewhat confident* category into the *somewhat confident* category (increased by 23 percentage points) and the *less than somewhat confident* category, which did not exist in the pretest data.

The decrease in confidence in some categories suggests that a more stringent standard of analysis output was adopted. As reviewed in a report published by the National Research Council (NRC, 1994, chap. 8), “self-confidence” is related to goal choice. If the respondents would settle for conventional analysis findings, their self-confidence would have been preserved—learning CAST did not preclude them from applying their previous analysis techniques. The change in confidence suggests that they recalibrated their conceptions of blame-eschewing causal factors and effective safety interventions, adopting a new and more stringent standard from the exposure to the example CAST results. The changes in the attitude agreement data also supported this interpretation. Concurrent to this recalibration, however, was the perception that the new standard presented extra challenge, and some respondents did not believe that they were capable of meeting the standard to the same extent as with the previous, conventional standard. Afterall, the NRC (1994, p. 173) report describes self-confidence as “a judgement about capabilities for accomplishment of some goal”.

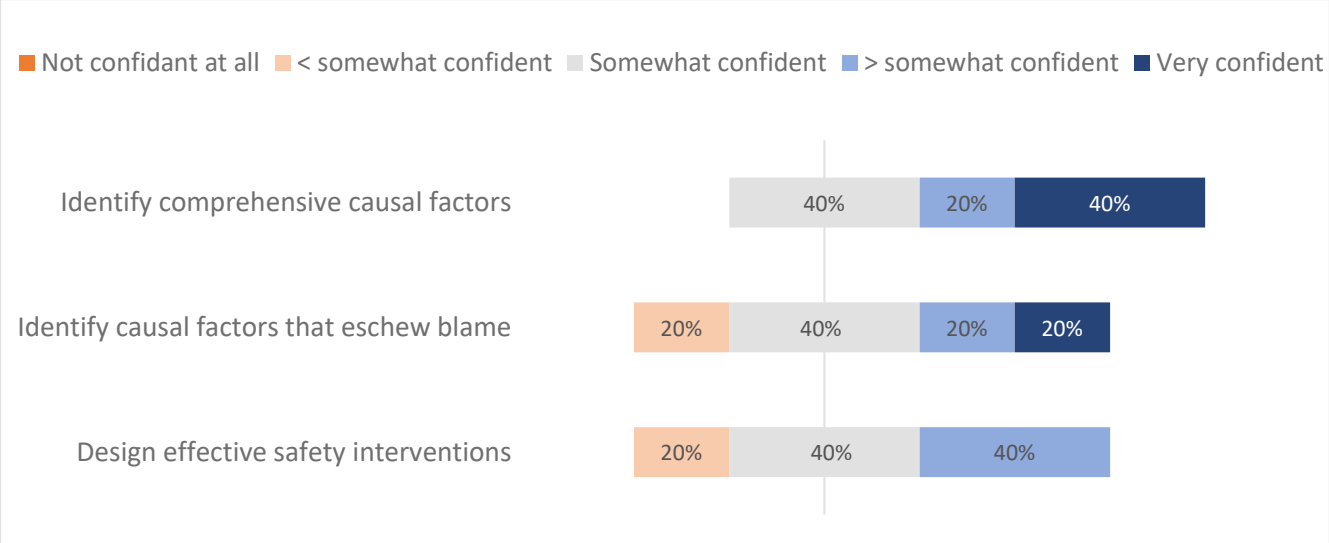


Figure 37 Confidence in analysis abilities after training (n=5)

Given the assessment of the CAST analysis output, a mismatch existed between the confidence data and the actual performance. In reality, the safety team was able to identify causal factors fairly comprehensively that also eschewed blame. The team was also able to generate effective safety interventions with the potential for hazard elimination. However, these achievements contrasted with the self-reported confidence. Indeed, confidence data and actual performance do not always correlate, and this study was not the first to document a mismatch between self-reported confidence and actual performance. Numerous examples have been published in the medical setting alone (e.g., Barnsley et al. (2004); Liaw et al. (2012)).

Why do mismatches occur? Self-confidence is a subjective assessment based on self-confidence information: performance accomplishments, vicarious experiences, verbal persuasion, and physiological states (NRC, 1994). Among these, performance accomplishments are the most dependable because it is experienced firsthand by the individual. Tasks attempted independently further provide a stronger signal. In contrast, a weaker signal results from persuasive information such as evaluative feedback from instructors. A mismatch between self-confidence and actual performance occurs when the circumstances are ambiguous or when there is little information to support the judgement.

In this study, the mismatch suggests that the training program provided insufficient self-confidence information. Notably, the posttest self-confidence data were gathered after the training but before the safety team performed the CAST analysis. While the participants practiced the analysis tasks during training, the practices were coached, abbreviated and punctuated instead of being complete and independently undertaken. Moreover, most of the self-confidence information originated as evaluative feedback from the instructor. Therefore, the participants likely did not get sufficient and strong self-confidence information, leading to the mismatch.

Since the safety team was actually capable of performing a CAST analysis, did self-confidence matter and should the mismatch be resolved? Achieving high self-confidence is important. While self-confidence and actual performance do not always correlate, self-confidence influences motivation and future goal setting (NRC, 1994, chap. 8). Therefore, having low or reduced self-confidence may prevent the safety analysts from applying the skillset or investing further effort to develop the next level of expertise. In this light, achieving high self-confidence should be an independent objective of the training program, in parallel to the mastery of the analysis skills.

To improve self-confidence, the training program may warrant an extension. The training program implemented in this work was shorter than typical training for in-depth analysis techniques. To reiterate, the training took at most two and a half hours—only for the lead analyst. In contrast, even training for RCA, which embodies a simpler accident causation model, takes more time. The RCA workshop developed by Brubacher et al. (2019) to train resident physicians takes three hours. Similar classes developed by Duncan (2018) for supervisors at a health center take four hours. Indeed, 60% of the survey respondents in this study were willing to spend moderately more time on the program. The extended curriculum can incorporate additional exercises, perhaps done without instructor coaching, to create more firsthand self-confidence information. The wider availability of self-confidence information is anticipated to enable the participants to better judge their analysis capabilities, reducing the mismatch with actual performance. As shown, exploring the cause of the mismatch created insights on the training program. Future studies should also test if self-confidence improves after performing a complete CAST analysis independently.

5.3 Summary

The CAST enhancements were implemented in a radiation oncology department. Training videos and tutorials were provided to the safety team with a diverse professional background. The training videos covered fundamental concepts (e.g., control loop), and the interactive tutorials reinforced the participants' understanding. Moreover, the participants practiced the analysis tasks (e.g., creating a SCS). During the tutorial, some participant remarks revealed their baseline perspectives on analysis scoping and blame. The participants were coached to analyze components that may be outside their direct influence but relevant to an incident. Ultimately, the participants achieved the learning objectives despite the short training duration.

Overcoming cultural and conceptual barriers was crucial for CAST to be used effectively. Prior to the training, the participants did not widely agree with the principles that 1) reliability is not safety, 2) accidents are complex and non-linear, and 3) systems tend to migrate towards states of higher risk. After the training, there was a marked increase in agreement with the two latter principles. It suggests that a paradigm change may have been made. More work remains, however, to facilitate a change of thinking on the first principle. The principles that 4) blame is the enemy of safety and 5) human error is only a symptom of systemic flaws already received wide agreement at baseline, limiting the degree of increase that could be measured. Further work is required to better assess the effectiveness of the training to build agreement with these principles.

Assessing the ability to undertake a CAST analysis was of fundamental importance, and the analysis of a patient positioning incident provided data for this purpose. The analysis spanned both the frontline and the organizational aspect of the incident. Most of the modeling decisions made by the safety team are consistent with the customs of constructing SCSs. The safety team also identified the contextual factors for both frontline and organizational controllers. A systemic factor was also identified—a non-trivial task especially for novices. Lastly, the proposed safety interventions target different system levels, have the potential for hazard elimination, and can prevent dissimilar incidents.

In contrast, the original incident analysis of the same incident described the causes as a sequence of events, and the search for causes did not go beyond the RTTs. Also, the flawed actions were the focus instead of the factors underlying the actions. No systemic factors were identified. Taken together, the CAST analysis provided a more comprehensive understanding of the incident than the original incident analysis. Moreover, the safety interventions proposed in the CAST analysis were more comprehensive and effective.

The study team's CAST analysis output was at least comparable to, if not better than, that from past attempts by novices in terms of scope, contextual factors, and systemic factors. Notably, the

analysis in this study was produced in less time, with less training, and not under the guidance of an expert with advanced degree in safety science. The results suggest that CAST can be feasibly learned and applied with even less time and resources than in previous experiences.

Self-confidence was another important aspect to assess—it is a mediator of future behavior (e.g., applying CAST) and goal selection (e.g., developing expert proficiency in CAST). After the training, the respondents showed no substantial difference in their confidence in analysis abilities. This mismatch between self-confidence and actual performance suggests that the training provided insufficient self-confidence information to accurately judge capabilities. The training program should be revised to incorporate more firsthand self-confidence information. Reassessing self-confidence after the full CAST analysis would provide further insights as well.

The results should be viewed with the limitations in mind. First, the format of a single-site case study necessarily limits the generalizability of the results. A different safety team with a different background, expertise, or baseline agreement with the STAMP safety principles may not achieve the same performance. Second, without randomization and a control[††], the reported changes may have occurred due to confounds or naturally occurring changes over time. In particular, one participant did report simultaneously receiving other training on in-depth incident analysis technique. However, the effect on the results was considered to be small given the small number of participants affected and the uniqueness of CAST and its underlying theoretical foundation.

All things considered, the enhancements facilitated consistent and efficient application of CAST in one radiation oncology department, and the incident analysis was improved. By learning more effectively with a systems view of accidents, the safety team acquired the ability both to prevent the exact replication of incidents and to address more general system vulnerabilities. The achievements demonstrated to the wider healthcare system a previously contested possibility. Simultaneously, this study fulfilled one *raison d'être* of systems engineering: to augment the system (and human) capabilities by making the needed enhancements.

[††] Whether a randomized control trial is appropriate for safety research remains a debated subject (Webster, 2019).

Chapter 6. Towards a STELAR system

While more CAST adoptions in healthcare can improve the individual incident analyses, it does not directly improve the other IRS functions. As discussed in Chapter 1, IRSs may still be plagued by under-reporting, under-utilization of in-depth analysis or aggregate data analysis and insufficient learning dissemination. To fully achieve the potential safety improvement that reporting *can* bring about, the other IRS functions must also be improved.

To this end, a conceptual design for a **ST**AMP-**E**nhanced **L**earning **A**nd **R**eporting (STELAR) system is proposed. This chapter describes the design after examining some published requirements for healthcare IRSs.

6.1 Contemporary IRS requirements

Understanding the stakeholder and system requirements is an important part of any new development. Some requirements are provided by researchers, and more requirements are embedded in the standards and regulations from the regulatory and advisory bodies. Both requirements are highlighted below.

Lindberg et al. (2010) proposed some quality criteria on the IRS functions. Quality *reporting* entails capturing sufficient detail from all events that may be analyzed in-depth. Quality *triaging* entails selecting incidents with the highest learning potential for in-depth analysis. Quality *analysis* entails applying analysis techniques most useful to prevent future accidents. Quality *feedback dissemination* entails sharing the analysis output reaching all stakeholders who can prevent future incidents. Quality *preventive measure* entails applying the analysis output in preventing future incidents. The model also emphasizes a self-reflective aspect of IRS maintenance: regularly evaluating the IRS based on the experience of use.

Regulatory and advisory bodies have also issued requirements pertaining to IRSs. Recently, the World Health Organization (WHO) published a technical report on IRSs (WHO, 2020). The report states two fundamental objectives for IRSs: they make risks visible and they prevent harm. The Comprehensive Accreditation Manual published by TJC (2017) contains more specific standards describing the categories of incidents that the IRS should cover, the analysis, and the resolution, etc. (Table 14).

Table 14 Standards relevant to IRS issued by TJC

Standard	Description

EC.04.01.01	The hospital collects information to monitor conditions in the environment.
	• The hospital establishes a process(es) for continually monitoring, internally reporting, and investigating the following:
	  ○ Injuries to patients or others within the hospital's facilities
	  ○ Occupational illnesses and staff injuries
	  ○ Incidents of damage to its property or the property of others
	  ○ …
	• Based on its process(es), the hospital reports and investigates [the above categories of reports]
	• …

LD.03.04.01	The hospital communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties.

- Communication processes foster the safety of the patient and the quality of care.
- …

LD.04.04.05	The hospital has an organization wide, integrated patient safety program within its performance improvement activities.

- The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as close calls [, near misses,] or good catches) to hazardous conditions and sentinel events.
- The leaders provide and encourage the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment.
- The leaders define patient safety event and communicate this definition throughout the organization.
- The hospital conducts thorough and credible comprehensive systematic analyses (for example, root cause analyses) in response to sentinel events as described in the "Sentinel Events" (SE) chapter of this manual.
- The leaders disseminate lessons learned from comprehensive systematic analyses (for example, root cause analyses), system or process failures, and the results of proactive risk assessments to all staff who provide services for the specific situation.
- …

The cited publications together provide a compatible set of requirements for IRS design. The WHO objectives provide a simple but fundamental description of IRSs. The TJC standards then shape IRSs at two levels: First, they explicitly require an IRS to be able to collect incident information, analyze incidents and make safety improvement based on analysis results. Because only Sentinel Events are required to undergo comprehensive systematic analyses (while other reports can be analyzed based on local processes), the ability to triage safety reports is implicitly required as well. Second, they specify some elements of performance (the detailed bullet points) that need to be achieved. Complementary to the WHO objectives and the TJC standards, Lindberg et al. laid out the appraisal criteria for the various aspects of IRSs.

6.2 A proposed conceptual design for the STELAR system

With the requirements understood, a conceptual design for the STELAR system was created. The STELAR system incorporates six broad functions: report collection, triage, in-depth analysis with CAST, aggregate analysis, safety intervention design, and feedback dissemination (Figure 38). Besides directly producing safety learning, the aggregate analysis function has the added objective to assess IRS effectiveness. These functions serve as the building blocks for the STELAR system.

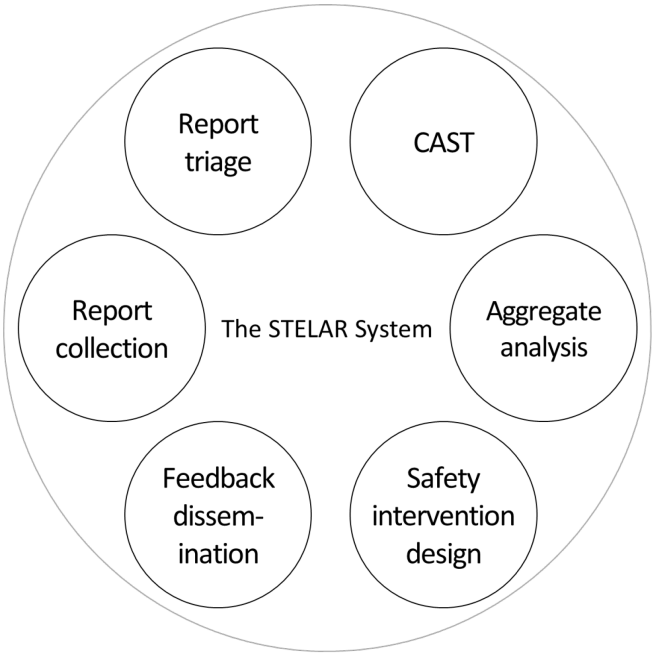


Figure 38 Six broad functions in the STELAR system

A two-part design philosophy underlies STELAR. First, other than improving the individual functions, enhancing the compatibility between the functions is important. This is because the effectiveness of an IRS is an emergent property, resulting from many interactions (Figure 39). For instance, the information collected in the incident report informs report triaging; the formatting of the in-depth incident analysis results drives what aggregate analysis can be performed, etc. Second, IRS effectiveness needs to be designed into the system. This is because the frontline use of the IRS depends on many organizational decisions. For instance, report collection would be hampered if protected time is not given to frontline staff to submit a safety report.

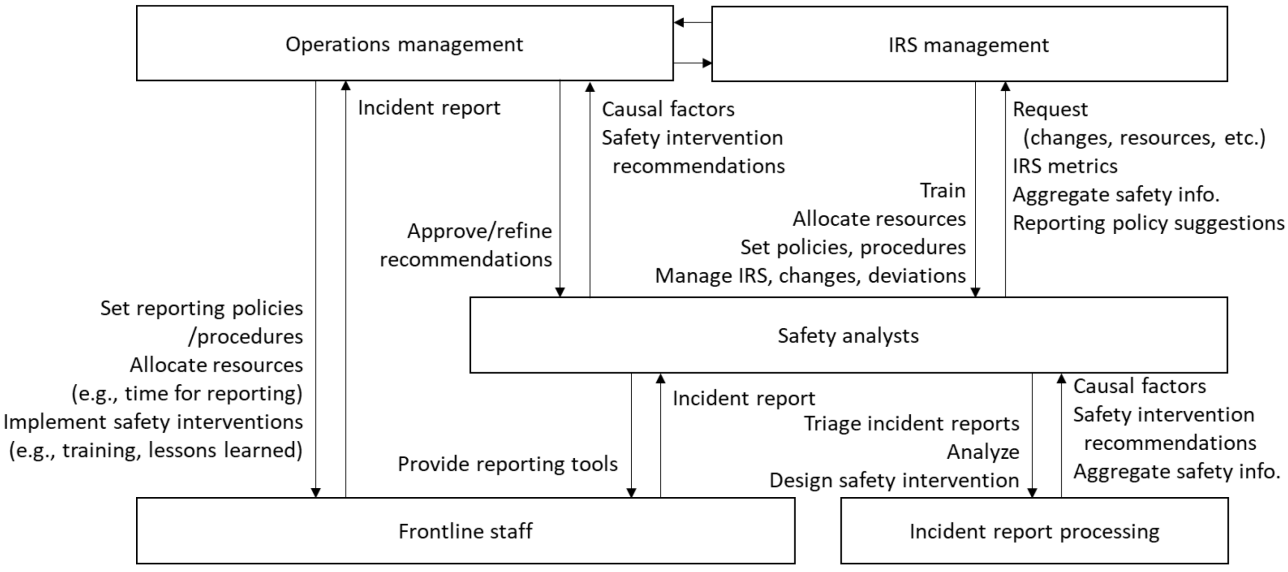


Figure 39 An IRS modelled as a hierarchical control structure

Interdependencies are designed into the STELAR system to meet specific objectives, and one objective is to avoid under-triaging incidents for CAST analysis. Some incidents (e.g., Sentinel Events)

are mandated to be analyzed in-depth. A substantial number of incidents, however, do not meet the mandated threshold, and there are not sufficient resources to analyze all the incidents in-depth. Therefore, some incidents are selected by discretion. Under-triaging is basically not selecting an incident to be analyzed when it would generate more learning than another incident that is selected.

Three functional interdependencies are conceptualized around the report triaging function to avoid under-triaging:

- *Connecting triaging and CAST.* Previous CAST analyses are used to assess the novelty of an incident report. To this end, the SCS helps visualize what flawed interactions are known to exist in the system. The novelty is then used in the discretionary triaging of incidents. An incident report with low novelty is processed in a more expedited fashion by exploring why the implemented safety interventions are not effective.
- *Connecting triaging and aggregate analysis.* The capacity to perform in-depth incident analysis has to, at least, meet the demand from regulatory and accreditation requirements. Aggregate analysis is used to estimate the demand, so strategic resource planning builds in extra capacity to accommodate discretionary analyses. In addition, aggregate analysis is also used to assist each triaging decision by estimating the likelihood for an imminent mandated analysis that would compete for analysis resources. The validity and potential for this application require further research—the predictive value may be severely reduced by changes in the system and the environment.
- *Connecting triaging and report collection.* The report originator often experiences the reported incident firsthand, while triaging is done by administrators distant from the incident. The rich details may be lost in translation, undermining the triage decision. With this in mind, report originators have the option to request incidents to be analyzed in-depth. The option affords more control to the report originator, which also mitigates under-reporting.

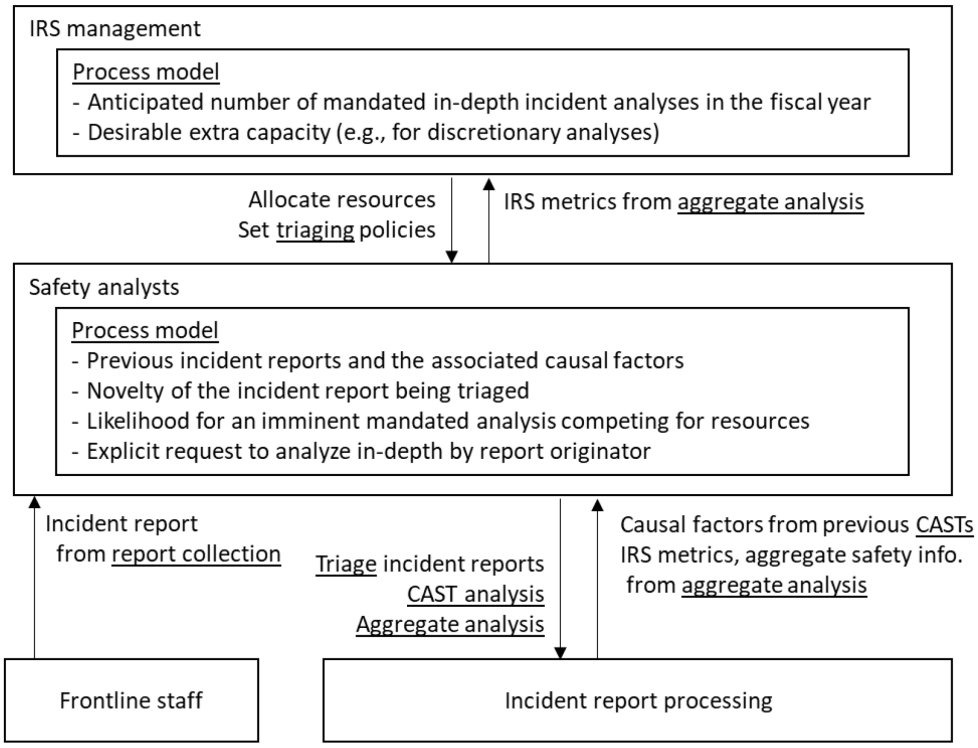


Figure 40 The interdependencies translate into interactions in the hierarchical control structure. The underlined labels show the associated control actions and feedback.

These interdependencies translate into interactions in the hierarchical control structure (Figure 40). For instance, safety analysts can build a much more sophisticated process model of previous causal factors if the previous CAST analyses are readily available and compiled in a usable format. When a new incident report is submitted, safety analysts can then gauge the novelty of the report and make an informed triaging decision.

Other objectives include improving CAST analyses and safety intervention design as well as mitigating under-reporting. Three functional interdependencies are used:

- *Connecting report collection and CAST.* Because fallible memory adversely affects incident analyses (Kelloway et al., 2004), soliciting process model information at the time of reporting is useful. Additional research should explore the time cost of this feature. The time investment is especially worthwhile if report triaging produces considerably delay, exacerbating memory loss or inaccuracy. Identifying the process model flaws early may also help assess the novelty of an incident, facilitating triaging.
- *Connecting report collection and safety intervention design.* Pursuing a participatory approach to safety improvement is useful and frontline staff often have unique insights, so safety intervention ideas are solicited in the reports. However, the feature does not lessen the need for further analysis especially to generate a more detailed understanding of the incident to inform more comprehensive safety intervention design.
- *Connecting report collection and feedback dissemination.* Because incidents typically occur after changes (Leveson, 2019), all changes, including the implementation of safety interventions, require close monitoring. The details of the safety interventions (e.g., objective, mechanism, timeline) being put in place need to be clearly communicated in feedback dissemination. Importantly, the conditions that signal unintended consequences or a lack of effectiveness are described, so reporting can be made for such occurrences.

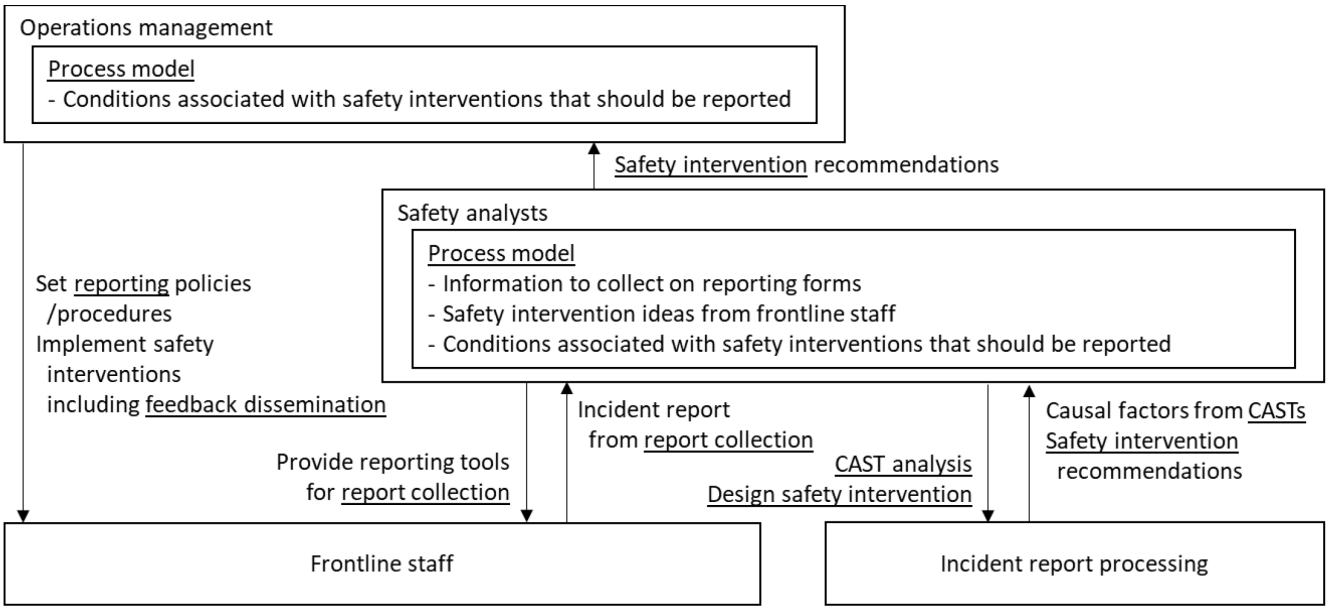


Figure 41 The interdependencies between report collection and three other functions illustrated with the hierarchical control structure.

These interdependencies are similarly incorporated into the hierarchical control structure (Figure 41). For instance, the conditions that signal unintended consequences are compiled when safety analysts design safety intervention. The information is passed to operations management as part of the

safety intervention recommendations. In turn, operations management set reporting policies accordingly and disseminate the information to frontline staff. Ultimately, should the conditions arise, frontline staff can get them addressed by filing an incident report.

For long-term safety and IRS effectiveness improvement, aggregate analysis is coupled with other IRS functions:

- *Connecting aggregate analysis and CAST.* While the findings surrounding individual controllers from different CAST analyses are not always related, the findings on systemic factors are. Aggregate analyses of the systemic factors reveal the extent of the problem (in the system) and its persistence.
- *Connecting aggregate analysis and safety intervention design.* The proposed safety interventions over time are analyzed with aggregate analysis. For instance, examining the theoretical effectiveness (e.g., hazard elimination vs. reduction) provides insights on the design process. Also, assessing the disparity between the ideas selected for implementation against those proposed reveals any bias towards superficial solutions.
- *Connecting aggregate analysis and feedback dissemination.* First, whether the lessons learned are *always* shared with report originators is analyzed with aggregate analysis. An imperfect performance spurs "fix and forget" practices and needs to be rectified. Second, wider distribution of the lessons learned recruits additional participation and investment for safety improvement. Aggregate analysis is used to assess the scope of distribution, so the efficacy of the IRS is observable without creating an information overload.
- *Connecting aggregate analysis and report collection.* The reporting disparity is dynamically assessed among staff types and the parts of the system (e.g., radiation oncology, anesthesiology). In response, *potential* under-reporting is further examined and mitigated.

Finally, to mitigate under-reporting, under-triaging and to improve safety analysis, additional interdependencies are conceptualized with the safety information derived from proactive hazard analyses based on STAMP (i.e., Systems Theoretic Process Analysis (STPA)) and other information sources such as observation, medical record review, etc. (Shekelle et al., 2013):

- The STPA analysis output enhances report collection, triaging, and aggregate analysis. First, the loss scenarios support the creation of event-specific reporting forms, enabling targeted information gathering. Second, the conceivable but unreported scenarios inform the creation of a dynamic reporting guidance, enabling the IRS to take a more active posture. Third, the loss scenarios provide a more comprehensive set of conceivable incidents to gauge the novelty of the report being triaged. Lastly, the leading indicators (Leveson, 2015) identified from the STPA analysis provide the metrics for use with aggregate analysis.
- The data from other safety information sources also improve report collection and safety intervention design. First, the data better estimate the actual incidence of the safety events (Shekelle et al., 2013). The incidence information then enables a more accurate under-reporting estimate and its resolution. Also, the information enables empirical—rather than theoretical—assessment of safety intervention effectiveness.

While some features (e.g., using aggregate analysis to estimate the likelihood for an imminent mandated analysis that would compete for analysis resources) require much more research and development, others can be readily implemented after a careful consideration of the local context. For instance, connecting report collection and safety intervention design can be as simple as adding a field in the reporting form, but the implementation should account for the interest and knowledge of the

local staff. Potentially, exposing the staff to a brief training on safety intervention design and past successes is useful. As another example, analyzing the systemic factors from CAST analyses can be done as soon as a repository of CAST analyses is built. In a broader sense, researching and creating the interdependencies requires resources. However, adopting the more advanced design has the potential to improve IRS effectiveness, thereby reducing safety incidents and saving cost. The objective also aligns with the medical ethics enshrined in the Hippocratic Oath.

In summary, the conceptual design of STELAR is proposed to overcome the limitations of current IRSs and previous attempts to improve IRSs. The proposed design focuses on improving the interdependencies internally among IRS functions and externally with other safety information. Further research and development is required to mature the design.

Chapter 7. Conclusion and future work

Overall, this work paves the way for substantially improving healthcare safety by increasing effective safety learning. Adopting CAST and improving IRS effectiveness can help achieve safety improvement in healthcare as in the other high-risk industries.

However, the advancement from this work is necessary but insufficient. This work primarily applied a technical approach, creating solutions to the technical problems constraining CAST application and hampering IRSs. Nonetheless, overcoming cultural barriers is equally critical. Questions on how to create a culture that welcomes the new method of safety learning (e.g., expanded scope of incident analysis) and IRS features remain to be answered. For instance, can the culture be abruptly changed or more gradually shifted (Carroll and Quijada, 2004)? In terms of implementation, how do safety experts, who may not have patient care experience or qualifications, earn the trust and cooperation of management and frontline staff? Is it through starting relationship building early and continuing with multiple tactics (DiBenigno, 2020)? Ultimately, even when staff is willing to give a new analysis methodology and a redesigned IRS a try, sustained participation would only result from demonstrable safety improvement, so how do safety analysts convince management to implement more effective safety interventions that sometimes require more investments? The potential for a quantum leap in safety will be increased by additional work tackling these and other organizational and sociopolitical aspects.

7.1 Introducing CAST into healthcare

Research and development was undertaken to improve incident analysis in healthcare. Seven enhancements were created to make CAST more efficiently and consistently applied. For instance, the generic SCS provides information that can be adapted and reused in each analysis, and the graphical safety intervention design process renders an unstructured task more specific and manageable for safety analysts without advanced engineering training.

The implementation at a radiation oncology department demonstrated the feasibility and impact of applying CAST. The safety team learned CAST in a short time (less than some RCA training programs) and also analyzed a patient positioning incident within the regular time allotment. The analysis output was superior to another analysis of the same incident with the conventional approach. Comparing to the past attempts to introduce CAST to novices, the analysis from the safety team—produced with less training, time, and guidance—was at least comparable, if not better. In short, CAST can be feasibly applied in healthcare, and it improves safety learning.

Refinement of the enhancements should be made based on the implementation experience. Analysis scoping and the details of a control loop can benefit from more elaboration. Curriculum rearrangement should be explored, especially to reinforce the principles that reliability is not safety and that human error is only a symptom of systemic flaws. Independent analysis exercises should be incorporated to create more firsthand self-confidence information. The templates should be reviewed for efficiency enhancement as well.

While this work provided evidence about the feasibility of CAST application in healthcare, it has limitations, primarily from the case study design. Even if a randomized control trial remains out of reach, a more elaborate quasi-experiment should still be conducted, e.g., by using control groups (Privitera and Ahlgrim-Delzell, 2018; Shadish et al., 2002). To this end, this work hopefully provides the evidence it takes to encourage study participation.

The measurement instruments used in the study should be refined, and additional applications should be explored. The survey to assess self-reported attitude agreement suffered from measurement

saturation in one principle. The use of a different instrument should be attempted in future studies. Moreover, this work was the first to use attitude agreement results to assess STAMP associated training outcomes, so no data existed to serve as a basis of comparison. A broader effort to capture and analyze attitude agreement deserves further consideration. For instance, cross-sectional and longitudinal studies assessing attitude agreement among STAMP practitioners may help characterize paradigm change and expertise development.

Additional enhancements are needed to further CAST expertise development beyond entry level. Development of expertise requires practicing deliberately to overcome specific areas of weakness (Davidson and Sternberg, 2003). Common weaknesses for healthcare safety analysts need to be identified. Conducting longitudinal studies to track performance (e.g., the quality of the analysis output, the time and effort required) will give additional insights.

Finally, additional materials should be generated for the other specialties in healthcare. While the methodological refinement and templates are applicable to specialties other than radiation oncology, the generic SCS and reference controller responsibilities are not. Specialty-specific generic SCSs and lists of reference controller responsibilities will be useful. These can be created by following the described process of development. Incorporating specialty-specific examples in the training program helps make it more relatable for practitioners outside radiation oncology as well.

7.2 Designing a more effective IRS

Besides CAST implementation, a conceptual design for the STELAR system was also created. The design incorporates favorable interdependencies among IRS functions internally and externally with other safety information.

Several of the STELAR design features require further research: assessing the novelty of a safety report with past CAST analyses, triaging based on potential competing analysis demands, and soliciting mental model information during reporting. The additional work will support a more detailed IRS design.

7.3 Broader contribution

This work advanced a strategic goal in healthcare—researching, developing, and applying systems engineering tools. Collaborations between healthcare and systems engineering are uncommon. The fields have different incentive structures, and problems in healthcare are often not perceived to merit engagement by engineering faculty (Kaplan et al., 2013). The rare successful collaborations in the past have depended on “an extraordinary combination of circumstances, leadership, culture, and resources” (p. 13), and this dissertation was no exception. Much work remains to proliferate such collaborations because they clearly improve both fields and benefit humanity. Ultimately, healthcare benefits both from the providers of care, and those focused on improving care delivery.

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Appendix A. The ineffective prevention of transfusion error at an academic medical center

A 75-year-old woman was taken to a hospital on December 2, 2018, and her condition was so critical that she required a blood transfusion. Later that evening, the patient's condition further deteriorated, and her blood pressure dropped significantly. Blood was discovered in her urine. Subsequently, her blood pressure continued to decrease to a dangerous level, with systolic pressure at 60 mmHg. The patient eventually had four cardiac arrests, and her family terminated care by the fourth episode.

Did something go wrong? Maybe not. Granted, the patient was very sick to begin with—she arrived at the hospital in an altered mental status. The patient was diagnosed to have a head bleed, an impaired function to coagulate, a severe infection with complications, and several other conditions.

Yet, the case was anything but ordinary, even for a very sick patient. When the Department of Health and Human Services (DHHS) conducted an investigation in response to a complaint, they found numerous flaws that ultimately resulted in the patient having "a transfusion reaction, developed severe complications, and died" (Centers for Medicare & Medicaid Services, 2019, p. 17). For instance, the patient had B+ blood type but received incompatible A+ blood products because, among several other factors, a different patient's blood sample was sent to the laboratory for screening. Also, clinical staff did not notice the transfusion reaction as the patient deteriorated.

Importantly, the DHHS found that the tragedy was not an isolated incident at the hospital. Mislabeled blood specimens or labeling problems, which was mentioned as one of the flaws, occurred in 122 incidents in the four months leading up to the investigation. There was another case of potential transfusion reaction in which the patient had a cardiac arrest and received CPR, but this case was not even reported to the Quality Director at the hospital.

All these cases did not prompt effective actions to rectify the situation. Not all cases received in-depth analyses, nor did safety information reach the relevant personnel. At the time of the DHHS investigation, corrective actions were not adequately implemented either. For instance, nursing staff still had an incorrect understanding of the capability of the electronic medical record software, believing that it would accurately and comprehensively discern a transfusion reaction and provide an alert. Problems with the electronic documentation of transfusion process also had not been corrected by the time of the investigation. Simply put, the IRS was not effective in improving safety.

Appendix B. CAST analysis of a radiation therapy incident

Step 1: Basic information

This section identifies the basic information of the incident, defines the scope of the analysis, and closes with a sub-analysis of the physical process where the physical equipment produced and/or experienced the loss.

High-level incident description and scope of analysis

The incident took place in the course of treating a 6-year-old patient with a right-thigh sarcoma. Radiation therapy (RT) was included as a means of treatment. The treatment involved radiation delivery of 50 Gray over 25 fractions. During chart rounds when the patient had already completed 15 fractions, the care team realized that the treatment plan was approved without leveraging the available magnetic resonance (MR) images and was based on computed tomography (CT) images alone. With the MR images fused to the CT images and re-contoured, the revised treatment plan revealed that the original target volume was 30% larger than necessary. The enlarged target volume resulted in an increased risk of growth delay and infertility.

In terms of context, the RT clinic had 4 linear accelerators (linacs) and treated about 140 patients per day at the time. The staff was experienced in treating various medical conditions of differing complexity. Besides the healthcare organization delivering RT, the manufacturer(s) of the treatment planning system (TPS) and electronic health record (EHR), and the regulatory and advisory bodies were part of the system of interest as well.

Proximal events

ID	Event	Question raised
1.	Primary radiation oncologist reviewed diagnostic MR images with radiologist.	-
2.	Primary radiation oncologist requested the MR images to be fused just prior to departing for a conference.	• Was the standard practice to fuse it for a sarcoma case? • Was the standard practice to fuse it before or after the review between the radiation oncologist and radiologist? • Why were the MR images not fused by the dosimetrist earlier? • Was the dosimetrist in the Radiation Oncology Department or Radiology? • What was the standard practice to communicate with/task the dosimetrist?
3.	MR images were not fused prior to the primary radiation oncologist departing for a conference.	• Why was a dosimetrist not available to fuse the MR image? • Why was the physician assigned the patient if he could not complete treatment planning before departing for a conference?
4.	Primary radiation oncologist completed the contouring on CT only and created an electronic note in *Treatment setup notes* to alert the covering radiation oncologist to review the MR images before approving the plan.	• Why was contouring done without the MR images being fused? • Was it a standard practice to split the contouring and treatment plan completion between different radiation oncologists? • What was the standard practice to communicate with/task the covering radiation oncologist? • What was the training on the use of electronic note and treatment plan review and approval? • Did the electronic note require acknowledgement? • Did the software selection process consider usability/discrepancy of usage?
5.	The dosimetrist completed the treatment plan and asked the covering radiation oncologist to review and approve it.	• Was the dosimetrist aware that the MR images needed to be fused?

6.	Covering radiation oncologist reviewed and approved the treatment plan without reviewing the MR images.	• Did the covering radiation oncologist receive the same training, if any, on the use of electronic note and treatment plan review and approval?
7.	Treatment delivery began for the patient.	-
8.	The case was scheduled to be discussed at previous chart rounds but the discussion was postponed due to lengthy discussions of other cases.	• Why was case review not done prior to treatment delivery? • Did the case get increasingly high priority to be reviewed as more treatment fractions were delivered? • Why was adequate time not budgeted for chart rounds?
9.	Chart round discussion identified that the MR images were not used in treatment planning	-
10.	The target volume was redrawn to complete the rest of the patient's treatment.	• Was it a standard practice to replan if a discrepancy was found in a treatment plan? • Was any medical intervention provided to address any actual or potential adverse effects from wrong dose?

Physical failure

There was no physical failure associated with the devices that actually interacted with the patient. Specifically, the linac functioned as programmed. Also, at the CT and MR image acquisition, the machines performed as intended and acquired the respective images as well. The unsafe physical interaction involved the linac delivering radiation to an area larger than necessary for a portion of the treatment regimen, and it was an accuracy problem involving complex decision making. In other words, there was no physical controls that could readily address this without looking at the wider system.

Step 2: Safety control structure

In this section, the complex sociotechnical system that was involved in the incident is described through a graphical model—the safety control structure. Highlighted boxes depict the controllers of interest. The labels of the controllers, control actions and feedback with a reduced font size were *irrelevant* to the incident.

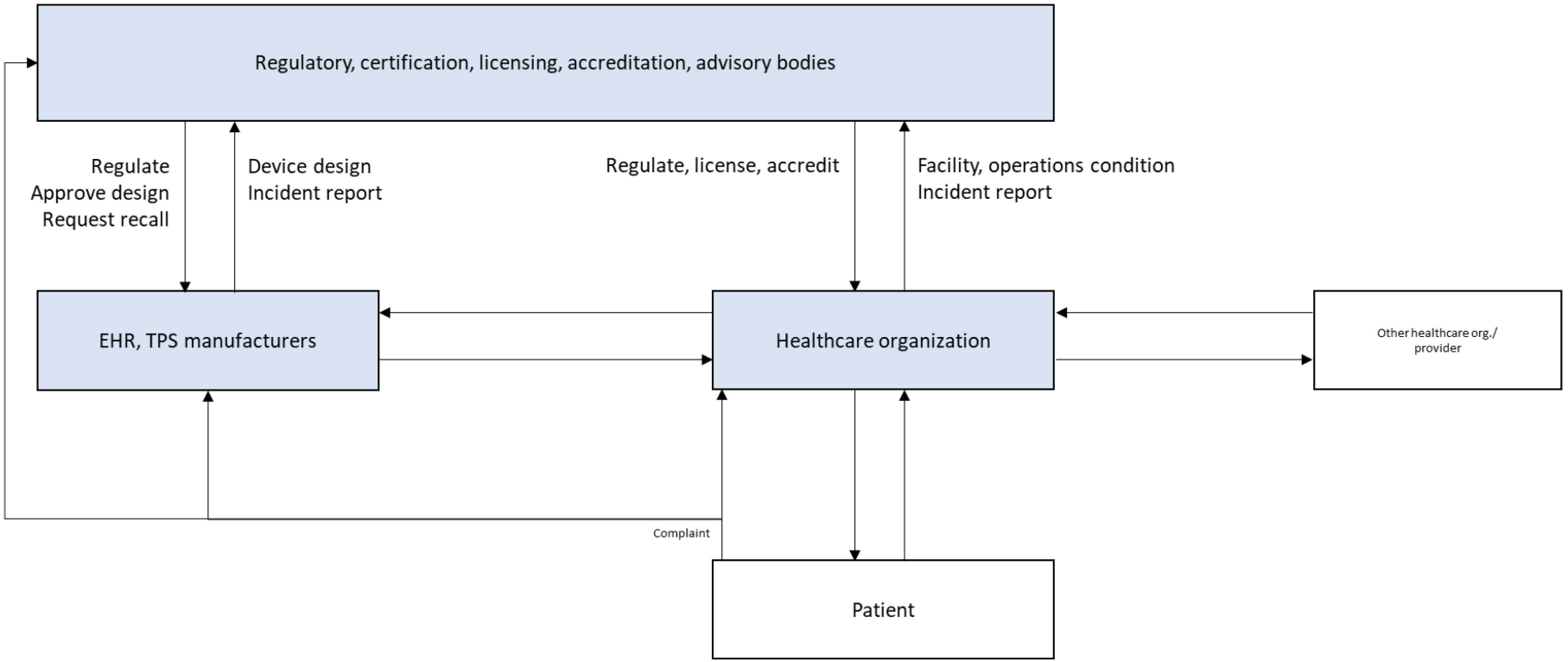


Figure 42 The SCS for the RT incident
(EHR = electronic health record; org. = organization; TPS = treatment planning system)

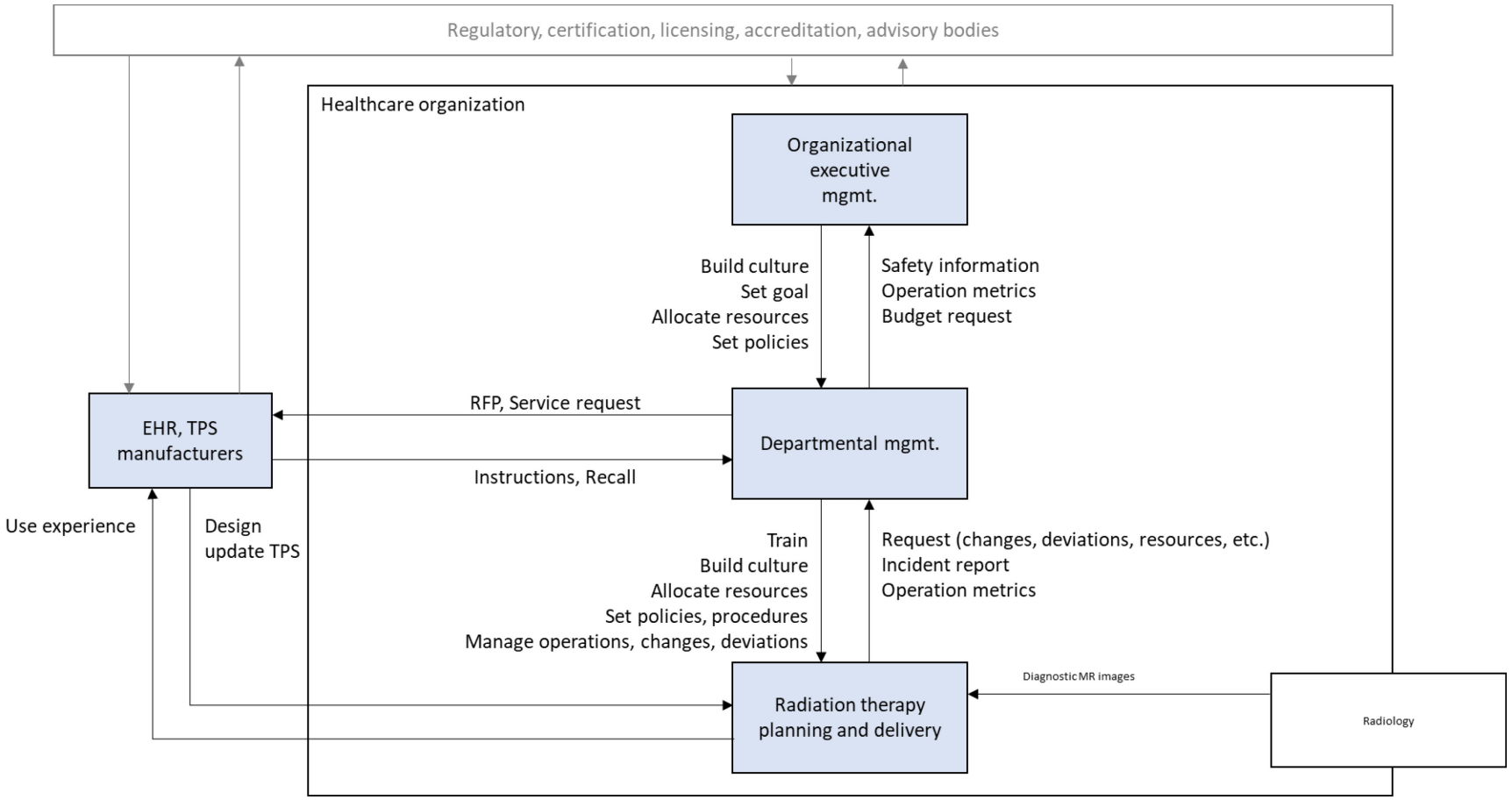


Figure 43 The part of the SCS showing the details of the healthcare organization (mgmt.. = management; MR = magnetic resonance; RFP = request for proposal)

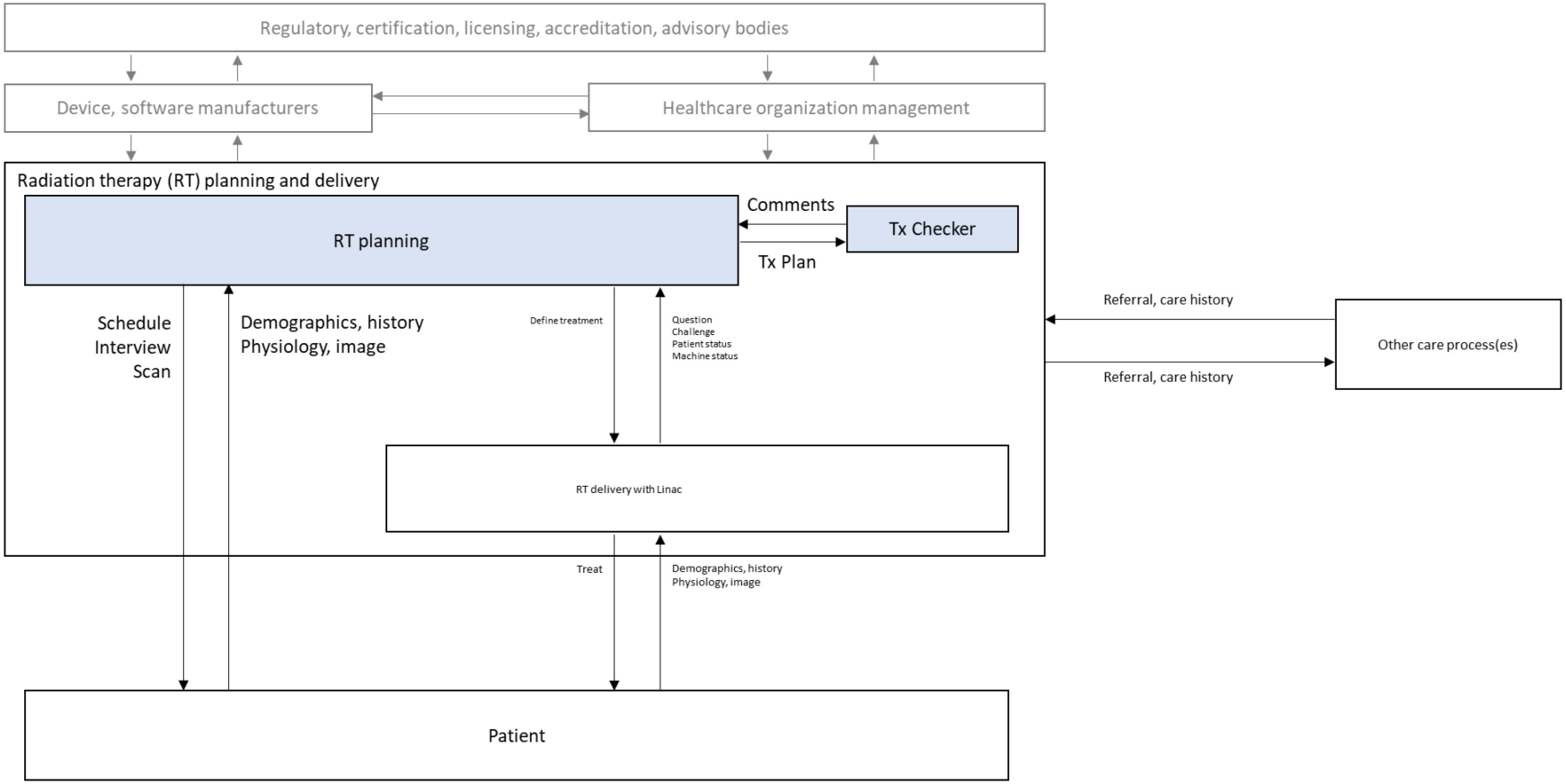


Figure 44 The part of the SCS showing the details of RT Planning and Delivery (Tx = treatment)

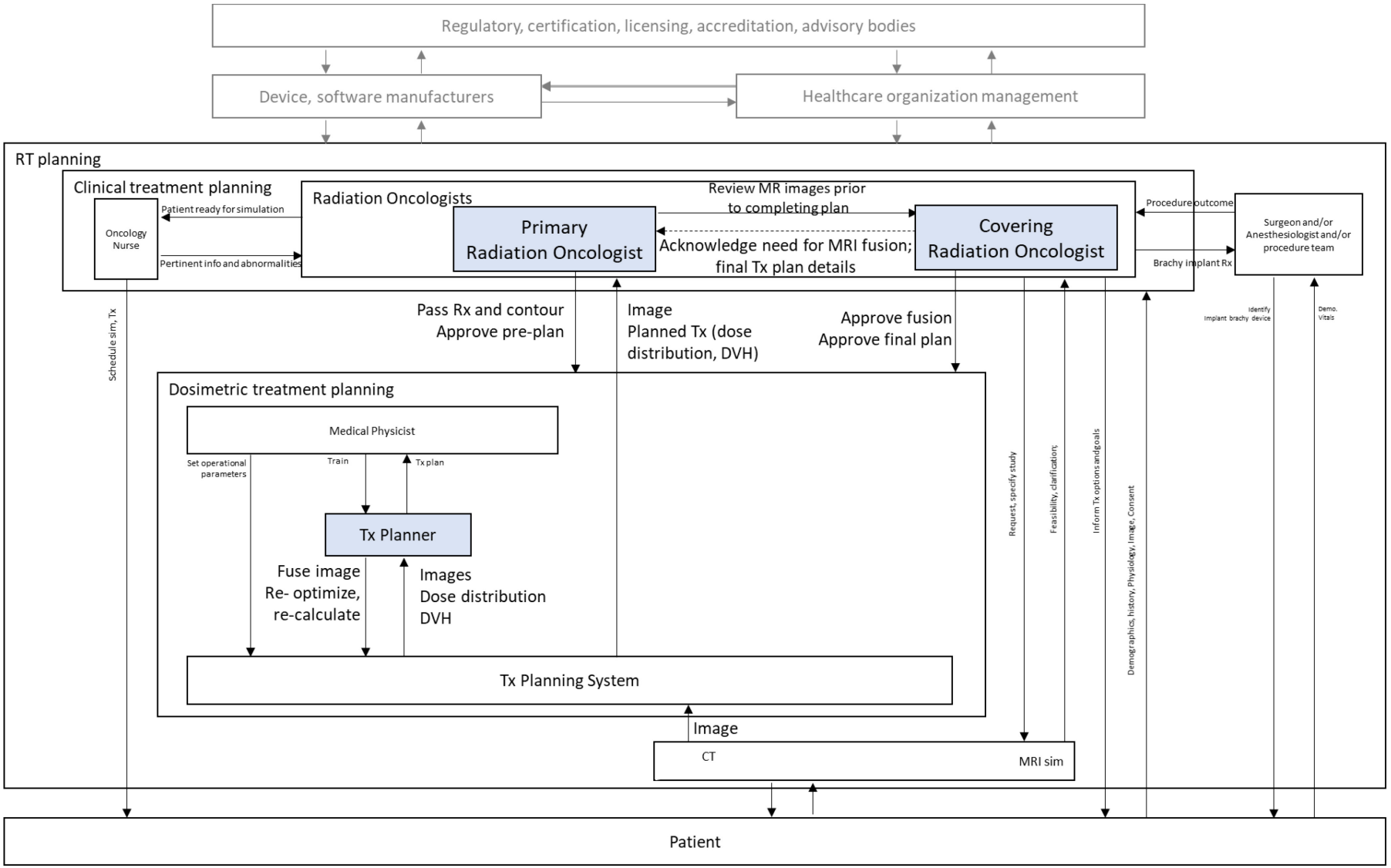


Figure 45 The part of the SCS showing the details of RT Planning
(CT = computed tomography; DVH = dose-volume histogram; MRI = magnetic resonance imaging; Rx = prescription)

Step 3: Component factors

This section shows the potential explanations for the behavior of each controller, beginning from the lower level of the safety control structure and moves upward. The explanations are formulated around flaws in the understanding of the controller and the contextual factors that shaped these flaws. Where applicable, unanswered questions are documented as well.

Treatment Planner (Dosimetrist)

Responsibility relevant to this safety incident

- Fusion and registration (primary)

Contribution to the hazardous state

- Did not fuse MR image to CT for contouring

Process model flaw

- Did not know the need to fuse the MR image

Contextual/process model factors

- Fusion of MR image for a sarcoma case was the norm but a physician order was still required for its execution. The original request by the physician to start the treatment planning process was likely issued to shorten the time to treatment plan review and did not include the fusion order.
- As the physician subsequently called to request the MR image to be fused, the physician did not reach the dosimetrist handling the case because it was the end of the work day, and there was no dosimetrist available to perform the task.
- The request was also transmitted with an electronic note in the TPS to the covering radiation oncologist, but this note was not read subsequently. Ultimately, the dosimetrist did not actually get an active request for MR image fusion.
- The TPS did not require MR image fusion for sarcoma patient before other contouring or treatment planning activities could be performed.
- The treatment plan did receive final approval

Primary Radiation Oncologist

Responsibilities relevant to this safety incident

- Confirm registration, when applicable
- Define the target volumes on the images obtained during simulation
- Specify the normal tissues requiring segmentation
- Specify dosimetric objectives and priorities for the target(s) and OARs
- Detail the total desired dose, fractionation, treatment technique, energy, time constraints, on-treatment imaging and all other aspects of the radiation prescription. In some cases, the prescription may be modified based on the results of the treatment planning process.

Contribution to the hazardous state

- Likely requested treatment planning to start without ordering MR image fusion

- Requested MR image fusion subsequently with a phone call to the dosimetry planning group without reaching the dosimetrist in charge of the case
- Requested the covering radiation oncologist to review MR images with an electronic note that was not read in the end
- Did not discuss the case at the originally scheduled chart round

Process model flaws

- Likely believed that starting the treatment planning process before MR image fusion was completed would quicken the process, allowing the plan to be finalized before departing for the conference
- Considered the phone call to the dosimetry planning group a request for MR image fusion
- Believed that the covering radiation oncologist would read the electronic note
- Thought that both the phone call and the electronic note were sufficient in getting the MR image fusion completed

Contextual/process model factors

- The radiation oncologist was departing for a conference, and there was urgency to commence treatment for the patient.
- There was likely no standardized method or training for the use of electronic (treatment setup) notes. Therefore, discrepancy existed on the legitimacy of its use to coordinate treatment plan review activities between staff.
- Communication or request between the primary and covering radiation oncologists was likely not standardized by channel and content.
- Case review at chart rounds was continuously delayed due to lengthy discussion of other cases.

<u>Covering Radiation Oncologist</u>

Responsibilities relevant to this safety incident

- Selecting and formally approving the plan ultimately chosen for treatment, verifying that it satisfies the clinical requirements and prescription(s) and that it can be carried out accurately

Contribution to the hazardous state

- Reviewed and approved final treatment plan without reviewing MR images

Process model flaws

- Believed the contouring was accurate
- Did not know the need to review the MR image

Contextual/process model factors

- There was urgency to commence treatment for the patient.
- The TPS did not alert for the presence of electronic (treatment setup) note nor did it prompt for acknowledgement.

- There was likely no standardized method or training for the use of electronic notes. Therefore, discrepancy existed on the legitimacy of its use to coordinate treatment plan review activities between staff.
- Communication or request between the primary and covering radiation oncologists was likely not standardized by channel and content.

Treatment Checker (Medical Physicist)

Responsibilities relevant to this safety incident

- Review of final treatment plan (final review)

Contribution to the hazardous state

- Did not identify that the MR image was not fused to CT for contouring in final review

Process model flaws

- Possibly
    - believed that the lack of MR image fusion was justified
    - did not know that MR image fusion was the norm for sarcoma cases

Contextual/process model factors

- In general, by the time that a treatment plan gets to the medical physicist for checking, it has already been iterated between the treatment planner and the radiation oncologist and is typically just one day or hours from patient treatment. At this time, the physicist would look at the dose-volume histogram to see if there is any gross anomaly or discrepancy from dose constraints. An independent calculation and comparison is not done nor required.
- The medical physicist likely thought that the MR image was not included as a justified exception by the radiation oncologist(s). Ultimately, the fusion of MR image was an oncologist decision and the medical physicist did not raise this as a question as a norm.

Unanswered questions

- Was the Treatment Checker rushed for this case?

Departmental Management

Responsibilities relevant to this safety incident

- Share concerns with the vendors and work with them to improve products
- Establish management of change requirements for evaluating all changes for their impact on safety, including changes in the safety control structure.
- Provide physical and personnel resources for safety-related activities. Provide adequate resources for personnel, equipment, and time for commissioning

Contribution to the hazardous state

- Selected and implemented TPS and EHR with which use discrepancies between staff occurred

- Did not set and train staff for procedure to coordinate treatment planning tasks, with or without the use of TPS and EHR
- Did not staff dosimetrist to fuse MR image when primary oncologist called to request
- Did not allocate sufficient staff time for chart rounds (or have enough staff to complete chart rounds on schedule).

Process model flaws

- Regarded the electronic note a minor feature of the information systems
- Considered staff experienced with care coordination
- Possibly considered staffing and work hour arrangements adequate

Contextual/process model factors

- The general practice of procurement requirement specification did not include the level of detail pertaining to electronic note. The procurement process, including the generation of RFP, as practiced in healthcare industry did not involve the level of time, staffing, (systems engineering) expertise that engineering/defense industries had.
- The alternatives for information systems were few thus the department did not have much bargaining power for customization.
- More major features in the information systems took up training time.
- Opinion can differ on the need of MR image fusion for sarcoma cases. It may not be indicated or bring value for particular cases. In general, clinician autonomy is highly valued.
- Treatment planning for each case typically runs over weeks from the first patient consultation and many care coordination tasks routinely take place without complication. This creates a false sense of security.
- Information of safety events involving TPS and EHR systems, particularly of nature similar to the current incident, would not typically get reported as information system users may not consider these events reportable. While accreditation standards, e.g., APEx by the American Society for Radiation Oncology (ASTRO), stipulate the need for safety event reporting within the healthcare organization, it does not have specifics covering information system incidents.
- The case volume in the department may have prevented chart rounds to be extended. Chart round delays are not uncommon across systems. Also, the case volume target is typically set at the institutional level.

Unanswered questions

- Was there a previous incident report on task coordination, or TPS use discrepancy?
- Was a request submitted to organizational executives to budget for dosimetrist overtime work and increased capacity for chart rounds?

<u>TPS, EHR Software Manufacturer</u>

Responsibilities relevant to this safety incident

- Educate the user as to the capabilities and limitations of their products
- Create user-friendly products to maximize the probability that they are used as intended

Contribution to the hazardous state

- Produced TPS that allowed treatment plan approval without MR image fusion for sarcoma case
- Produced TPS that had information in an electronic note that was missed by the recipient
- Did not provide sufficient information to healthcare system and user for potential use discrepancy

Process model flaws

- Considered TPS, as produced, facilitated safe treatment planning
- Considered the communication methods, e.g., electronic note feature, effective in conveying information to intended recipient
- Considered the information provided to healthcare system and user sufficient for software implementation and use

Contextual/process model factors

- The TPS was functionally capable of performing MR image fusion; capturing and displaying the information in the electronic note. There was no design requirement in the request for proposal (RFP) specific to these features. Moreover, the FDA did not request information on the training program as part of the premarket submissions.
- Medical providers need to retain the authority and ability to make medical decisions. The TPS (or the manufacturer) cannot provide treatment advice.
- Enough flexibility needs to be preserved in the TPS, and EHR as different healthcare systems have different preferences. Restricting the design and functions too much would limit market share. Again, clinician autonomy is highly valued.
- How to implement and use the information system is also dependent on the healthcare organization. Different organizations have different budget, time, staff desire for training.

Unanswered questions

- Did the manufacturer know about similar instances of missed electronic notes?

<u>Organizational Executives</u>

Responsibilities relevant to this safety incident

- Formulate organization mission and key goals.
- Ensure high quality financial management. Provide physical and personnel resources for safety-related activities.
- Create an organizational safety policy
- Establish organizational safety standards and then implement, update, and enforce them. Establish incident and accident investigation standards and ensure recommendations are implemented and effective.
- Establish management of change requirements for evaluating all changes for their impact on safety, including changes in the safety control structure.

Contribution to the hazardous state

- Did not adjust staffing level or patient goals effectively when cases are continually delayed in chart rounds and no dosimetrist could work overtime for end-of-work-day image fusion request
- Did not set or enforce an effective information system procurement policy to prevent the use discrepancy between staff with the TPS and EHR systems

Process model flaws

- Possibly believed that departmental staffing levels were adequate
- Believed that information system procurement in the organization was effective

Contextual/process model factors

- There were national recommendations, but not regulatory requirements, for staffing. Moreover, based on industry norms, even when staffing levels are adjusted, it may be incremented as a fraction of a full-time equivalent (FTE). This is hard to operationalize in the real world. If temporary staff is brought in, proficiency development takes time and may not provide much relief in the near term. Temporary staff also goes through high turnover.
- While organization-wide information systems get executive level attention for its selection, implementation, and management, the TPS and EHR systems in this incident are specialty-specific (for use in radiation oncology) and do not get the same treatment. Specialty-specific information systems selection, implementation, and management are left to departmental discretion as executives are not experts in each medical specialty.

Unanswered questions

- Was the organization facing financial challenges?
- What was the actual staffing level in the periods of time surrounding the event (e.g., as chart rounds kept being delayed)?
- What was the target patient volume set by the executives and how was staffing adjusted?

<u>Regulatory, certification, licensing, accreditation, advisory bodies</u>

Responsibilities relevant to this safety incident

- Set regulations, standards, and policies that identify organizational outcomes that hospitals must achieve
- License providers to use specialized devices

Contribution to the hazardous state

- Approved TPS and EHR systems that contributed to the contouring incident
- Did not request TPS and EHR manufacturer to update the software or facilitate training to mitigate the potential of use discrepancy, lack of image fusion for sarcoma cases
- Did not set adequate requirements on staffing needs, and information system procurement and implementation that prevented the incident’s occurrence

Process model flaws

- Believed that TPS and EHR systems were adequately safe in their design, implementation and use

- Considered individual organizations could establish and maintain staffing requirements locally for safe operation.

Contextual/process model factors

- FDA’s requested content of premarket submissions for software did not include training. It is unclear whether this omission was a conscious decision by the agency to minimize burden for manufacturers.
- There is wide disparity in views of whether technology was a facilitator or barrier to clinical guideline implementation. Specifically, some physicians and nurses consider decision support with alerts hampers care delivery due to the increased time needed. Using TPS as a means to implement the MR image fusion recommendation would be controversial.
- Information of safety events involving TPS and EHR systems, particularly of nature similar to the current incident, is not typically get reported both within an organization (mentioned previously) and at a state or national level. At the national level, some software and software functions, TPS specifically, are a regulatory oversight focus of the FDA and thus qualifies for medical device reporting. However, the bar that mandates reporting is set very high—only if the incident involves a malfunction for manufacturers and there is serious injury or death occurs for device user facilities. Therefore, the current incident where the information system did not malfunction and it is unclear that the patient was actually harmed would not qualify for mandatory reporting.
- National staffing recommendations, e.g., “[m]inimum of one radiation oncologist present during treatment hours” and “[a]s needed, ~ one [dosimetrist] per 250 patients treated annually” are set but not requirements. Notably, the recommendation on radiation oncologist is not parameterized by patient volume. It was reported that staffing needs vary greatly among organizations based on case volume and complexity, technology used, and the presence of satellites or affiliated practices. Therefore, the onus of setting the requirements is placed on individual organizations. For example, accreditation standard, e.g., APEx by ASTRO, requires "radiation oncology practice establishes, measures and maintains staffing requirements for safe operations in clinical radiation therapy."

Step 4: Systemic factors

This section describes the systemic causal factors, which negatively impacted the behavior of many or even all of the components in the system. In other words, these factors undermined the ability for multiple controllers to fulfill their safety responsibilities.

Communication and coordination

In the complex system to deliver RT, communication and coordination is crucial. Inadequate or inaccurate information is a flaw that commonly contributes to safety events as it leads to poor decision making. This flaw certainly manifested in this incident.

It is evident that some communication and coordination links were missing in the frontline setting. Despite the value of MR image in RT planning for soft-tissue sites, the lack of image fusion was not conveyed to the multiple members of the care team. In general, the decision to omit image fusion, even when properly made, was not routinely justified and transparent to the team. Therefore, the treatment planner, covering radiation oncologist, and the treatment checker likely had a potential assumption that the omission was by intention.

Next, the coordination between primary and covering radiation oncologists was uni-directional. This lack of close-loop communication likely led to a potential assumption by the primary radiation oncologist that the treatment plan was approved by the covering radiation oncologist after having reviewed the MR images. Furthermore, chart round delays hampered coordination between primary and covering radiation oncologists.

The TPS, which was the platform of interest, did not provide adequate feedback to the covering radiation oncologist nor the primary radiation oncologist regarding the request to review the MR images and the acknowledgement, respectively. Also, the TPS did not have provisions to indicate the lack of image fusion and potential justification.

Beyond the frontline activities, flawed communication also manifested in practice management activities. The means to coordinate treatment activities was not defined and communicated by the management to frontline staff, as with the situation regarding the chart round delays or any potential need to readjust resource allocation to prevent further delay.

Safety information system

A safety information system identifies, stores, and distributes information (hazards, identified loss scenarios, actual safety events, etc.) that indicates the effectiveness of safety controls. Safety information are provided to the relevant decision makers for action. Flaws in the safety information system can lead to inaction or unsafe action. In this incident, it is unclear if the safety information system was effective in identifying signals that could have prompted actions to prevent the incident.

Specifically, known vulnerabilities exist with incident reporting systems in general: insufficient reporting guidance, sparse and incomplete in-depth analysis, and low sharing of information beyond the organization. With this knowledge, there were likely other instances of electronic notes in the TPS being overlooked but were not reported. Even reported, it was likely considered a user error and trivialized. Further sharing of this information with the software manufacturer or the FDA was unlikely, reinforcing the perceived satisfactory quality of the TPS instead of providing a signal to improve the product or the way it was used.

Moreover, it is unclear if the safety information system tracked relevant quality metrics routinely. For instance. the lack of fusion of MR image for sarcoma patients. Without this

information, care team and departmental leaders likely misunderstood the need for improvement.

Economics

In the conventional fee-for-service payment model, quality and safety activities are not directly reimbursed. Training (e.g., on the use of TPS), reporting safety incidents (and participating in their analyses), supporting the development of consensus guidelines, or evaluating software options for procurement and the practicality of a workflow do not carry financial incentives. Yet, these activities were obviously inadequate in this incident. The lack of financial incentives may have compressed the time that staff member could contribute to these activities, enabling the incident to take place.

Changes and dynamics

It could not be determined whether changes and dynamics contributed to the incident. Given more information, exploration would have been made into the following areas:

Staff, software, policy, and procedure: Were the staff (both frontline staff and management) new hires or did they just return from an extended leave of absence? Similarly, was there implementation of new software (e.g., the TPS), or procedures pertaining to treatment planning? Were there any changes to billing or personnel policies? If any of these conditions applied, the staff may not have been ready to perform the job functions and the changes may not have been well managed. The process to develop and implement these changes should be examined. For instance, was the change accurately communicated? Was training provided and adequate? Was safety, proficiency, and practicality assessed? Were lessons learned shared and the software, policy, and procedure refined?

Patient volume: Was there an abrupt increase in patient volume? As mentioned, the staffing decision tends to be made at the organizational level and takes time before adjustments can be effectively made. If patient volume increases in a relatively short period of time, it could strain the care team, impacting the abilities for dosimetrists to fuse images and radiation oncologists to fully specify and review treatment plans, discuss cases at chart rounds without delay, etc. If applicable, the process to control the patient volume (e.g., referrals and scheduling) should be examined.

Step 5: Safety intervention recommendations

This section documents the recommendations to address the identified causal factors. For readability, the recommendations are organized around keywords. While a keyword is selected for each recommendation, multiple keywords may actually be applicable.

Practice change

- RT planning is to use MRI-only treatment planning for sarcoma patients unless MRI cannot be acquired for patient-based reasons

Specific to MR image fusion

- Radiation oncologist is to use a modified Rx template that requires justification if MR image fusion is to be omitted for sarcoma patients
- Departmental management is to modify departmental procedure to require the need for MR image fusion to be specified in a Rx, and to set a policy that allows MR image fusion omission (for sarcoma patients) only for patient-based reasons
- Departmental management is to cover the need to specify MR image fusion in Rx during the orientation training for oncologists
- Departmental management is to cover the need to seek clarification for MR image fusion if the information is missing from Rx; that an incident report should also be filed to pursue further improvement in the orientation training for dosimetrists
- Safety committee is to audit justification for MR fusion omission (for sarcoma patients) every month.

Technology

- Regulatory and other advisory bodies are to define RT best practices for incorporation in TPS, EHR; regulate and approve TPS, EHR designs based on the assistive features to facilitate RT best practices.
- Regulatory and other bodies are to regulate and approve TPS, EHR designs based on past safety events and to request recall promptly based on safety events
- EHR, TPS manufacturer is to update EHR, TPS to provide error message and perhaps even restrictions from plan finalization when there is a deviation from normative practices (e.g., omission of MR image fusion for sarcoma patients).
- The department is to include design requirement for assistive features that facilitate RT best practices in RFP
- EHR, TPS manufacturer is to design and update EHR, TPS with assistive features to facilitate RT best practices.
- EHR, TPS manufacturer is to design and update EHR, TPS to reflect the learning from safety events

Safety information

- The department is to create an efficient and simple reporting template that staff can use to report safety events involving TPS and EHR systems
- The department is to train staff to report safety events that involve TPS and EHR systems
- The department is to analyze TPS and EHR safety events to derive learning and manage changes to these systems based upon the learning
- The executive is to allocate resources for safety analysis of TPS and EHR safety events

- EHR, TPS manufacturer is to more proactively collect use experience to identify safety events
- The department is to share safety information regarding TPS and EHR via direct communication with manufacture safety/technical staff
- EHR, TPS manufacturer is to send instructions or recall products promptly based on identified safety events
- Regulatory and other bodies are to more proactively collect incident report for safety events with TPS, EHR
- Healthcare organization is to more proactively file incident report for safety events with TPS, EHR via voluntary reporting
- Quality metrics on the utilization of MR image for sarcoma patient is to be automatically generated from TPS, EHR; safety committee to audit metrics every month
- The executive is to monitor safety reports on the effectiveness of safety analysis and safe procurement decision making

Communication

- (Not applicable if requesting through direct interaction, e.g., phone call; otherwise,) the Primary radiation oncologist is to use Outlook reminder feature for task requests.

  Similar approaches for others making task requests of the Tx planner and covering radiation oncologist.
- The department is to conduct an operational study by observation/survey to identify communication means that are used for task requests.
- The department is to configure TPS for electronic note acknowledgement and automatic re-prompting. If this feature is not available, either manufacturer is to build this feature or task requests should not be sent through TPS.
- The department is to train and set procedures for using agreed and acceptable communication means for task requests between treatment planning team members.
- The department is to require agreed content for task requests and set the associated training and procedures. The department is also to produce communication templates for the anticipated task requests and communication means.

Care coordination

- Patient scheduling is to be done with a scheduling program that checks for planned leave of planning team members. If a planned leave is imminent, a covering team member is to be incorporated at the start of treatment planning.
- Patient scheduling is to be done with a scheduling program that checks for case review backlog and bandwidth. If the backlog exceeds a safe threshold, patient is scheduled at a time that allows the backlog to reduce below threshold.

Change management

- The department is to allocate resources and make procurement decision based on a safety analysis that comprehensively account for unsafe interactions
- The executive is to set policies that require comprehensive safety analyses, accounting for unsafe interactions, for procurement decisions; and to allocate resources for such safety analyses

Role and responsibility

- If the scope of the treatment plan checking by the Tx checker is to be expanded, the department is to change procedure to provide additional time and to allocate staffing accordingly
- If the scope of the treatment plan checking by the Tx checker is to be expanded, the department is to train for the additional tasks.

Management

- The department is to monitor automated reports of aggregated staffing, treatment hours and trend and forecast at the tactical level
- The executive is to monitor automated reports of aggregated staffing, treatment hours and trend and forecast at the strategic level
- The department is to allocate staffing based on treatment hour forecast; to reschedule patient if needed
- The executive is to set goals for a time horizon that aligns with staffing changes; to set goal thresholds with built-in buffer for staffing limitations
- Regulatory and other advisory bodies are to improve the minimum quality and safety activities that is required for licensing and accreditation
- The executive is to provide financial incentive, time allocation, promotion consideration based on staff's contribution to quality and safety activities

Appendix C. Generic safety control structure

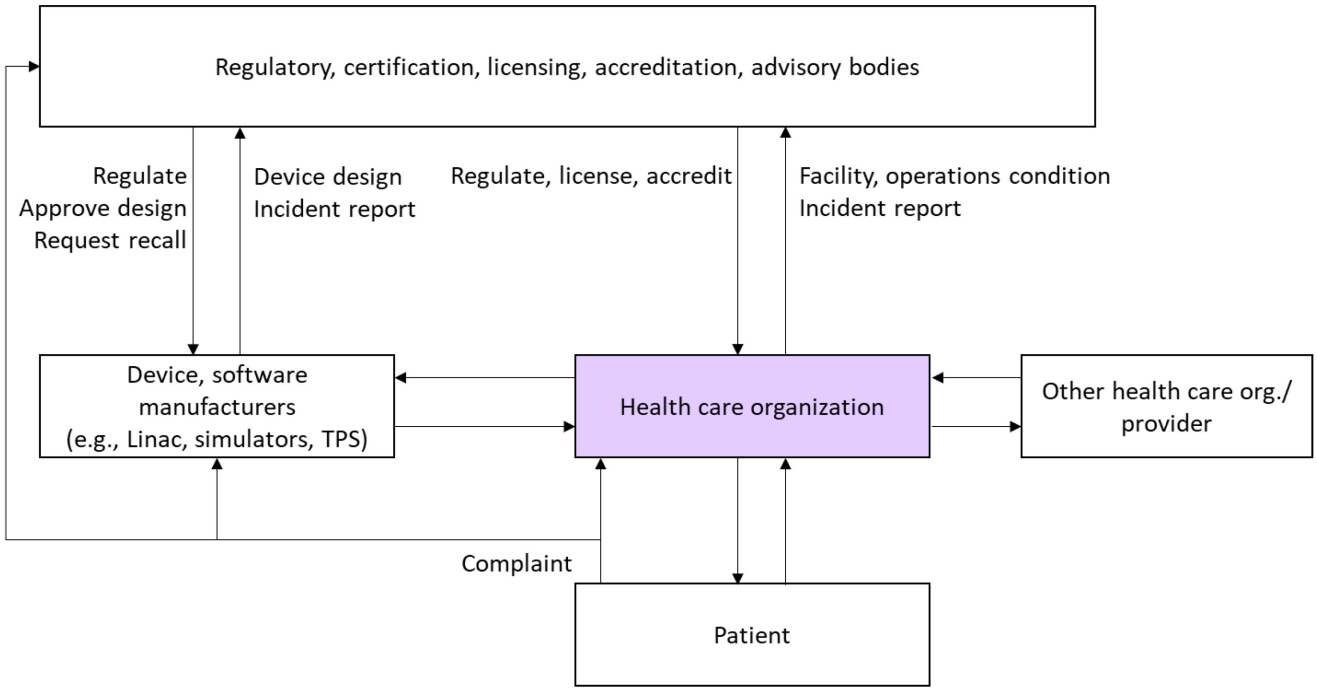


Figure 46 The overall safety control structure of RT. Unlabeled arrows are elaborated in later figures. (Linac = linear accelerator; org. = organization; TPS = treatment planning system)

The overall SCS (Figure 46) shows the inter-organization interactions to achieve RT safety. Regulatory, certification, licensing, accreditation, advisory bodies (hereafter "regulatory and advisory bodies") serve as the controller at the highest hierarchical level. The Food and Drug Administration (FDA) and the Nuclear Regulatory Commission (NRC) are the main federal regulators. These entities are complemented by their state counterparts (e.g., Massachusetts Department of Public Health) (Killewich and Singleton, 2011; Vetter, 1997). Non-governmental accreditation and advisory bodies also exist (e.g., the American Board of Radiology (ABR)).

The components shown are interconnected. The regulatory and advisory bodies control not only the healthcare organization that delivers RT (hereafter "treating healthcare organization") but also the manufacturers of many devices and software that are used in radiation oncology. The treating healthcare organization also coordinates with other healthcare organizations or providers (e.g., primary care physician, emergency department, etc.) in the larger healthcare system.

The interactions of most interest in Figure 46 are those involving the regulatory and advisory bodies. To start, they regulate, license and accredit the treating healthcare organization. Besides the regulations that govern general medical care, additional laws apply due to the involvement of radioactive materials. For instance, the NRC stipulates special procedures to be used with unsealed radiation sources (Pawlicki et al., 2019). Accreditations and certifications also shape the treating healthcare organization. Of these, the Joint Commission (TJC), and the Centers for Medicare & Medicaid Services (CMS) often provide the more general ones whereas the Quality Oncology Practice Initiative (QOPI) by the American Society of Clinical Oncology is an example of the more specialized one (Jost, 1994; McNiff et al., 2009; Roberts et al., 1987). Other than the focus, the level of detail varies as well. For instance, the Accreditation Program for Excellence (APEx) by the American Society

for Radiation Oncology (ASTRO) specifies even the required documentation elements in a patient evaluation prior to the initiation of RT (ASTRO, 2019).

Licensure and certification also affect individual clinicians. Professional certifications are provided by entities such as ABR, Oncology Nursing Certification Corporation, etc. (McMillan et al., 2002). Maintenance of certification is a recurrent process. For instance, the ABR requires a clinician to be in good professional standing, to have met the continuing education, knowledge, judgement, skills requirements, etc. for recertification (Kun et al., 2007, 2005).

The technology manufacturers are also subject to control. The FDA not only approves technology but also has the authority to request recall when any product shows unmitigated or newfound risk (FDA, 2020). However, not all technology is subject to the premarket notification and approval requirements. For instance, the medical image digitizer—arguably an important component in radiation oncology—is part of the exemption (FDA, 2019).

To exercise their control authority, the regulatory and advisory bodies are informed by a variety of feedback. For instance, FDA device approval is predicated upon the submission of the device information in the premarket notification; recall decisions are triggered by incident reports through the postmarketing surveillance program. Similarly, the accreditation bodies make site visits to assess facility conditions and operational status. Patient complaints play a critical role as well.

The treating healthcare organization is handled as a “black box” in Figure 46 thus its innerworkings are hidden. The details of its interactions with manufacturers and other healthcare providers are the next focus.

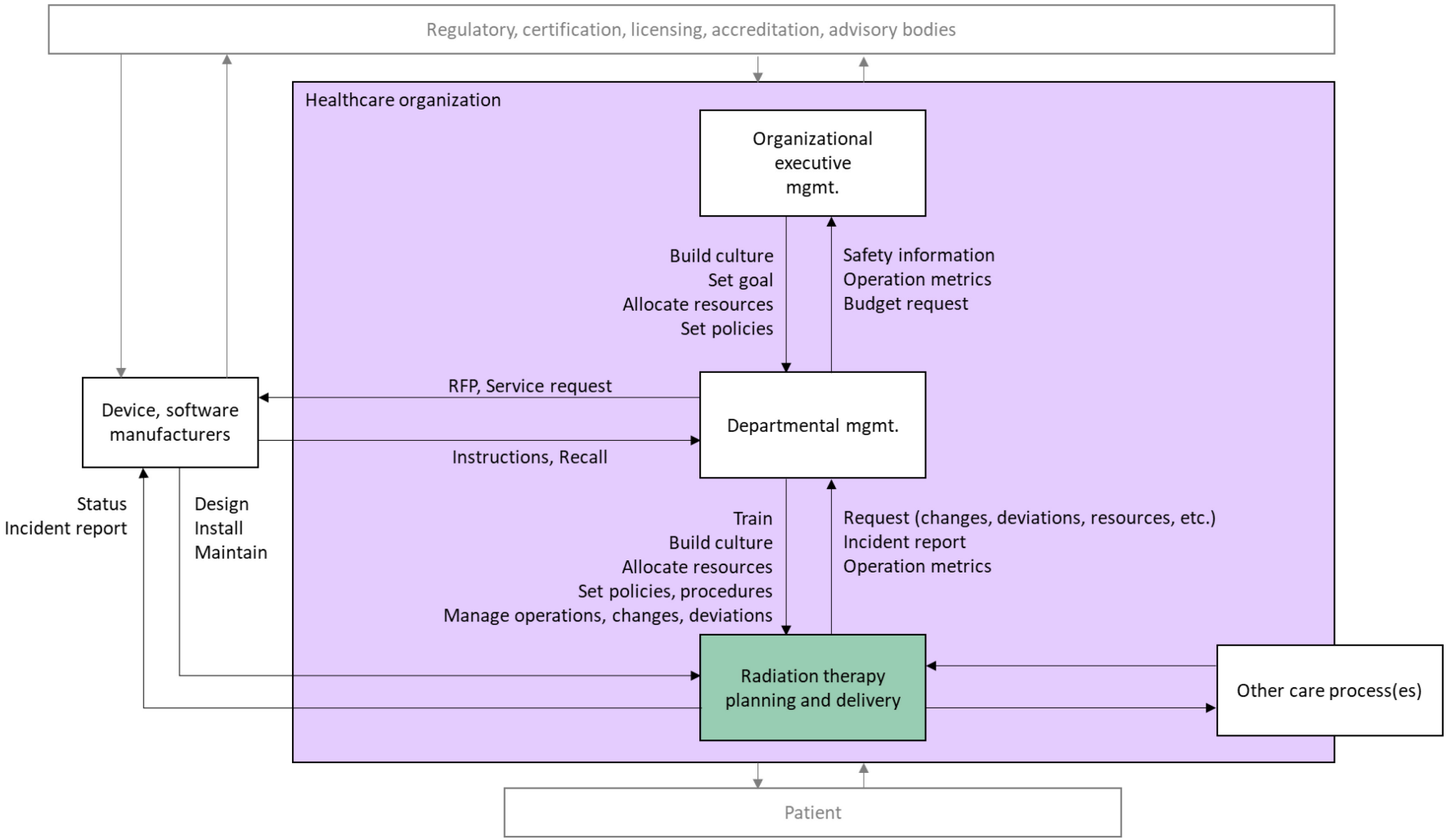


Figure 47 The details of healthcare organization managment

(mgmt. = management; RFP = request for proposal)

Expanding the details of the treating healthcare organization (Figure 47), the controllers include the organizational executive management and the radiation oncology departmental management. External to the organization, the manufacturers also play a part, and the interactions are included in this figure. These controllers directly determine how RT planning and delivery is performed by frontline workers.

Working under the regulatory, licensing and accreditation requirements—control inputs—from the regulatory and advisory bodies, the organizational executive management performs a few control actions that carry far-reaching impact and are challenging to do well. With the ultimate authority in the organization, the executives build a culture that permeates the organization (Leveson and Thomas, 2018, chap. 7). For a safe culture to exist, words must be accompanied by actions. Therefore, resource allocation and goal setting are control actions that either reflect or conflict with the safety messages. These control actions further shape the work conditions on the frontline. If the resource allocation is not compatible with the set goal, the care capacity will be exceeded, creating time and emotional stress. This compatibility is critical given the ever increasing demand for cancer care (IOM, 2013).

In terms of feedback, safety information and operational metrics are crucial to keep the executives informed. Curating the information comprehensively is a difficult task and often requires a dedicated institutional team. Budget requests also inform resource allocating. Competing budget requests from different departments may render the task very challenging given the current backdrop of rising costs and changing payment system (Hartman et al., 2020; Teckie et al., 2014).

Shifting the focus to the radiation oncology departmental management, the controller has control actions (e.g., staffing allocation, deviation and change management, and procedure setting) that are more technically detailed and dynamic than those of the organizational executive management.

Clinical and operational staff are a critical resource that requires dynamic allocation. Staffing needs vary based on the volume and complexity of the cases, the technology used and the situation at satellites or affiliated practices (Pawlicki et al., 2019). Therefore, detailed operation metrics are useful to the departmental decision makers in assessing the time pressure and adequacy of staffing on the frontline.

Managing “deviation” is another tactical aspect of departmental management. Being human, patients are complex and may render the most thoughtful standard operating procedures inapplicable. For instance, a patient may have an implant of unknown MRI compatibility, but MR images would greatly improve the accuracy of treatment planning for the patient. In this case, the departmental management takes the role of adjudicating the MRI use. Occasionally, this decision has to be made in a short amount of time as well.

Inevitably, changes need to be implemented on the frontline, and the departmental management is responsible for designing, assessing, planning and implementing these changes. For instance, practice improvement ideas may arise from the frontline or as regulations and standards evolve. Past incident reports and operation metrics may be useful to inform these decisions. Also, monitoring the contemporaneous incident reports and operation metrics is crucial once the changes are implemented.

The departmental management also provides training to develop a pool of safe and proficient staff. This should be done in concert with the other control actions, such as managing changes. Furthermore, the training standards are often a control input from regulatory and advisory bodies. Again, incident report and operation metrics are crucial feedback for determining training effectiveness and needs.

Turning to the last controller of interest in Figure 47, device and software manufacturers also enable and shape RT planning and delivery on the frontline. The device manufacturers design, install and maintain the technologies. These control actions are informed by status reports and incident

reports. The level of detail, accuracy and timeliness of the information are important. Besides frontline care delivery, the manufacturers also interact with the departmental management. The manufacturers provide information that influences purchasing decisions, training, staffing, operational use, etc. In return, the manufacturers' actions are driven by requests for proposals, service requests, etc.

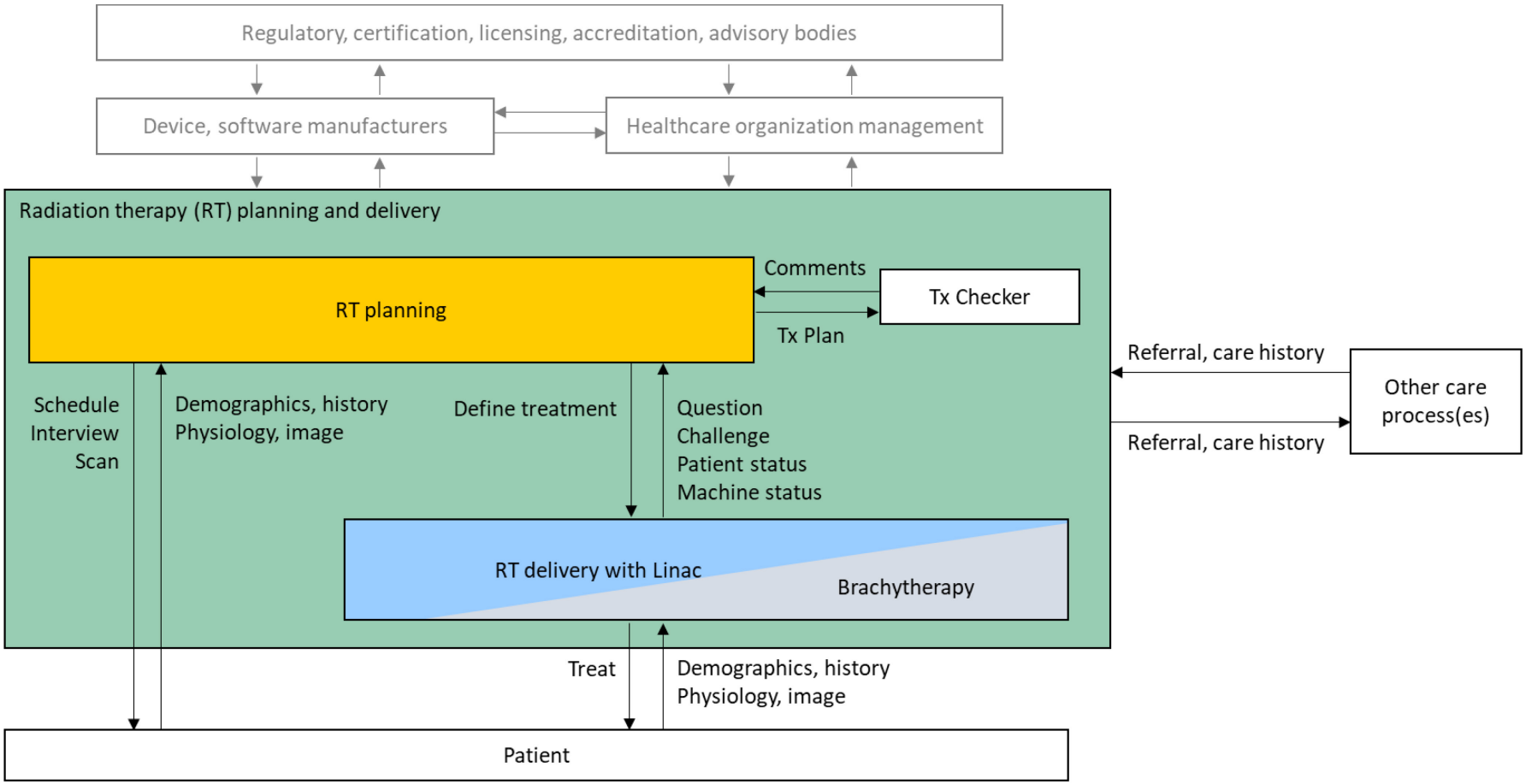


Figure 48 The details of RT planning and delivery
(Linac = linear accelerator; RT = radiation therapy; Tx = treatment)

The frontline RT planning and delivery interactions are separated into individual functions (Figure 48). While RT delivery could be viewed as an actuator that simply executes the treatment plan defined by RT planning, there are a great many decisions—medical, technical and operational—to be made in RT delivery. Therefore, it is explicitly modeled it in its own right. Two delivery modalities are further distinguished: linac and brachytherapy. They are modeled with different figures.

Before going into the details in the other frontline parts, we note that treatment plans are independently reviewed by a treatment checker, usually a medical physicist, prior to being sent for RT delivery. This independent check usually takes place a day or just hours prior to the first treatment session; the treatment checker examines the planned dose for the anatomical structures to treat and to avoid.

Lastly, the patient is intuitively a part of the system in this frontline setting. Because patients may also be undergoing other care process(es) (e.g., receive a cardiology consult on the same hospital visit), the interactions, potentially crossing the system boundary, are depicted also.

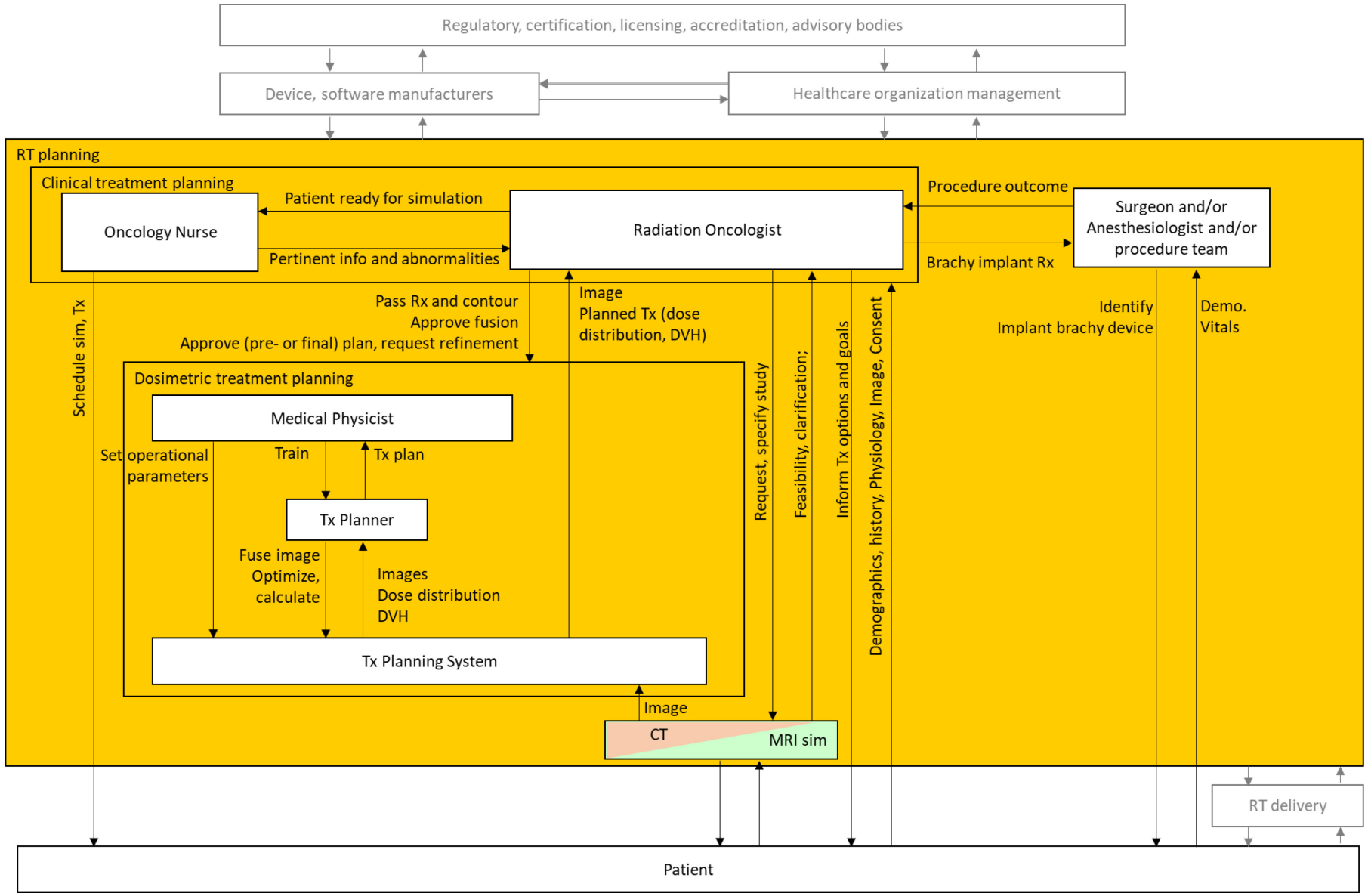


Figure 49 The details of RT planning
(DVH = dose volume histogram; Tx = treatment; Rx = prescription; RT = radiation therapy; CT = computed tomography; MRI = magnetic resonance imaging; sim = simulation)

Expanding the details of RT planning, Figure 49 shows that it involves a diverse team. Oncology nurses and radiation oncologists perform clinical treatment planning, and physicists and treatment planners (who can be dosimetrists or medical physicists) conduct dosimetric treatment planning with the use of TPS. Surgeons, anesthesiologists and/or procedure teams also help prepare the patient by implanting applicator(s) in some brachytherapy cases (Mayadev et al., 2014).

During clinical treatment planning, the patient is heavily involved. Patient interaction starts when the radiation oncologist provides an evaluation in response to a referral or patient request. The physician obtains information such as “pertinent history, current and recent symptoms, physical findings, imaging studies, pathology and laboratory results” (Pawlicki et al., 2019), so treatment options and goals can be offered to the patient. Consent is obtained from the patients if treatment is desired. The physician then works with the oncology nurse to gather additional patient information (e.g., social history—alcohol, tobacco use; daily schedule, commute distance to treatment location, etc. (Rosenzweig et al., 2014)) to enable other visits to be scheduled. Any pertinent or abnormal information is communicated back to the physician to aid planning. The physician then formally specifies a simulation study with a physician order. The detailed interactions to acquire CT and MRI images for simulation are modeled later (Figure 50 and Figure 51).

With the acquired images, the radiation oncologist performs contouring. In some cases, MR and CT images are fused together to improve the image quality. With contouring done, the physician prescribes “areas to be treated, dose, dose fractionation and treatment schedule” (Pawlicki et al., 2019b) with a clinical treatment plan.

Dosimetric treatment planning entails the conversion of the clinical treatment plan into instructions that the treatment devices use to actually deliver the treatment. The treatment planner accomplishes this with the TPS. Modern TPSs have advanced functionalities that optimize the plan and calculate dose. Graphical displays of anatomy, dose distribution and dose volume histogram (DVH) inform the treatment planner so the need for further refinement can be appraised. Once satisfied, the treatment planner notifies the radiation oncologist to review the treatment plan. The physician may approve the plan or request further refinement based on the concordance with the clinical treatment plan. Commonly, dosimetric treatment planning involves several iterations.

Besides handling patient cases directly, medical physicists also train treatment planners. Specifically, medical physicists supervise the work of novice treatment planners and continue the training until proficiency is developed. Medical physicists also set many operational parameters in the TPS.

Simulation is the process to define a geometric relationship between the patient anatomy and the treatment device (Pawlicki et al., 2019). This is done to enhance accuracy and reproducibility of a treatment plan, especially if it involves multiple treatment visits.

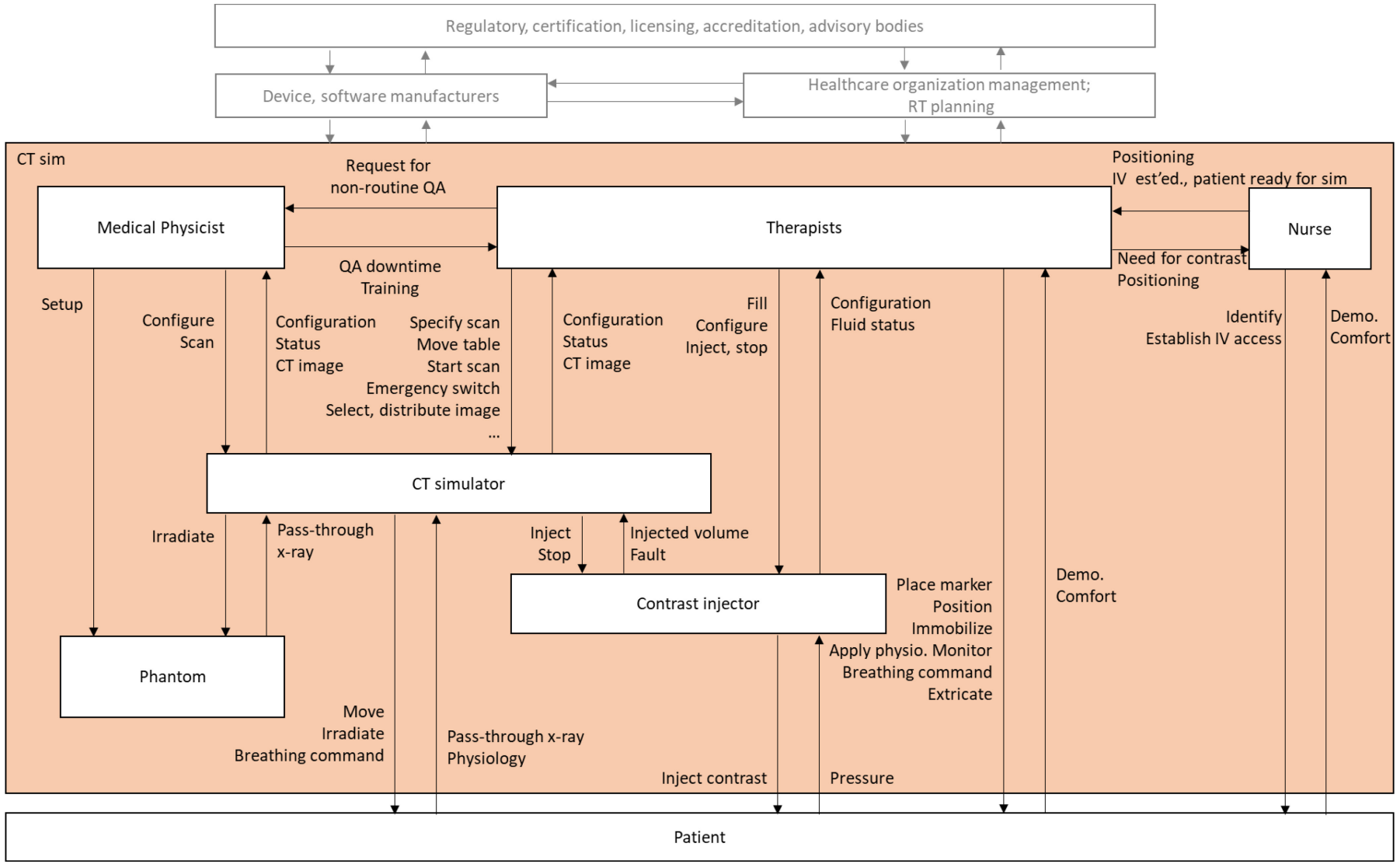


Figure 50 The details of CT simulation
(Demo. = demographics; est'ed.= established; IV = intravenous; QA = quality assurance)

Multiple components contribute to CT simulation (Figure 50), and the process is governed by the study request from the radiation oncologist. In the most straightforward cases, the process involves therapists and a CT simulator. Based on the study request, the therapists place the patient in the treatment position, tag landmarks (with fiducials or tattoos, etc.) and immobilize the patient to prevent movement (sometimes with a device tailor-made for the patient). Getting the demographics and feedback on comfort from the patient is critical for safety. To image the patient, the therapists control the simulator using the displayed configuration and status. The simulator moves the patient into the bore, irradiate the patient and senses the pass-through x-ray to produce CT image(s). If beneficial (e.g., when the organ-of-interest is subject to movement), the therapists may apply physiological monitoring (e.g., heart rate) and/or provide breathing command either directly or with pre-recorded programs in the CT simulator. This enables the CT simulator to irradiate in a specific temporal window based on the patient's physiology to improve image quality.

If the use of contrast is beneficial, a nurse establishes intravenous access. Coordination with the therapists enables the contrast injector to be filled and configured. Where the CT simulator and the contrast injector are interoperable, the former can start and stop injection based on the feedback on the injected volume and faults from the injector. The information enables the CT simulator to irradiate and acquire images as the contrast arrives at the target location. If the CT simulator and the contrast injector are not interoperable, the therapists manually control the contrast injector and command the CT simulator to irradiate.

Some CT simulations do not involve a patient. The medical physicists configure the CT simulator and examine CT image quality by making scans of "phantoms": objects with known characteristics. These activities constitute the quality assurance (QA) of the system. QA may be done at scheduled intervals or in response to a request by therapists or other frontline staff. The medical physicists also coordinate with therapists on the downtime for QA.

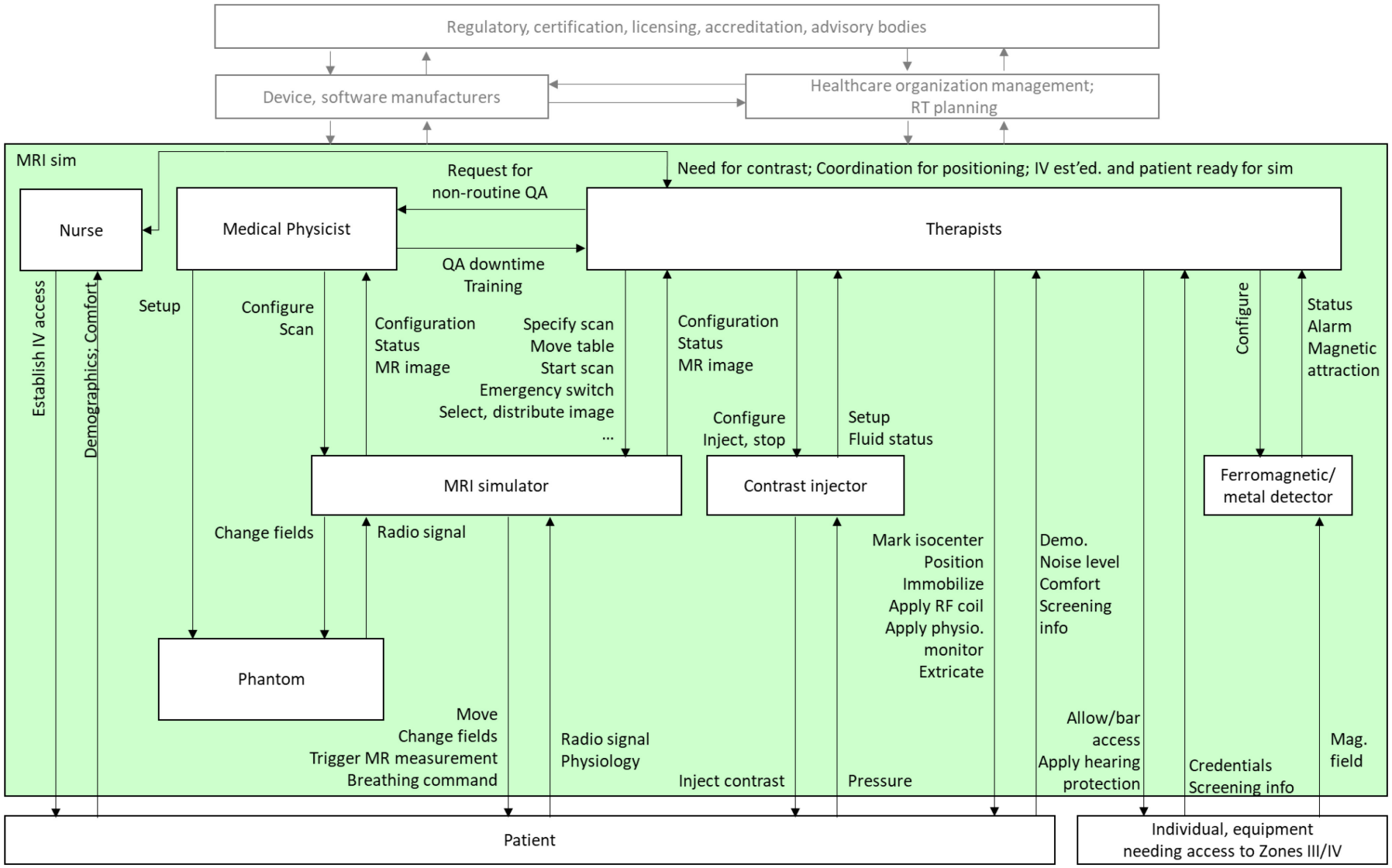


Figure 51 The details of MRI simulation
(Demo. = demographics; est'ed. = established; IV = intravenous; mag. = magnetic; MR = magnetic resonance; QA = quality assurance; RF = radio frequency; sim = simulation)

While the purposes are similar to CT, MRI simulation (Figure 51) involves slightly different hazards. The exposure of humans to ionizing radiation is replaced with exposure to loud noise, heat, and potentially helium as well as the exposure of ferromagnetic objects to strong magnetic field. Therefore, there are additional control actions and feedback. The therapists provide hearing protection to anyone accessing the area and survey any equipment or individual entering the areas *near* (Zone III) or actually where the MRI scanner is located (Zone IV) with ferromagnetic/metal detectors. Informed also by credentials and the safety screening responses, the therapists allow or decline access.

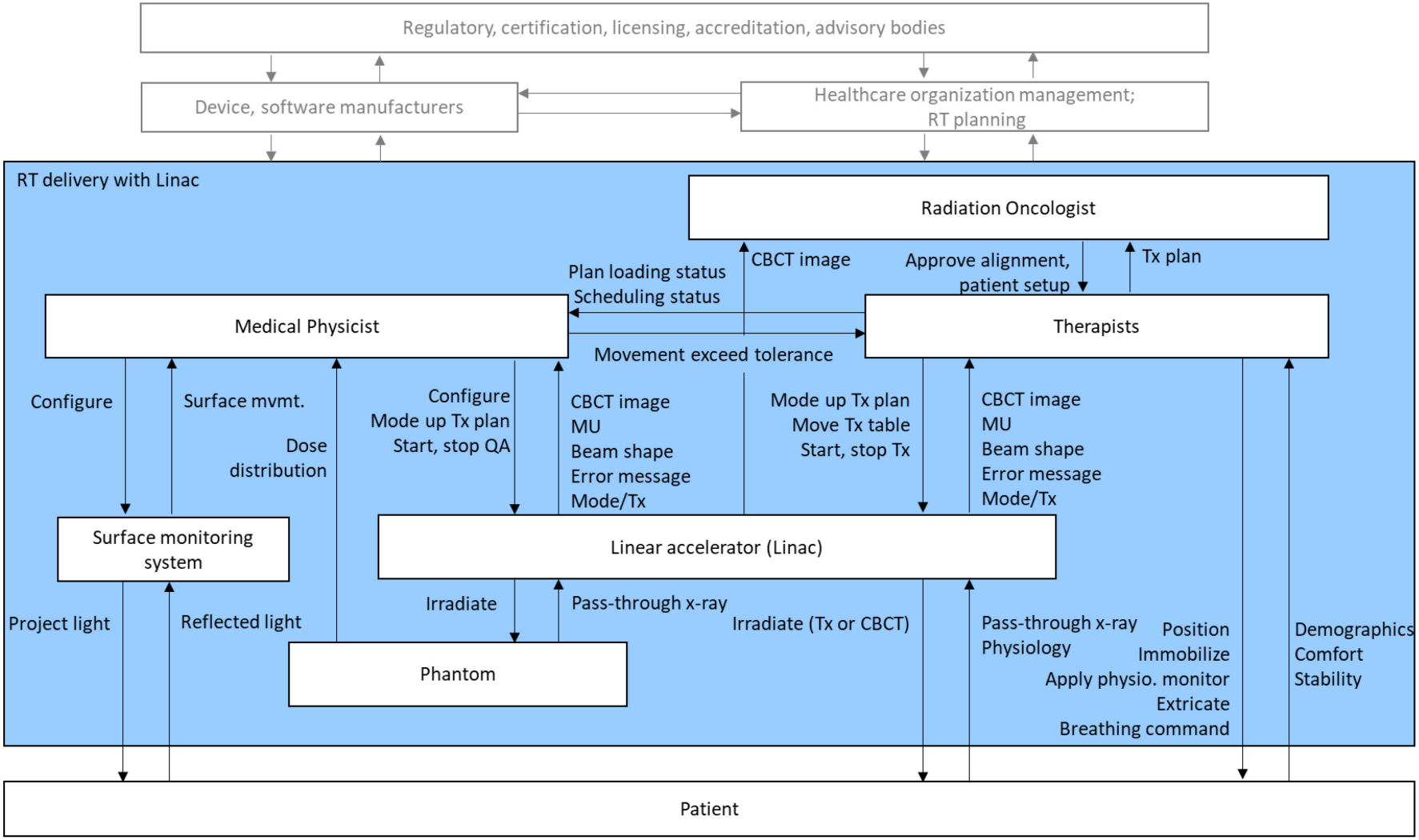


Figure 52 The details of RT delivery with linac
(CBCT = cone beam computed tomography; MU = monitor unit; mvmt. = movement; QA = quality assurance; Tx = treatment)

Switching to part of the system that delivers RT, the operation and maintenance of the linac (Figure 52) is staff-intensive. Therapists, medical physicists, and radiation oncologists are commonly involved. To deliver RT with a linac, the therapists replicate the patient positioning from the simulation session. For image-guided radiation therapy (IGRT), imaging (e.g., cone beam CT) is used to assist with alignment. The radiation oncologist then approves the alignment based on the treatment plan. The therapists configure and operate the linac while monitoring the output (e.g., monitor unit, shape), machine status, etc. For treatment requiring extra precision, the medical physicist operates a surface monitoring system to identify the extent of surface movement. If movement tolerance is exceeded, the medical physicist coordinates with the therapists to stop the treatment and realign the patient.

In terms of the roles of the machines, the linac delivers radiation based on the programmed spatial-temporal trajectory. The intensity and beam shape are also modulated in the newest devices. When treating organs that are subject to movement, the radiation beam can be triggered automatically based on physiology information (e.g., respiratory motion) in some linacs (Freislederer et al., 2015).

The medical physicists again provide QA by testing the different functionalities of the linac using phantoms. Configuration are changed in response to the results.

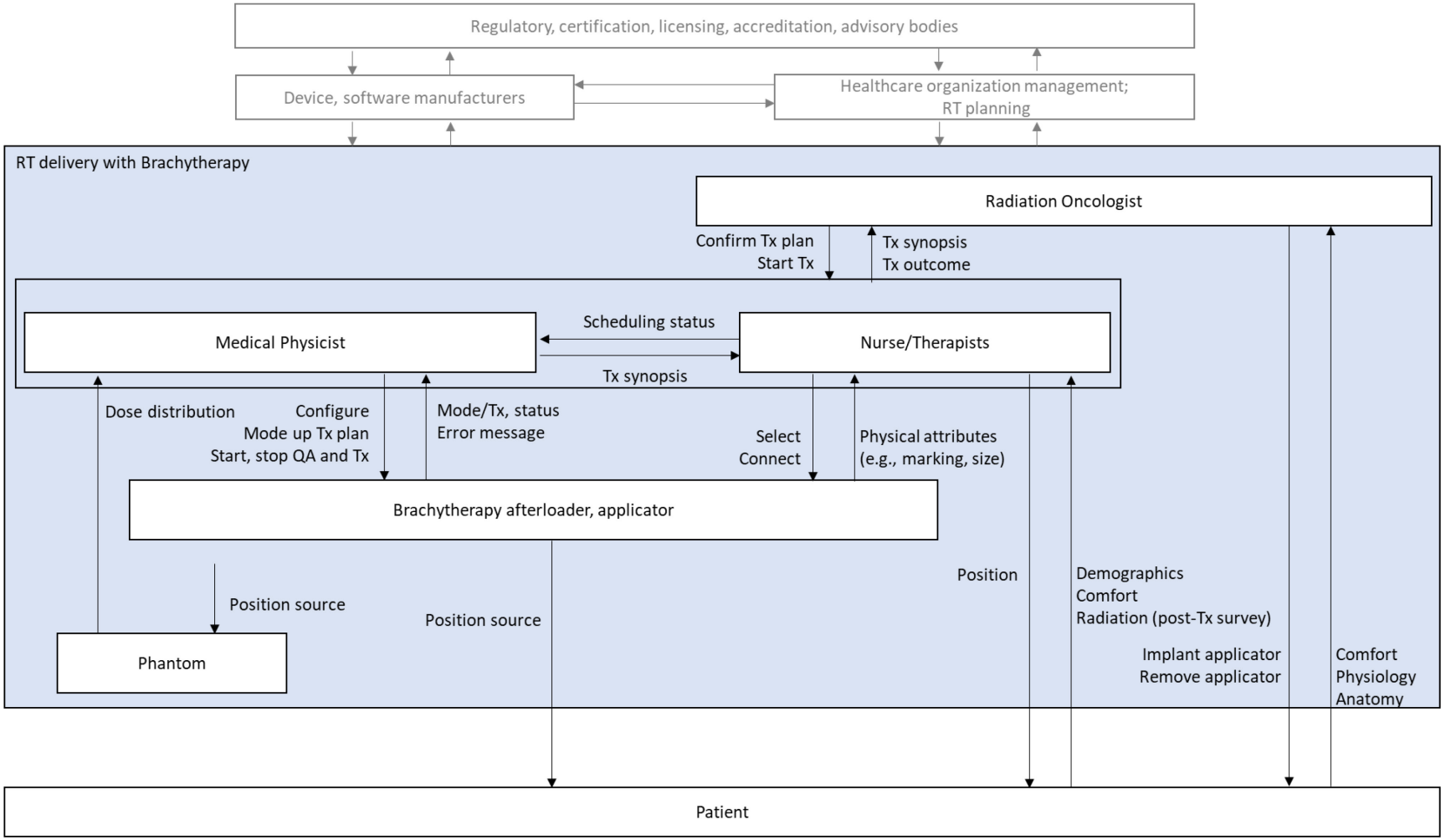


Figure 53 The details of RT delivery with brachytherapy
(QA = quality assurance; Tx = treatment)

Similarly, brachytherapy also involves a diverse staff and equipment (Figure 53). Radiation oncologists, medical physicists and nurses/therapists are the typical staff for operation and maintenance. In terms of equipment, applicator(s) and an afterloader are used (Bidmead et al., 2004).

To treat, the nurses or the therapists prepare the equipment needed for the session. An applicator is selected based on the treatment plan and can be distinguished by its physical attributes (e.g., marking, size). If not preplaced with a surgical procedure, the radiation oncologist implants the applicator inside or on the patient's body. The nurses or the therapists then connect the applicator to an afterloader, which houses the radiation source. The medical physicist loads the patient's treatment plan on the afterloader and starts the treatment as directed by the radiation oncologist. The afterloader then sends the radiation source to the applicator, stopping at the planned location for the specified dwell time. At the conclusion of the treatment, the afterloader removes the radiation source from the applicator. The nurses or the therapists then perform a post-treatment radiation survey of the patient to ensure that no radiation source is left on or in the patient.

As in other subsystems, the medical physicists conduct QA of the afterloader and applicators with phantoms.

Appendix D. Reference controller responsibilities

Controller	Context	Responsibility	References
Regulatory and Other Bodies	General	• Protect the health and safety of the public • Set regulations, standards, and policies that identify organizational outcomes that hospitals must achieve • License specialized devices for use • Ensure timely access to all safe/effective medical devices • Inform the public of safety concerns related to medical devices in a timely manner	What Is Driving Hospitals' Patient-Safety Efforts?, Devers et al. 2004 Technology, governance and patient safety: systems issues in technology and patient safety, Balka et al., 2007
Device, software manufacturers	General	• Ensure that the products comply with regulatory requirements, and provide after sale service • Educate the user as to the capabilities and limitations of their products • Create user-friendly products to maximize the probability that they are used as intended • Participate in post-market surveillance (reporting customer complaints/incidents)	Safety is No Accident, Pawlicki et. al., 2019 Technology, governance and patient safety: systems issues in technology and patient safety, Balka et al., 2007

Controller	Context	Responsibility	References
Healthcare Org Executive	General	• Be champions of safety • Oversee the safety and quality of care provided • Formulate organization mission and key goals. • Ensure high levels of executive performance. • Ensure high quality of care. • Ensure high quality financial management. Provide physical and personnel resources for safety-related activities. • Create an organizational safety policy • Establish organizational safety standards and then implement, update, and enforce them. • Establish incident and accident investigation standards and ensure recommendations are implemented and effective. • Establishing and monitoring the safety control structure • Establish management of change requirements for evaluating all changes for their impact on safety, including changes in the safety control structure.	Safety is No Accident, Pawlicki et. al., 2019 Responsibility for Quality Improvement and Patient Safety: Hospital Board and Medical Staff Leadership Challenges, Goeschel et al., 2010 Engineering a Safer World, Leveson, 2011

Controller	Context	Responsibility	References
RadOnc Departmental Management	General	• Be champions of safety • Develops initiatives related to patient safety • Ensures that a mechanism for reporting and monitoring safety events is in place • Monitors appropriate compliance with local, state and national safety, licensure and credentialing standards. • Develops mechanisms to analyze all events reported through the incident learning system • Disseminates safety information to all staff through various communication methods and meetings • Share concerns with the vendors and work with them to improve products • Provide physical and personnel resources for safety-related activities. Provide adequate resources for personnel, equipment, and time for commissioning • Support the time required for personnel to develop standard operating procedures • Support continuing education for all personnel. • Provide support for individuals to be able to halt any procedures that are deemed unsafe • Establish management of change requirements for evaluating all changes for their impact on safety, including changes in the safety control structure.	Safety is No Accident, Pawlicki et. al., 2019 Safety consideration for IMRT, Moran et. al. 2011 Engineering a Safer World, Leveson, 2011
Medical Physicist	General	• Weekly evaluation • Modify existing QA programs to make them as effective as possible for the new treatments	Safety is No Accident, Pawlicki et. al., 2019
Medical Physicist	RT Planning (incl. sim)	• Patient, family education • Patient-specific QA (primary) • Device evaluations necessary for compliance with applicable state and federal regulations	Safety is No Accident, Pawlicki et. al., 2019 Safety consideration for IMRT, Moran et. al. 2011

Controller	Context	Responsibility	References
Medical Physicist	RT Delivery	• Verification and documentation of the accuracy of treatment delivery as related to the initial treatment planning and setup procedure • Device evaluations necessary for compliance with applicable state and federal regulations • Calibrating the absolute dose output for any therapeutic radiation emitting device • Treatment delivery (supervisory)	Safety is No Accident, Pawlicki et. al., 2019 Safety consideration for IMRT, Moran et. al. 2011
Nurse	Sim and RT Delivery	• Complete skilled nursing procedures	The Role of Licensed Nursing Personnel in Radiation Oncology, Moore-Higgs et al., 2003
Oncology Nurse	RT Planning and Delivery	• Clinical evaluation • Ongoing psycho/social evaluation • Patient, family education • Coordination of care • Weekly evaluation • Follow-up • Survivorship	Safety is No Accident, Pawlicki et. al., 2019
Radiation Oncologist	General	• Equipment, software and system acceptance testing, maintenance and commissioning	Safety is No Accident, Pawlicki et. al., 2019

Controller	Context	Responsibility	References
Radiation Oncologist	RT Planning	• Clinical evaluation • Understanding the natural history of the patient's disease process, conceptualizing the extent of disease relative to the adjacent normal anatomical structures, and integrating the patient's overall medical condition and associated comorbidities • Decision to deliver RT • Patient positioning (supervisory) and image acquisition • Confirm registration, when applicable; • Define the target volumes on the images obtained during simulation; • Specify the normal tissues requiring segmentation; • Specify dosimetric objectives and priorities for the target(s) and OARs; • Identify patients with prior radiation history and other patient-specific considerations documented during the initial consultation • Detail the total desired dose, fractionation, treatment technique, energy, time constraints, on-treatment imaging and all other aspects of the radiation prescription. In some cases, the prescription may be modified based on the results of the treatment planning process. • Selecting and formally approving the plan ultimately chosen for treatment, verifying that it satisfies the clinical requirements and prescription(s) and that it can be carried out accurately • Coordinate care with other specialists • Patient, family education • Ongoing psycho/social evaluation • Patient-specific QA (advisory) • Weekly evaluation • Follow-up • Survivorship	Safety is No Accident, Pawlicki et. al., 2019 Safety consideration for IMRT, Moran et. al. 2011 APEx® Program Standards, ASTRO, 2019

Controller	Context	Responsibility	References
Radiation Oncologist	RT Delivery	• Accurate identification and localization of catheters or needles immediately prior to treatment delivery • Management of organ motion during treatment delivery • Monitor accuracy of delivery (ports, dose, etc.) • Treatment delivery (supervisory) • Verification and documentation of the accuracy of treatment delivery as related to the initial treatment planning and setup procedure	Safety is No Accident, Pawlicki et. al., 2019 Safety consideration for IMRT, Moran et. al. 2011
Surgeon and/or Anesthesiologist and/or procedure team	RT Planning	Safely implant applicators, catheters, or other devices, or assist in intraoperative brachytherapy	ACR–ABS Practice parameter for the performace of radionuclide-based high-dose-rate brachytherapy
Therapist	RT Delivery	• Coordinate care • Patient, family education • Patient positioning (primary) and image acquisition • Dose calculation • Review of final treatment plan (secondary) • Patient-specific QA • Treatment delivery • Monitor accuracy of delivery • Weekly evaluation	Safety is No Accident, Pawlicki et. al., 2019 Safety consideration for IMRT, Moran et. al. 2011
Therapist	Sim	• Coordinate care • Patient, family education • Patient positioning (primary) and image acquisition • Weekly evaluation	Safety is No Accident, Pawlicki et. al., 2019

Controller	Context	Responsibility	References
Tx Checker	RT Planning	• Review of final treatment plan (final review)	Safety is No Accident, Pawlicki et. al., 2019 Safety consideration for IMRT, Moran et. al. 2011
Tx Planner	RT Planning	• Patient positioning (supervisory or advisory) and image acquisition • Fusion and registration (primary) • Contouring/segmentation • Dose-volume constraints • Dose calculation • Review of final treatment plan (compared to physician request) • Treatment delivery (advisory)	Safety is No Accident, Pawlicki et. al., 2019 Safety consideration for IMRT, Moran et. al. 2011

Appendix E. Templates

Step 1: Basic information

High-level incident description, proximal events, and causal factors at the physical level

Incident description

Content questions

- Did the incident involve a specific patient (as compared to non-patient specific activities, e.g., device upgrade)? If so, what was the patient being treated for?
- Briefly, what actions occurred and/or did not occur?
- What was the impact—potential or actual?

Content generated

Proximal events

Hint text
The goal of listing the proximal events is not to immediately identifying the causes. Instead, this should lead to investigation questions seeking to answer why the particular actions or lack thereof as transpired. Be conscientious and avoid hindsight bias—instead of using terminologies such as "failed to", or "should have", simply identify that an actor "did" or "did not" perform an action.

ID	Event	Question raised
1.		•
2.		•
3.		•
4.		•
5.		•
6.		•
7.		•
8.		•
9.		•

Physical failure

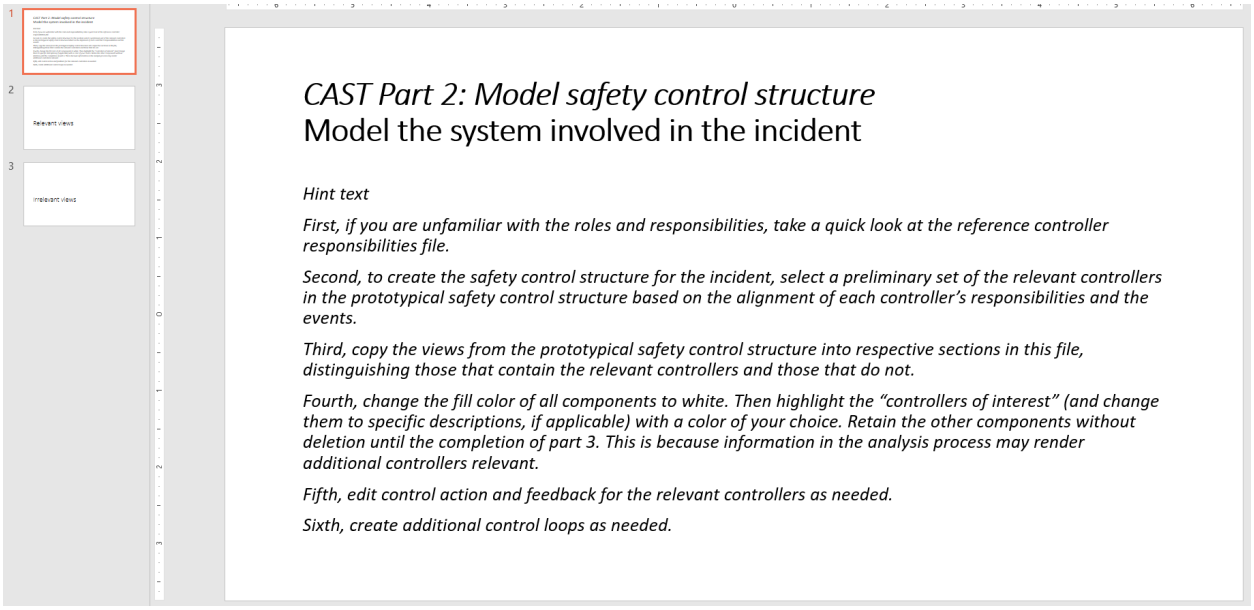
Hint text
This subpart focuses on the most tangible aspect—physical processes and controls. Examining if any physical failure took place establishes "what happened" and would inform the identification of the "whys" in the rest of the analysis.

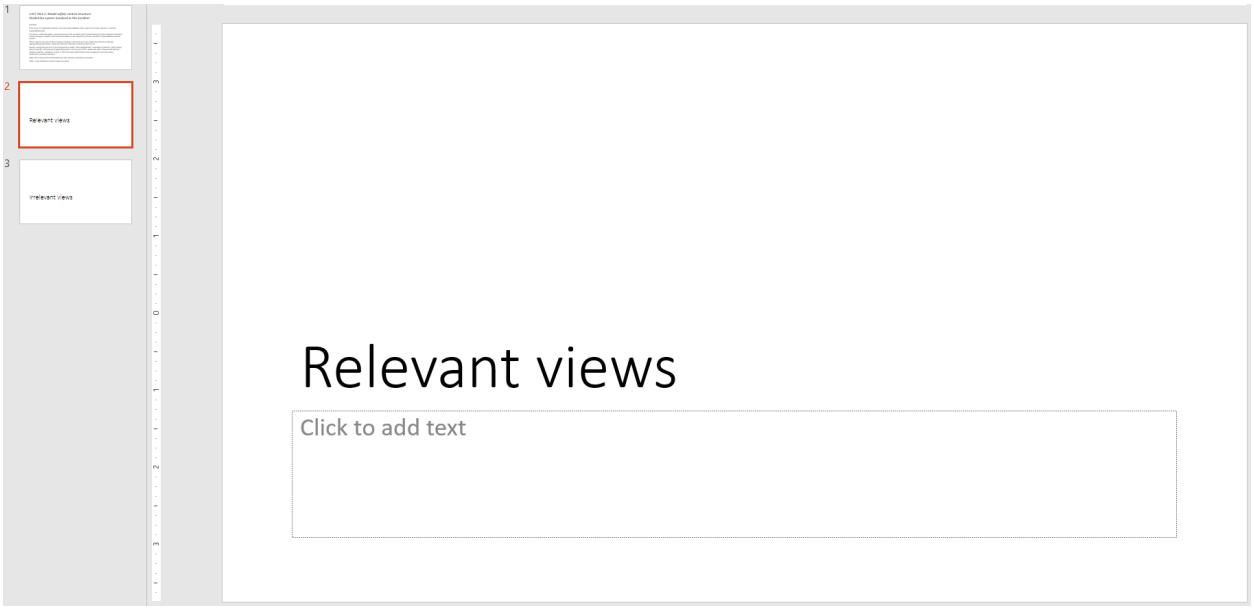
Content questions

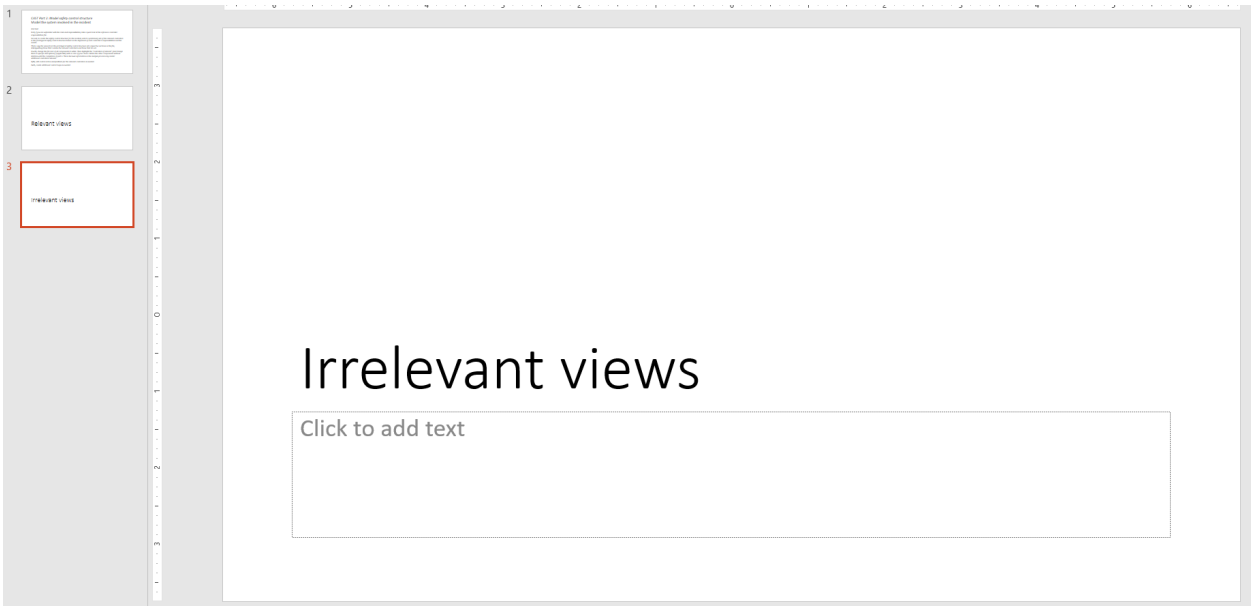
- Did the safety report address a physical process? Was there (the potential of) physical injury or losses?
- What was the physical control (e.g., MRI quench, physical interlock, mechanical stop) to prevent accidents?
- Was there any physical failure (e.g., structural deformity; non-performance of a designed function by a physical control)?
- Was there any unsafe interaction?
- What physical controls might have otherwise prevented the accident? Why were these not present?

Content generated

Step 2: Safety control structure



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Relevant views
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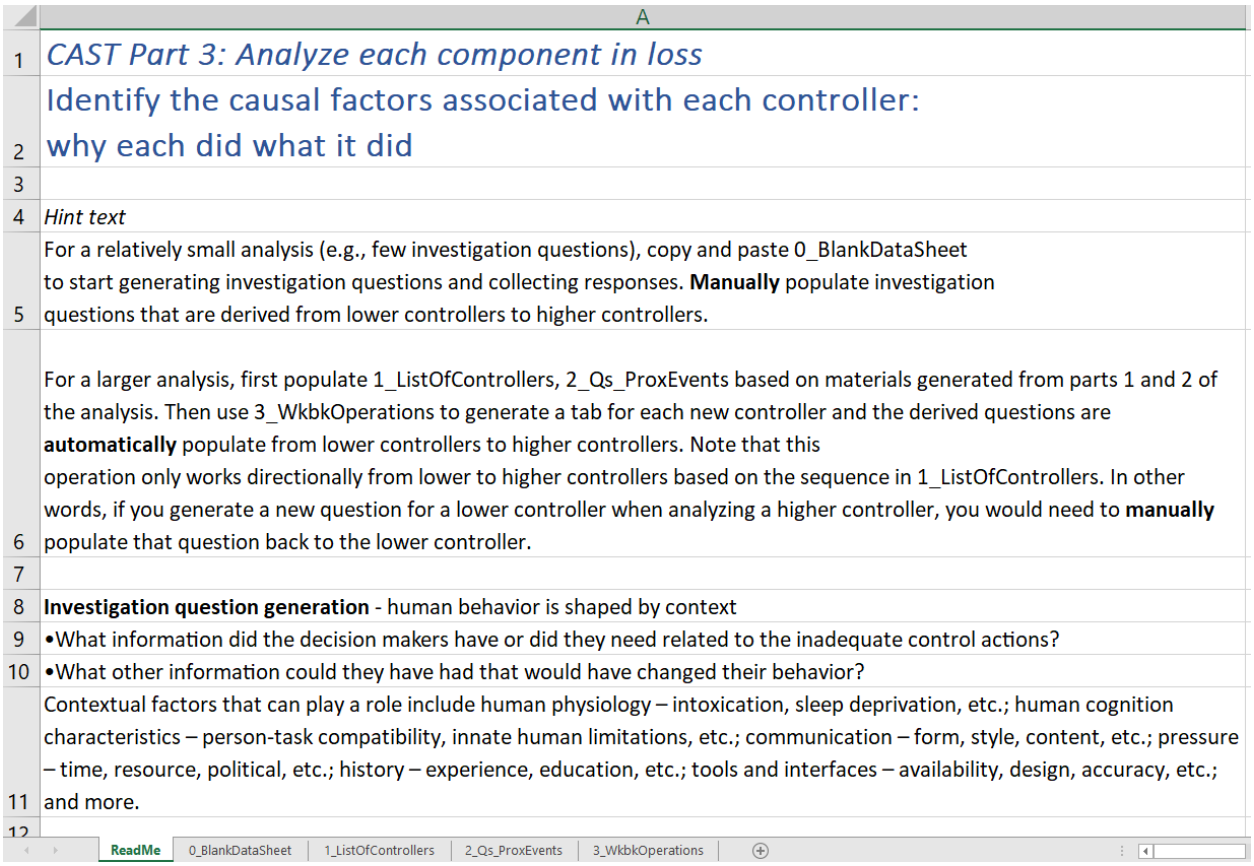
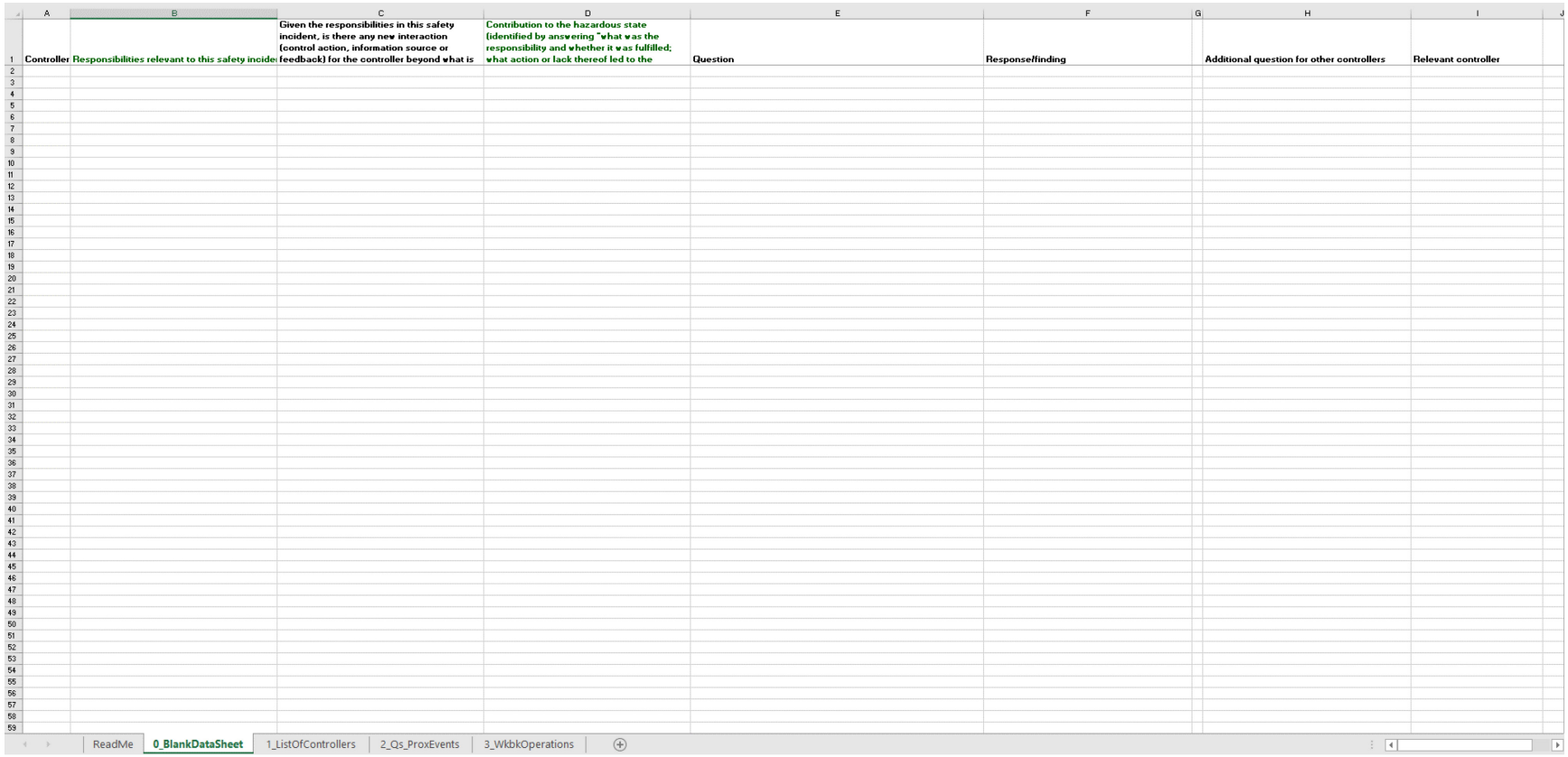
Step 3: Component analysis



	A
1	*CAST Part 3: Analyze each component in loss*
2	Identify the causal factors associated with each controller: why each did what it did
3	
4	*Hint text*
5	For a relatively small analysis (e.g., few investigation questions), copy and paste 0_BlankDataSheet to start generating investigation questions and collecting responses. **Manually** populate investigation questions that are derived from lower controllers to higher controllers.
6	For a larger analysis, first populate 1_ListOfControllers, 2_Qs_ProxEvents based on materials generated from parts 1 and 2 of the analysis. Then use 3_WkbkOperations to generate a tab for each new controller and the derived questions are **automatically** populate from lower controllers to higher controllers. Note that this operation only works directionally from lower to higher controllers based on the sequence in 1_ListOfControllers. In other words, if you generate a new question for a lower controller when analyzing a higher controller, you would need to **manually** populate that question back to the lower controller.
7	
8	**Investigation question generation** - human behavior is shaped by context
9	•What information did the decision makers have or did they need related to the inadequate control actions?
10	•What other information could they have had that would have changed their behavior?
11	Contextual factors that can play a role include human physiology – intoxication, sleep deprivation, etc.; human cognition characteristics – person-task compatibility, innate human limitations, etc.; communication – form, style, content, etc.; pressure – time, resource, political, etc.; history – experience, education, etc.; tools and interfaces – availability, design, accuracy, etc.; and more.
12	

ReadMe | 0_BlankDataSheet | 1_ListOfControllers | 2_Qs_ProxEvents | 3_WkbkOperations



	A	B	C	D	E	F	G	H	I	J
1	Controller	Responsibilities relevant to this safety incide	Given the responsibilities in this safety incident, is there any new interaction (control action, information source or feedback) for the controller beyond what is	Contribution to the hazardous state (identified by answering "what was the responsibility and whether it was fulfilled; what action or lack thereof led to the	Question	Response/finding		Additional question for other controllers	Relevant controller	
2										
3										
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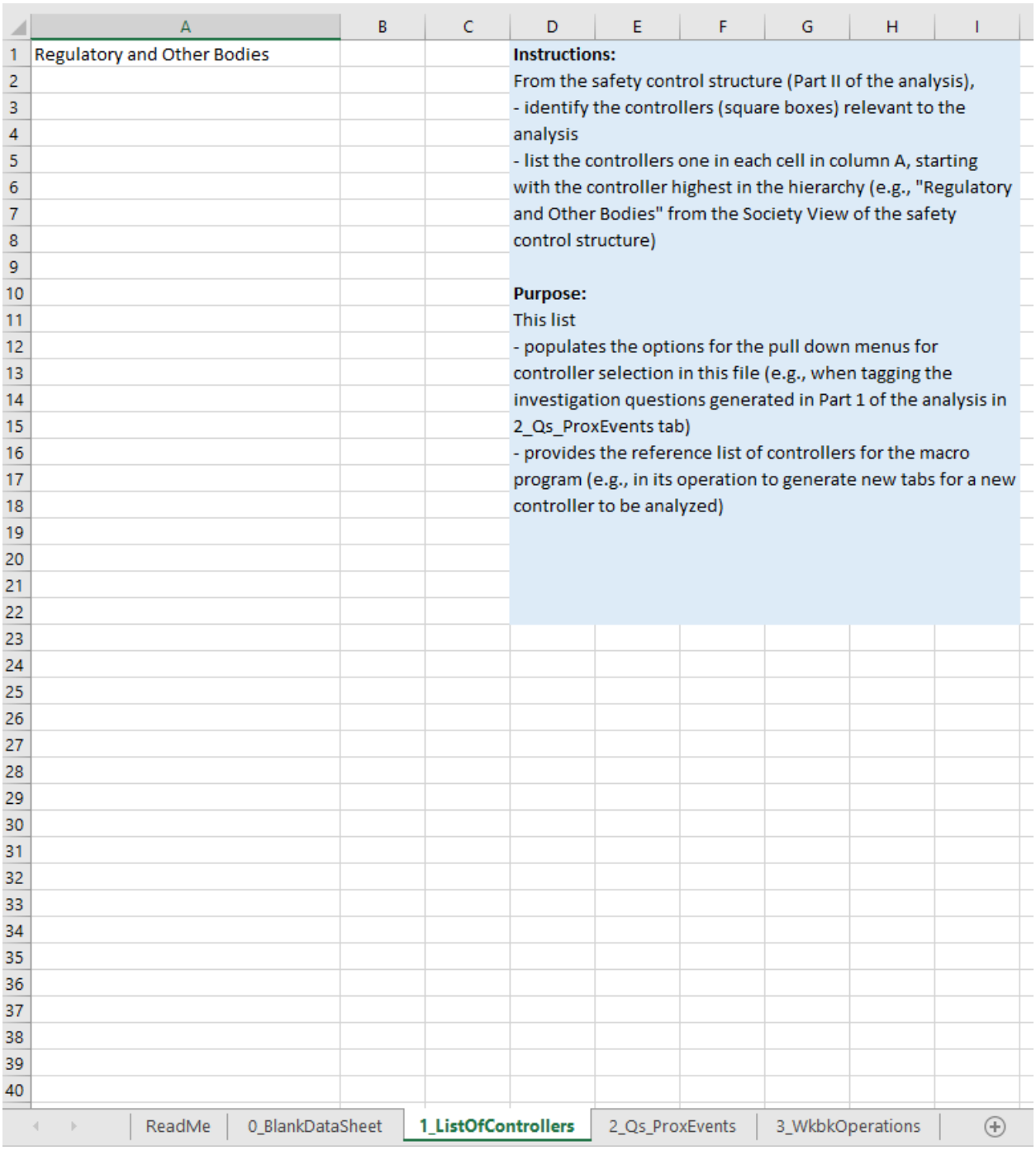
ReadMe | 0_BlankDataSheet | 1_ListOfControllers | 2_Qs_ProxEvents | 3_WkbkOperations


Regulatory and Other Bodies
Instructions:
From the safety control structure (Part II of the analysis),
- identify the controllers (square boxes) relevant to the analysis
- list the controllers one in each cell in column A, starting with the controller highest in the hierarchy (e.g., "Regulatory and Other Bodies" from the Society View of the safety control structure)
Purpose:
This list
- populates the options for the pull down menus for controller selection in this file (e.g., when tagging the investigation questions generated in Part 1 of the analysis in 2_Qs_ProxEvents tab)
- provides the reference list of controllers for the macro program (e.g., in its operation to generate new tabs for a new controller to be analyzed)
ReadMe
0_BlankDataSheet
1_ListOfControllers
2_Qs_ProxEvents
3_WkbkOperations

	A	B	C	D	E	F	G	H	I	J
1	**Question**	**Relevant controller**			**Instructions:**					
2					From the table of proximal events (Part 1 of the analysis),					
3					- list each of the question raised in column A					
4					- tag each question with the relevant controller					
5					- if a question is relevant to multiple controllers, insert					
6					additional rows, copy and paste the question, and tag distinct					
7					controllers as applicable					
8										
9					**Purpose:**					
10					This list of questions					
11					- forms the starting set of investigation questions relevant to					
12					each controller					
13					- gets populated by the macro program, BuildWorksheet (in					
14					3_WkbkOperations tab) to the individual tabs associated with					
15					a given controller. It is in these tabs where the answers to					
16					the questions are captured and documented.					
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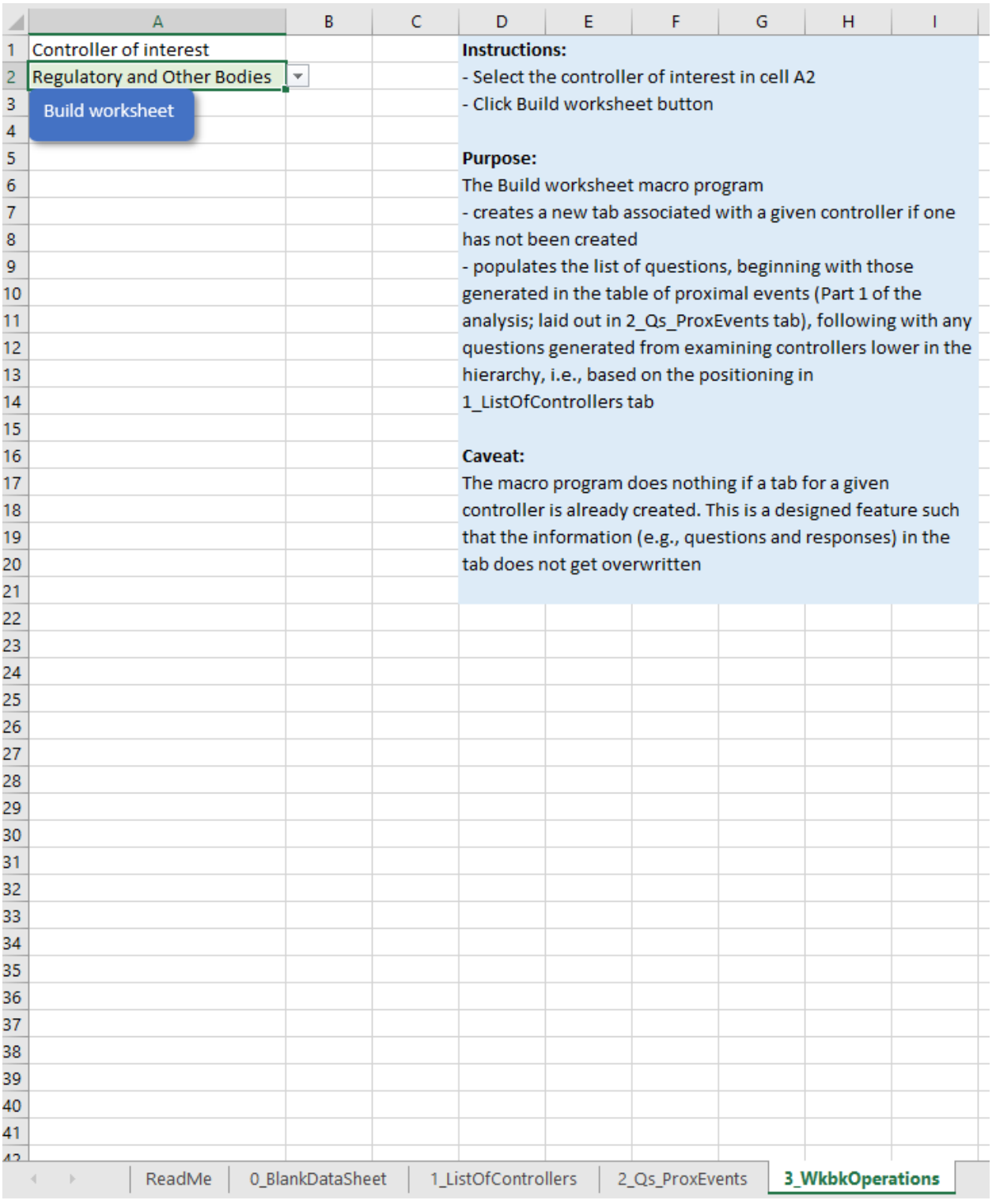
ReadMe | 0_BlankDataSheet | 1_ListOfControllers | **2_Qs_ProxEvents** | 3_WkbkOperations


Controller of interest
Regulatory and Other Bodies
Build worksheet
Instructions:
- Select the controller of interest in cell A2
- Click Build worksheet button
Purpose:
The Build worksheet macro program
- creates a new tab associated with a given controller if one has not been created
- populates the list of questions, beginning with those generated in the table of proximal events (Part 1 of the analysis; laid out in 2_Qs_ProxEvents tab), following with any questions generated from examining controllers lower in the hierarchy, i.e., based on the positioning in 1_ListOfControllers tab
Caveat:
The macro program does nothing if a tab for a given controller is already created. This is a designed feature such that the information (e.g., questions and responses) in the tab does not get overwritten
ReadMe
0_BlankDataSheet
1_ListOfControllers
2_Qs_ProxEvents
3_WkbkOperations

Step 4: Systemic factors

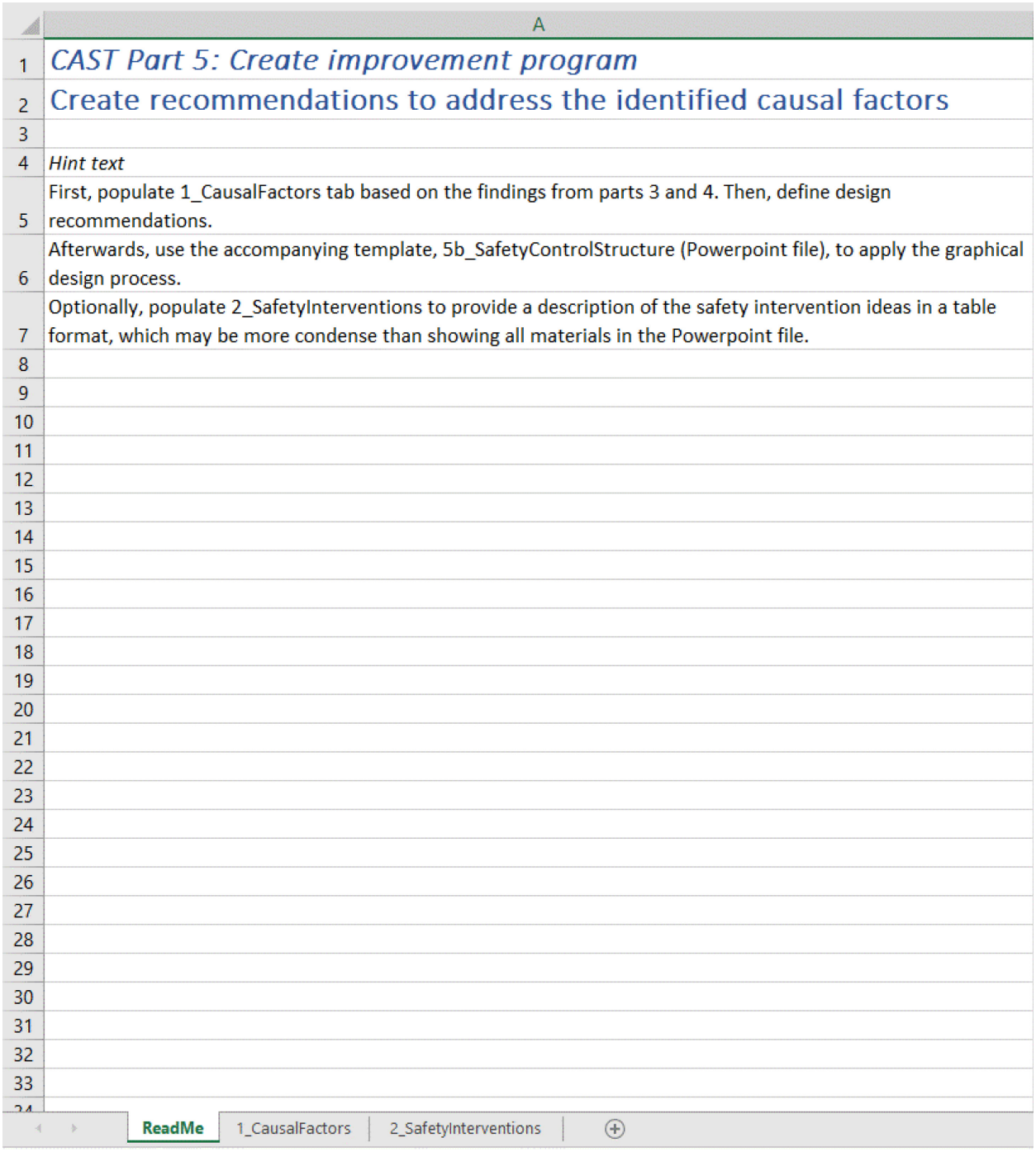
Identify factors that negatively impact the behavior of many or even all the components

Hint text

There is no exhaustive list of possible systemic factors to check against. Instead, look for patterns in the previously identified causal factors by broadening the perspective to the entire system rather than one controller at a time. The previously identified causal factors may also give clues to some underlying conditions that spur their development. If you are stuck, take a look at the training materials—"Cases illustrating systemic factors"—for some commonly occurring factors and how to identify them.

<Systemic factor> Description of how it impacted the components

Step 5a: Causal factors and interventions



	A
1	*CAST Part 5: Create improvement program*
2	Create recommendations to address the identified causal factors
3	
4	*Hint text*
5	First, populate 1_CausalFactors tab based on the findings from parts 3 and 4. Then, define design recommendations.
6	Afterwards, use the accompanying template, 5b_SafetyControlStructure (Powerpoint file), to apply the graphical design process.
7	Optionally, populate 2_SafetyInterventions to provide a description of the safety intervention ideas in a table format, which may be more condense than showing all materials in the Powerpoint file.
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ReadMe | 1_CausalFactors | 2_SafetyInterventions

	A	B	C	D	E
1	**Causal factor type**	**Controller (if applicable)**	**Causal factor**	**Design recommendation (DR)**	**DR ID**
2	"Controller"				DR-1
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ReadMe | **1_CausalFactors** | 2_SafetyInterventions

	A	B	C	D	E
1	DR ID	Interaction of opportunity (Control action = CA; Feedback = FB)	Means of implementation	Description	Keyword
2					
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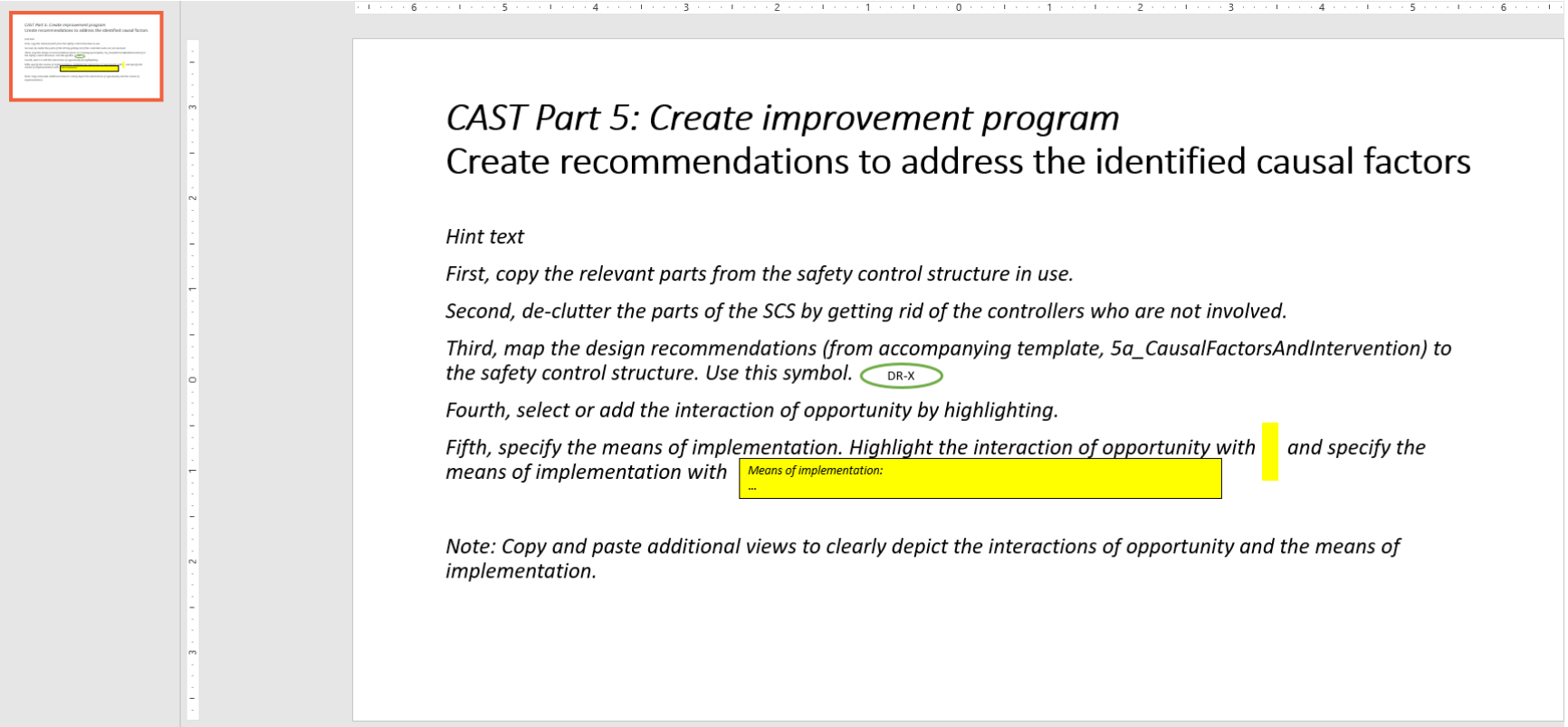
ReadMe | 1_CausalFactors | 2_SafetyInterventions

Step 5b: Safety control structure



CAST Part 5: Create improvement program

Create recommendations to address the identified causal factors

Hint text

First, copy the relevant parts from the safety control structure in use.

Second, de-clutter the parts of the SCS by getting rid of the controllers who are not involved.

Third, map the design recommendations (from accompanying template, 5a_CausalFactorsAndIntervention) to the safety control structure. Use this symbol. DR-X

Fourth, select or add the interaction of opportunity by highlighting.

Fifth, specify the means of implementation. Highlight the interaction of opportunity with *and specify the means of implementation with* *Means of implementation: ...*

Note: Copy and paste additional views to clearly depict the interactions of opportunity and the means of implementation.

Analysis report

Hint text
Replace the <place holders> with relevant information. Most of the information can be copied and pasted from the templates of each step of the CAST analysis.

CAST analysis of <incident title>

Step 1: Basic information

This section identifies the basic information of the incident, defines the scope of the analysis, and closes with a sub-analysis of the physical process where the physical equipment produced and/or experienced the loss.

High-level incident description and scope of analysis

<Paragraph 1: incident description>

<Paragraph 2: scope of analysis>

Proximal events

ID	Event
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	

Physical failure

<Physical failure description and analysis>

Step 2: Safety control structure

In this section, the complex sociotechnical system that was involved in the incident is described through a graphical model—the safety control structure. Highlighted boxes depict the controllers of interest.

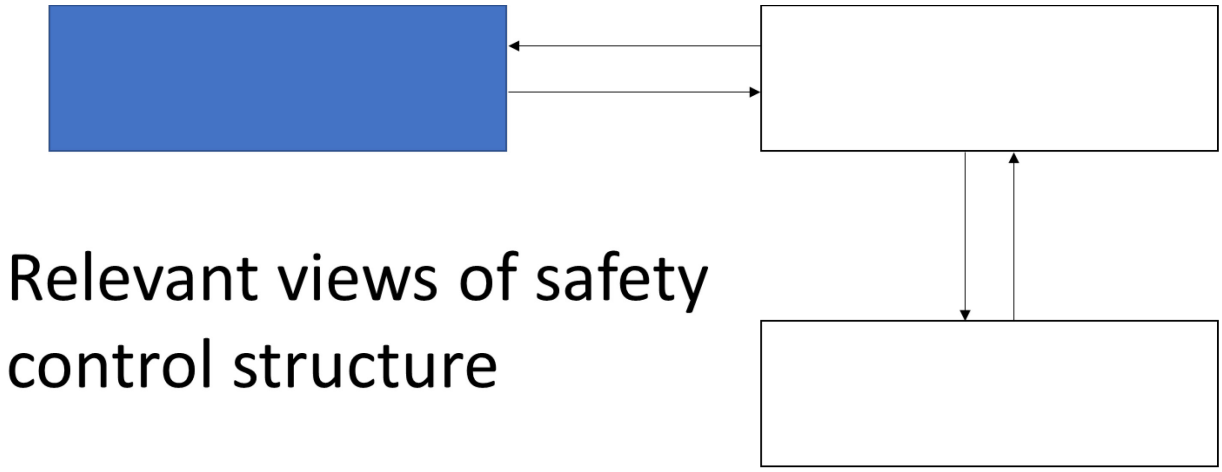


Figure 54 <caption>
(<abbreviation planation>)

Step 3: Component analysis

This section shows the potential explanations for the behavior of each controller, beginning from the lower level of the safety control structure and moves upward. The explanations are formulated around flaws in the understanding of the controller and the contextual factors that shaped these flaws. Where applicable, unanswered questions are documented as well.

Controller identity, e.g., Regulatory, certification, licensing, accreditation, advisory bodies

Responsibilities relevant to this safety incident

-

Contribution to the hazardous state

-

Process model flaws

-

Contextual/process model factors

-

Unanswered questions

-

Step 4: Systemic factors

This section describes systemic causal factors, which negatively impacted the behavior of many or even all of the components in the system. In other words, these factors undermined the ability for multiple controllers to fulfill their safety responsibilities.

<Systemic factor>

<description>

Step 5: Safety intervention recommendations

This section documents the recommendations to address the identified causal factors. For readability, the recommendations are organized around keywords. While a keyword is selected for each recommendation, multiple keywords may actually be applicable. To fully appreciate the objective(s) and the basis or bases of each, see the worksheets that were used to design the recommendations.

<Keyword>

- <First recommendation>
- <Next recommendation>
- …

Appendix F. Cases illustrating systemic factors

Systemic Factor 1: Communication and Coordination

Information shaping the process model of a component also shapes the behavior. Therefore, communication is crucial—it conveys not only the control inputs from controllers at higher hierarchical levels but also the feedback. Similarly, information sharing harmonizes decision making for controllers at the same hierarchical level. This is especially important when identical control actions may be performed by multiple controllers or when control actions have direct dependencies.

The Safety Challenges of Supervision and Night Coverage in Academic Residency (Raffel, 2019)

A 64-year-old man complained of shortness of breath and was hospitalized. Oxygen was administered to maintain adequate oxygen saturation. The patient had bilateral pleural effusions and pulmonary emboli and was recently diagnosed with metastatic cholangiocarcinoma.

One night, the patient became acutely short of breath with altered mental status. The intern night float was paged to assess the patient by the bedside nurse. The intern reviewed the patient's clinical history, recent labs, and imaging from the electronic medical record. The signout received from the patient's primary team identified the patient as a full code. However, a contingency plan was not provided and the overall goal of care could not be determined. The intern ordered some imaging for chest and head, laboratory tests, and an electrocardiogram.

The patient's condition further deteriorated and had a decreasing blood pressure. The intern attempted to activate the rapid response team to escalate oxygen therapy with high flow nasal cannula. However, her attempt was in vain as she had an incorrect paging number. Eventually, the intern asked the nurse to page the team and they arrived.

The intern also paged the overseeing senior resident for assistance but, again, had the wrong pager number. Leaving the bedside environment to look for the resident was deemed infeasible due to the patient's unstable condition. Having toiled for an hour at the bedside, the intern caught sight of another senior resident who was passing by and requested his help.

The senior resident reviewed the laboratory test results, paged the ICU fellow, and suggested the intern to call the patient's family. They notified the family of the critical condition and inquired what resuscitative measures (e.g., intubation and use of a ventilator) they would prefer. After an in-depth discussion, the family decided to abstain from drastic measures, consented to a "Do-Not-Resuscitate" and "Do-Not-Intubate" order and elected for comfort care. The intern then provided symptom and air hunger management with morphine drip until the patient passed away a few hours later.

Systemic factor illustration

Providing night coverage is challenging—the amount of resources reduces yet patient condition can deteriorate precipitously as during daytime. In this challenging context, the full functioning of a system is crucial. Quality patient care requires adequate communication and coordination.

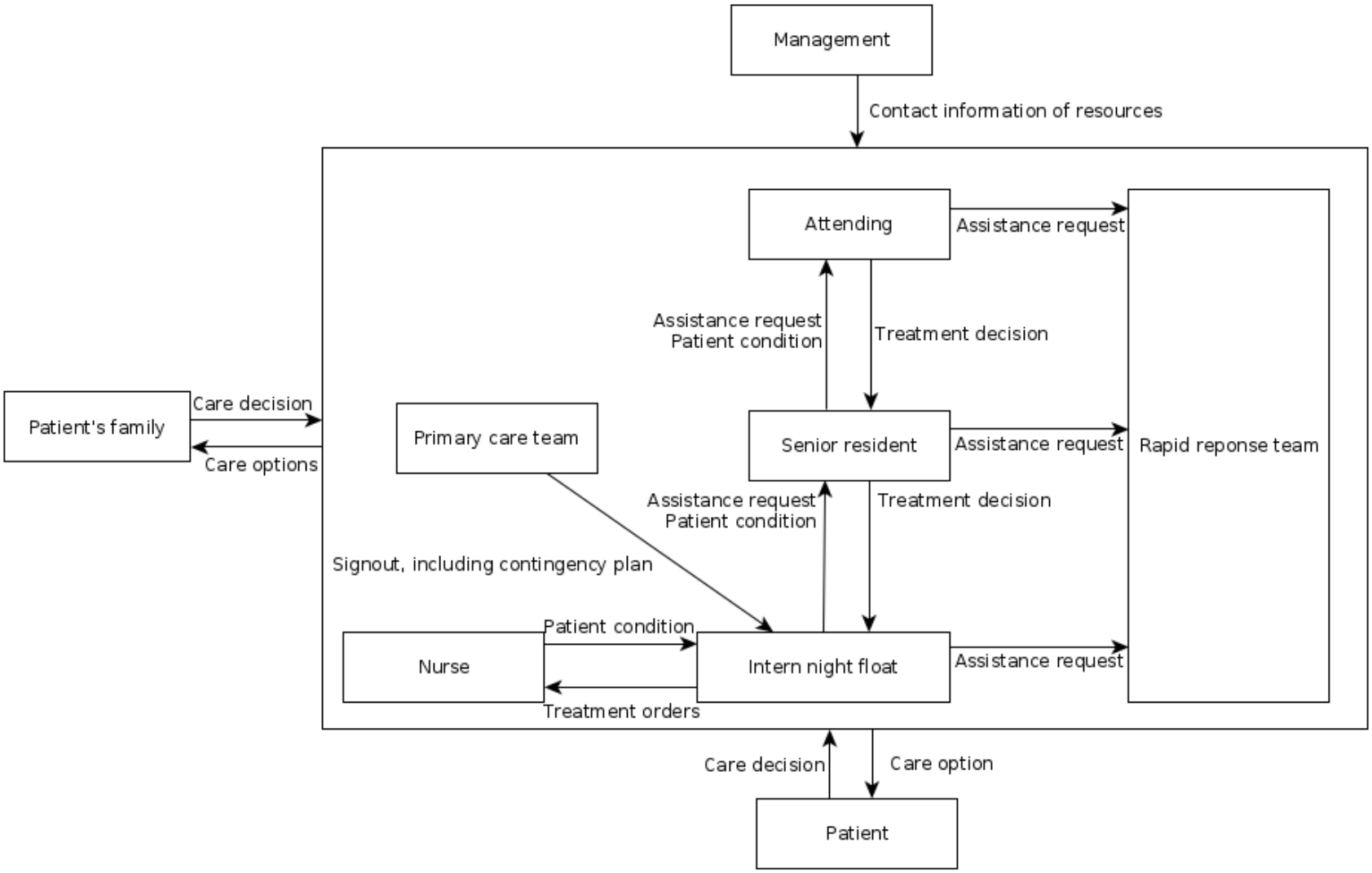


Figure 55 Communication network as intended to provide night coverage in academic residency

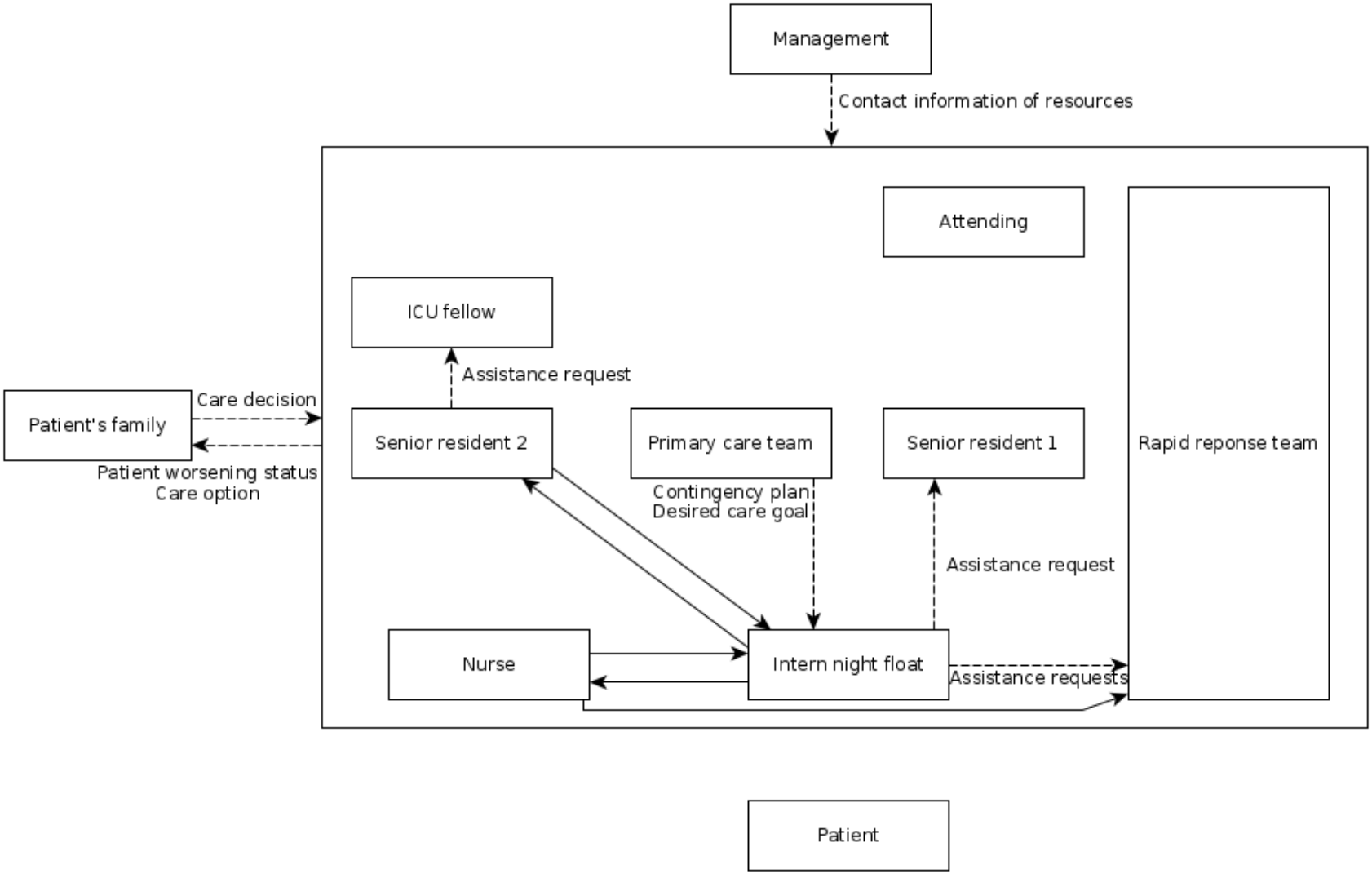


Figure 56 Actual communication network with many links missing. Senior resident 2 and ICU fellow constituted new components that were not in the original setup. Dash and dotted lines indicate the flawed communication.

In the designed setup (Figure 55), patient care is provided first and foremost by the bedside nurse and the intern night float. To augment the intern's ability to handle emergent situations, a senior resident, a rapid response team and an attending physician add not only hands to execute multiple tasks at once but also experience and knowledge in clinical decision making.

To render the system fully functional, different information needs to be exchanged. As night coverage begins, the patient's primary care team signs out the patient to the intern with comprehensive information: a description of the patient's health problem, information about the situation, consideration of available options and the action that is deemed desirable. The intern and the bedside nurse discuss the patient condition, so treatment orders can be issued. If the patient deteriorates and care needs to be escalated, the intern communicates the patient condition to the senior resident and the attending to request assistance. In turn, the intern may receive additional treatment decisions. Similarly, assistance request is sent to the rapid response team. From a strategic perspective, management defines the criteria and means of communications to facilitate the frontline activities. Lastly, the clinicians discuss care options with the patient (or the family, if applicable) in a prospective and recurrent fashion as the disease progresses, so patient-centered care decisions can be made.

As this incident unfolded, however, the system did not function as designed. Figure 56 shows the communication network in actuality. Due to chance encounter, new components were involved, whereas other communication links were missing, and still some other links were flawed.

Starting with the frontline, the primary care team did not provide a contingency plan in the signout to the intern, and the care goal desired by the patient could not be determined. The code status, as documented, was inaccurate—the patient's family already requested comfort care should he deteriorate. When attempting to request assistance from the rapid response team and the senior resident, the intern used the wrong pager number hence could not reach the parties as intended. Had the overseeing senior resident was contacted, perhaps he/she would have been cognizant of the appropriate code status of the patient, thus eliminating the need to put the patient's family through an emotionally traumatizing episode, questioning their earlier care decision. It is unclear if the ICU fellow was successfully contacted and provided any advice. Also, it is unclear why the senior resident did not suggest contacting the attending physician. Ultimately, the maximum amount of system knowledge was not brought to bear when a patient's life was at stake.

The communication problem extended beyond the frontline. The intern did not receive accurate pager information from management as part of the orientation—it was the intern's first rotation at the hospital, and she was providing last-minute coverage for another intern.

In summary, flawed communication and coordination affected many components in the system and prevented the best care to be delivered.

Systemic Factor 2: Incident Reporting System

An effective incident reporting system (IRS) improves safety performance by revealing the safety problems around the system that underlie the more visible care delivery issues on the frontline. On the contrary, safety events repeat if the IRS is ineffective.

Various aspects of the IRS can be flawed, leading to ineffectiveness. Filtering and suppression of incident reports is not uncommon. Incomplete report processing can also take

place. When an incident is analyzed individually, a myopic focus on the frontline may be adopted. For aggregate analyses, incompatibility of the collected data or ineffective analysis method may preclude accurate results. Effective safety interventions may not be proposed or implemented, and the lessons learned may not be disseminated to the appropriate audience, in a useful format, (n)or at the right time.

Mishandling of equipment failure (IAEA, 2000)

One day, staff discovered that a linear accelerator would not generate an electron beam. A maintenance technician happened to be on-site working on a ^{60}Co unit produced by the same manufacturer. The staff notified the technician, and a repair was made. Subsequently, while a beam was produced, the display showed 36 MeV regardless of the setting on the console. It was assumed that the energy selection correctly set the energy level, while the analog display was faulty.

Patient treatment with the machine resumed, but patients did not tolerate the treatment well, and some even had severe reactions. A report was then made to the hospital's Department of Physics and Radiation Protection 10 days after the malfunction. The Department performed a dosimetric check, revealing that the electron beam remained at 36-MeV regardless of the setting.

The manufacturer then sent technicians to perform another repair. It was discovered that a short circuit affected the path trajectory system and supplied a high current to the bending coil, causing the initial malfunction. In making the first repair, the technician placed the machine into manual mode and also increased the electron energy to 36 MeV to re-center the beam. Consequently, the machine ignored any console energy selection.

27 patients were treated and overdosed until the final resolution of the malfunction. For each patient, the volume of body mass irradiated was deeper than planned.

Systemic factor illustration

While it is clear that an IRS was present because a safety report was eventually filed, it is unclear if a similar event occurred previously and if learning was produced. In any case, the flawed IRS led to the machine being improperly repaired by a technician, who was possibly not qualified or prepared to do so. The verification of the repair was delayed, and the linac was operated by users with an incorrect understanding in the meantime.

Various aspects of the IRS were flawed in this incident. On data collection, the staff requested the assistance of the technician at the onset of the malfunction but did not file a safety report on the event. This resembled the "fix and forget" phenomenon not uncommon in many organizations (Hewitt and Chreim, 2015). It occurs usually due to a lack of visible response from the management or long delays associated with the IRS. Other barriers to reporting usually exist as well (e.g., report originators being culturally branded as "problem maker" or a burdensome reporting platform).

On data processing, there was a missed opportunity for the malfunction to be properly addressed in the first instance. Because the Department of Physics and Radiation Protection was not notified initially, the repair was deemed adequate, and treatments resumed without a dosimetric check. Had the Department been involved at the first instance, the qualification of the technician to make the repair and the adequacy of the repair could have been better assessed.

On information dissemination, the clinicians were misled that the “energy selection keys correctly indicated the energy selected” after the first repair. This created an inaccurate process model and a false sense of security.

Beyond the IRS of the healthcare organization, the adverse events also revealed the shortcomings of the IRS of the manufacturer. The manufacturer did not appear to have known about the first repair until prompted by the hospital. The manufacturer also did not appear to have actively sought out malfunction information from its users nor its technicians. It is unclear if the engineering team knew about similar malfunctions beforehand. Similarly, it is unclear if technicians were trained to accurately diagnose and repair the machine.

Systemic Factor 3: Changes and Dynamics

Changes are inevitable for all systems except those operating in complete isolation and with minimal longevity. Changes can occur in the “physical process, the operating procedures, individual behavior, the safety activities or processes, the management process, oversight practices (both internal and external), or in the environment” (Leveson, 2019). They can also be planned or unplanned. When safety controls are stripped away, changes can directly undermine safety. Similarly, they can introduce unintended consequences when incompatibilities are created between different components or between reality and the decision makers’ understanding.

Change dynamics is an additional dimension to consider. Changes can take place spontaneously or gradually over a long period of time. Changes that are either too fast or too gradual can be hard to observe and thus unsafe. For the latter case, migration towards an unsafe state can result from the constant drive to be more cost-effective (Rasmussen, 1997). Unless intentionally tracked, this erosion of the safety mechanisms tends to go unnoticed.

Abandonment of a ^{137}Cs machine (IAEA, 2000)

A medical institution moved to a new facility but a ^{137}Cs teletherapy unit was left behind in the original premises. A court case was underway, and the teletherapy unit could not be removed from the building. Complicating the situation further, the building was partially demolished, and the licensing authority was not notified.

On the fateful day, two people broke into the building and found the teletherapy unit. Scavenging scrap metal to be sold, they disassembled the unit and took with them the radiation source. They then sold some materials to a scrapyard. Given the intriguing glow of the cesium powder, the materials switched hands and were exhibited to friends and families.

Without knowing the radiation exposure that took place, some people fell ill with nausea and vomiting, swelling, etc. Eventually, it was realized that the materials were radioactive. 249 people were contaminated and four people died. Environmental survey was performed over 67 km^2, and remediation included the removal of 3,500 m^3 of waste.

Systemic factor illustration

The incident likely encompassed a combination of planned and unplanned changes. The relocation to a new facility was a planned change, and much of the equipment was moved. The original management of change likely did include a plan to fully account for the radioactive materials such that any release or public exposure could be avoided.

However, the move was abruptly halted by a legal dispute, and the ^{137}Cs unit was left in the original building. The court, knowing the presence of the teletherapy unit, did appoint a

guard to secure the facility. It is unclear when the partial demolition of the building took place and if it heightened the risk of theft. Notably, if this change took place subsequent to the court injunction, the security plan may not have been reevaluated to account for the heightened risk. The spontaneous interruption of the move likely also led to the licensing authority not being notified. Had the authority intervened, they may have been able to mediate between the litigants and the court to take custody of the unit in the interim.

In summary, there were changes associated with the geographical location, execution status of the relocation, and structural status of the original building. These changes created critical decision points for the medical institution, the court, the licensing authority, and more. Unplanned changes were not accounted for in the original decision making. Moreover, changes that were potentially unknown to the court and the licensing authority prevented adequate controls to be put in place to avoid the incident.

Systemic Factor 4: Safety Culture

Safety culture is the foundation underlying the safety rules, practices, policies and ultimately manifest as behavior and artifacts (e.g., safety analysis, etc.) (Leveson, 2011). Every organization has a safety culture but some are plagued. Undesirable safety culture can exist in various flavors. Past observations are summarized as follows (Leveson, 2019):

- A “culture of risk acceptance” is present when staff normalize accidents to be a necessary evil to complete the mission of the organization. For instance, some consider the goal of zero patient harm irrelevant because virtually all treatments have adverse effects. To overcome the culture of risk acceptance, we need to recognize that the future should not be limited by the status quo—for the goal of zero harm, recognizing that adverse effect is not inevitable given continued improvement.
- A “culture of ‘swagger’” exists when safety endeavor is labeled to be for the weak; risk taking, in contrast, shows strength.
- A “culture of denial” takes place in organizations where hazards are commonly rejected as immaterial. A favorable safety performance is depicted in hazard analyses as an artefact of confirmation bias. Little effort is spent on safety management activities because they are considered unnecessary and cannot improve the situation much.
- A “culture of compliance” exists when conformance with government regulations and advisory guidelines is treated as sufficient, especially in the face of other signs of inadequacy. To be clear, compliance can improve safety but it alone may not be sufficient—regulations are not comprehensive. Safety codes and hazard analysis are complementary. They should be pursued in an integrated fashion to achieve a safe design (Leveson, 1995).
- A “paperwork culture” is analogous to the culture of compliance, but instead of hiding behind external recognitions and assessments, the management prizes the volume of documentation and analyses as evidence of safety—the paperwork may not actually inform or influence safety practices.
- A “culture of low expectations” (Chassin and Becher, 2002) exists when the system is fraught with flaws and staff is attuned to working under these circumstances. In this setting, there is no longer an imperative to verify or improve the situation when safety deviation occurs. For instance, when a patient was inadvertently sent for an invasive procedure, staff invariably assume that the procedure is warranted despite it not being

documented in the chart. A presumption is made that it is ordered by clinicians in a more senior position without communication, etc.

Incorrect decay of a ^{60}Co source and fabrication of records (IAEA, 2000)

^{60}Co units have to be calibrated repeatedly to account for the decay of the source. At a hospital, calibration documents were produced by the physicist as directed by regulatory requirements and professional guidelines. However, patients experienced complications from treatment, and the leadership was eager to address the situation. Subsequently, the physicist identified that an error in the measuring system gave rise to incorrect calibrations. New calculations were made, and treatments continued.

Unfortunately, the situation worsened still, and the hospital enlisted consultant physicists to probe the cause. The investigation showed that nine of the calibration documents were fabricated, and calibrations were not verified with output measurements. In fact, the unit and the measuring system were functioning as expected. Instead, erroneous decay correction calculations were the cause of wrong dose delivery.

Hundreds of patients were affected. Overdose grew to 10% nearly half a year after the adoption of the calibration approach and reached 50% after 22 months. Some patients died as a result of the episode.

Systemic factor illustration

This grave case calls into question the safety culture at the facility. Instead of only asking why the physicist fabricated the calibration documents, it is critical to understand how the hospital viewed the safety landscape in the organization.

Naturally, the calibration documents provided a level of assurance to the leadership especially when they appeared to comply with regulatory and professional guidelines. Through a culture of compliance, these documents possibly created a false sense of security that blinded the leaders from the true cause of the increasing treatment intolerance. Safety culture underlies rules and practices; the culture of compliance likely prevented leadership from pursuing effective actions to rectify the situation. In this case, treatments with the wrong dose were allowed to continue for a substantial period of time.

Systemic Factor 5: Care Provision in a Training Setting

Training is provided in some medical settings (e.g., at the nearly 400 institutions in the Council of Teaching Hospitals and Health Systems (AAMC, 2018)). Trainees range from medical students, postgraduate trainees (interns, residents) to sub-specialty trainees (fellows). Beyond physicians, other allied medical professionals (e.g., nurses and medical physicists, etc.) go through postgraduate training in a clinical setting as well.

Patient outcome at academic medical centers is, in general, better (Burke et al., 2017), but the context also creates unique risk factors. By definition, trainees are less experienced than their more seasoned counterparts. They may also be less competent. For instance, trainees score lower than practicing cardiologists or teaching faculty in a cardiac examination test (Vukanovic-Criley et al., 2010). Beyond the lack of technical competence, insufficient supervision, handoff problems, excessive workload and fatigue are also notable contributing factors in adverse events in a training environment (Singh et al., 2007). Trainees can also be reluctant to challenge

authority figures, regardless of whether a hierarchical atmosphere exists or not (Sydor et al., 2013). This reluctance can have adverse safety implications.

At the organizational level, controls can be missing or ineffective to provide a safe training environment. Specifically, progressive autonomy (e.g., a defined list of tasks and decision making with their commensurate requirement for supervision) or competence-based assessment may not exist (Sterkenburg et al., 2010, Sawatsky et al., 2020). Also, a culture that applauds "strong" trainees who can handle a high workload without requesting assistance may be detrimental (Shojania et al., 2006).

Supervision and Entrustment in Clinical Training: Protecting Patients, Protecting Trainees (Cate, 2018)

A 65-year-old man was hospitalized for severe trauma from falling off a tree. He had to rely on mechanical ventilation and presented with unstable heart rate and blood pressure. Computed tomography (CT) imaging showed significant bleeding in his head and spine. For the condition to be further assessed, the patient was sent for a magnetic resonance imaging (MRI).

Making this trip was non-trivial. The MRI suite was located 10 floors below the intensive care unit (ICU), where the patient was being treated. A physician and a nurse were required to accompany the patient for the transit to handle any contingencies. An intern in his second month of postgraduate training was selected for the assignment. It was his first rotation at an ICU, and he had never transported a critically ill patient before. A nurse who had been caring for the patient was part of the contingent.

As the journey continued, there was a delay before the patient could be scanned. During the wait, which was more than an hour, the patient's heart rate twice dropped to 20 beats per minute, and the blood pressure was critically low. Not having been briefed on a contingency plan, the intern was not prepared to intervene. The nurse provided rapid intervention, thanks to her experience, and stabilized the patient's condition.

Just as the patient was about to start the 2-hour MRI scan, the chief resident appeared and excused the intern to attend a mandatory conference. A medical student was put in his place. The intern was reluctant to leave given the critical status of the patient but felt that he could not resist the chief resident's repeated insistence.

The scan eventually completed without further complications. It revealed that the patient had diffuse bleeding not amenable to repair. The patient's family was consulted, and care was withdrawn.

Systemic factor illustration

While no harm was apparently done to the patient during the hospital stay, the system of care was compromised in this episode. Specifically, several aspects of the training setting contributed to this event. The trainee was, understandably, inexperienced in managing the care of the acute and unstable patient. While an experienced ICU nurse was part of the care team and provided tangible assistance, the role and responsibility in the team likely deviated from the setup intended in the hospital policy, which existed to safeguard both patient and clinician wellbeing. Subsequently, when the medical student took the intern's place, the level of collective knowledge and competency in the care team further decreased. There was insufficient supervision and support for the trainees. This setup not only had the potential to compromise patient care, but it actually detracted from learning and leadership development as reported in this case.

Systemic Factor 6: Economics

Rising costs and reducing revenue can complicate resource allocation and thus impact safety. When hard pressed, management may scale back or defer investment in safety. The resulting impact is tangible on the frontline: roles solely dedicated to safety may be left vacant to reduce overhead, and equipment with advanced safety feature may be forgone for a lower-cost model.

Competitive pressure may play a role as well. Specifically, the pressure to bring novel therapeutics, techniques and technology to bedside may cause safety evaluation to be rushed or skipped. For instance, the use of surrogate endpoints can shorten clinical trials, but it may mask the actual toxicity (Montaner et al., 2001). In fact, economics is a critical factor even at the top of the system. Much of the FDA's salaries are funded by the applicants (drug, medical device, and therapeutic manufacturers) through user fees tied to the negotiated application review timeline. The review times have decreased, and the data requirement has been relaxed (Darrow et al., 2020).

"Systemic" Factor 7: Environment

The environment presents an interesting "systemic" factor. By definition, the environment encompasses the components outside the system boundary: those that we do not have control over. Yet, they can impact components within the system boundary, leading to incidents. With healthcare as the system of interest, the environment can be 1) the rest of the society beyond the healthcare system, 2) the rest of the world beyond the locale of interest, and 3) the natural world beyond human control. Notably, while the components maybe outside one's control, preparation can still be made to minimize the impact the environment may create.

As illustrated by the COVID-19 pandemic, factors in the environment can impact healthcare safety. For instance, trade embargos and export limitations can plummet the availability of personal protective equipment (Espitia, 2020). Furthermore, international relations and geopolitics can impact medical information transfer and policymaking (Burkle, 2020). These factors have widespread impact on the healthcare system and can precipitate safety events.

Appendix G. CAST analysis of positioning discrepancy

Incident Narrative

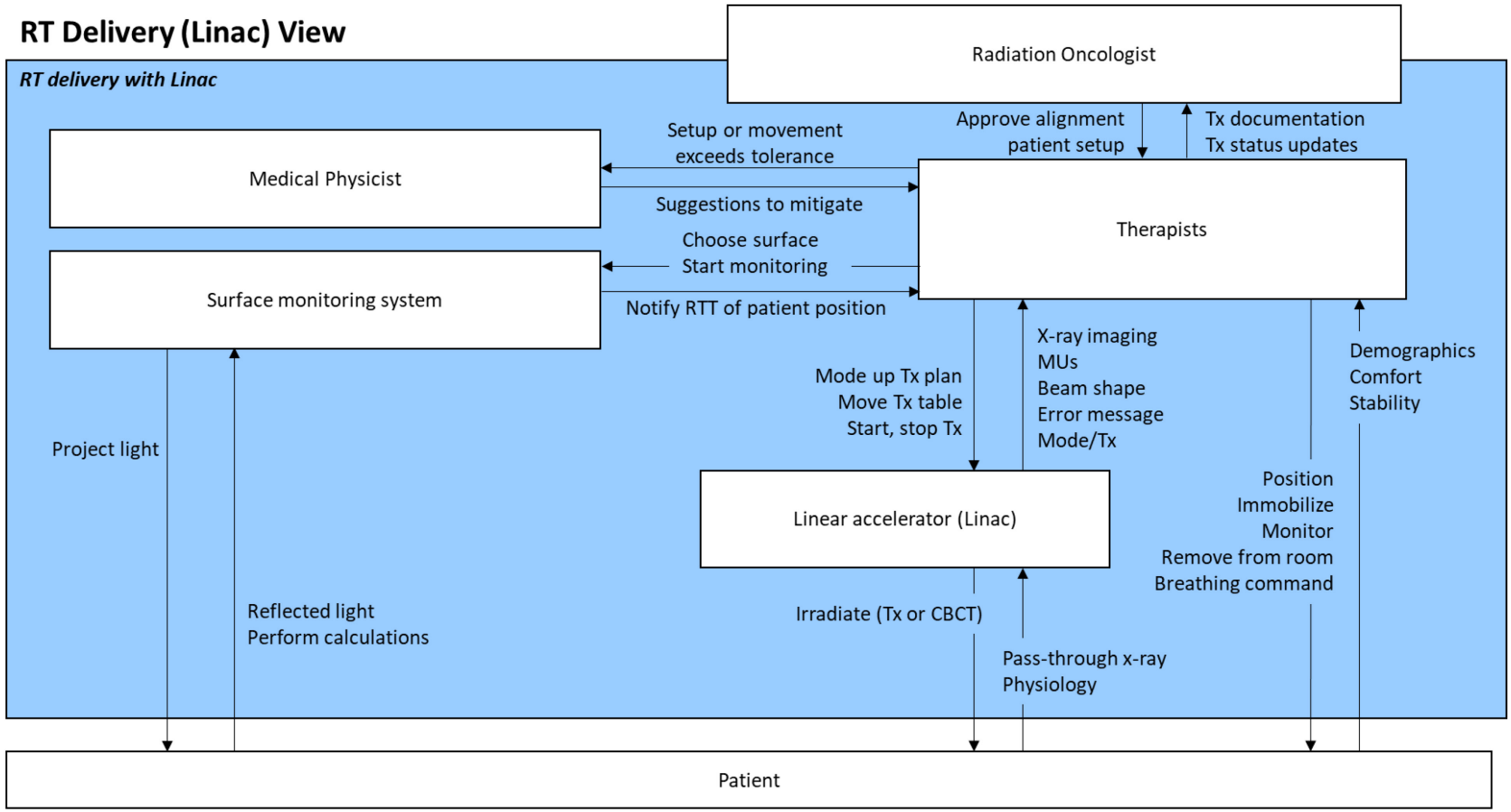
This was the 2nd fraction of a breast treatment that was simple tangent fields only. The [RT therapists (RTTs)] performed a timeout with patient. They loaded [the reference surface] belonging to the patient [into the surface monitoring system]. Then they positioned the patient using [the system], took a billing capture, and checked for elbow clearance [given the rotation of the linac]. The RTTs then left the room [and] performed pre-treatment timeout at console. [RTT A] was the driving therapist and beamed on. After treating the medial [treatment field], [RTT A] noticed the longitudinal [patient position] was different than acquired, but [the displacement was less than the threshold that required action]. The RTTs discussed the finding and thought that possibly the breast board was indexed incorrectly. They checked [the breast board and it] was okay. They then checked that the incline was correctly set, which [it] was. [RTT A] proceeded with lateral treatment field. [After the treatment, both] RTTs helped the patient off the table and escorted her out of the room.

[RTT A] noticed that the [the boost reference surface in the surface monitoring software] was open, then both RTTs discussed that finding and realized that the longitudinal [patient position] was in fact different because the incorrect [reference surface] was used for positioning the patient. After looking at [the surface monitoring system], they both realized that [the boost reference surface] is loaded first when loading the patient on the [the surface monitoring system].

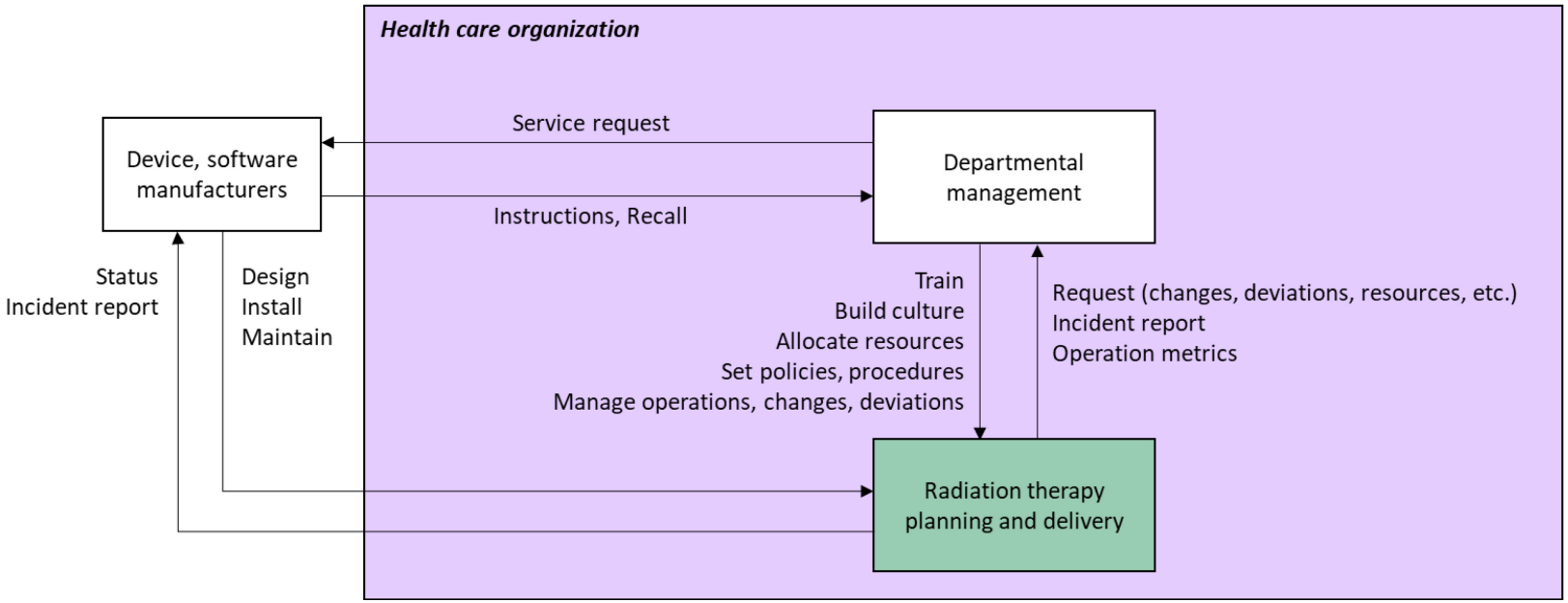
[RTT A] entered the event into [the IRS] and informed the physicist and the manager. The physicist contacted another physicist responsible for radiation safety to explain the event and determine if it was a reportable misadministration. It was determined that this fraction did not deviate by the amount that would make it a reportable event, so this is not a state-reportable event. The radiation safety physicist confirmed this analysis with the organization's radiation safety officer. The physician was informed of this single fraction treatment variance, and she decided to add another fraction of tangential whole-breast treatment. She determined that the variance did not result in a deviation that would be detrimental to the patient’s course of therapy after adding that additional fraction.

Applicable Safety Control Structures Used in the Analysis

The safety control structures shown below informed the analysis.



Health Care Organization View



Controller Contributions to the Incident

Controller: Vendors (Surface Monitoring System and Linac System)

- The vendors have provided the appropriate level of training on using both the [surface monitoring system] and the [linac] system so this was not considered [a] contribution to this incident.
    - Note that there was [a surface monitoring system] software [update] that the clinic was not familiar with but this is attributed to Department Management, not the vendor.
- The [surface monitoring system] and [linac] system are completely independent and do not link together in any way, i.e., it is possible to have [two] different treatments moded up on each system which is what happened in this case. The connection of the [surface monitoring system] and [linac] systems is not an available feature at this time.
- A tool exists from [the linac vendor] that allows the [surface monitoring system] to control beam-on and beam-off of the linac. This may have been a contributing factor since the [surface monitoring system] was not about to interlock the linac beam-on based on a deviation of the surface during setup.

Controller: Department Management

- The clinical staff were not completely familiar with [a surface monitoring system] software update that was related to inactivating surfaces that are not being used. While some clinical staff may have been aware of this new feature, it's value in preventing this type of incident was not appreciated.
- There was a standard operating procedure (SOP) for this type of treatment. Due to the reliance on the [surface monitoring system], the field light was not routinely checked prior to beam-on for these cases. It is noted that checking the field light only is valuable in catching large setup deviations (as in this case) and would not be valuable in catching smaller setup deviation on the order of a couple of centimeters or less.
- Radiographic imaging would have identified this setup deviation but this is not done routinely for simple tangent cases. It is best to always minimize radiation dose to the patient.
    - There are some differences with radiographic imaging policies among the different type of breast treatments. For example, for 3-field breast cases, there is additional imaging to ensure tangents and [supraclavicular (sclav)/posterior axillary boost (pab)] field matching. For [deep inspiration breath hold (DIBH)], [the satellite facility] requires imaging on 2 consecutive days (no imaging-only day) while [the main campus] required the first day to be imaging only, then 2 consecutive imaging days.
- [The surface monitoring system] or [linac] systems were not configured to trigger an interlock that would have required the therapists to override the one or both of the systems, which may have caused them to request additional help in troubleshooting the issue.
- There was not a specific SOP or consideration for the different types of treatment deviations that could occur when different procedure are used between the [the satellite facility] and [the main campus] approach to treating these cases.
    - Note that there have been similar deviations as this incident in [the main campus] but were caught and [corrected] prior to beam-on mainly from radiographic imaging.

Controller: Therapists

- One of the two therapists treating on the day of the incident were also treating on the previous day but we weren't sure what they were doing during the incident that may have been a contributing factor.
- [The satellite facility] does not use tattoos but they still use landmarks to set up the patient. For example, using the nipple line, freckle, or scar as a landmark. This was discussed and not considered an issue in this incident.
- The RTTs felt that something wasn't quite right with the setup, they performed an investigation prior to beaming on but weren't able to identify the issue. After checking it out, they felt it was Ok to proceed.
- The [the *boost* reference surface in the surface monitoring software] was labelled correctly in the software and not considered an issue.

Controller: Treatment Planner

- [The satellite facility] had their dosimetrist retire in December and another dosimetrist from [the main campus] is now permanently covering [the satellite facility] treatment planning remotely. The planning, setup, and treatment procedures between [the satellite facility] and [the main campus] are slightly different. The dosimetrist from [the main campus] was using [the main campus] procedures for this case. For example,
    - [The satellite facility] uses the same isocenter for the primary and boost while [the main campus] tends to use different isocenters.
    - [The satellite facility] tended to plan the primary and boost on different days whereas [the main campus] tends to plan both at the same time. It was thought that the planning on different days was due to billing requirements in [the satellite facility].

Systemic Factors Contributing to the Incident

We believe the center and the enterprise has a good safety culture but perhaps it is not optimally operationalized because we have not discussed near-misses such as this incident across centers in the enterprise. We pride ourselves on each professional group being expertly trained and to be able to work efficiency to ensure optimal throughput while maintaining safety, however, there is a lack of clear guidelines on how to 'pause' a process so that a sufficient level of investigation can be completed when the frontline workers sense there may be a potential issue with any step in the process of care.

Final CAST Recommendations

After a full analysis, it is clear that the major contributing factor to this incident was related to using [the main campus] planning and treatment procedures in [the satellite facility]. An immediate short-term recommendation is to either plan and [treat] these cases the [local] way or educate the clinic (and update the SOP) to plan and treat these cases the [way it is done at the main campus]. It is noted that

standardizing the planning and treatment procedures for these cases will be necessary for the start-up of our new [satellite facility—different from where the incident occurred].

With the information provided, the therapists took all appropriate actions. However, this type of treatment deviation can be mitigated by ensuring that only the current treatment surface is imported in the [surface monitoring] system or the surface(s) not being used are deactivated.

The vendor ([surface monitoring system]) should be notified of this type of incident to understand whether or not future features of their software can mitigate it.

Information on near misses, such as this one, generates value and leads to safety improvement. Staff are encouraged to continue the input of near misses in the quality systems.

Appendix H. Survey Questionnaire

Learning CAST Analysis - Pre-training Survey

Start of Block: Trainee background

How long have you been analyzing adverse events/near-misses?
(Please round to the nearest year)

_____

Prior to this program, were you **aware of** the CAST analysis technique?

- Yes
- No

Prior to this program, had you received training on the CAST analysis technique?

- Yes
- No

Prior to this program, had you used the CAST analysis technique?

- Yes
- No

End of Block: Trainee background

Start of Block: Trainee baseline confidence

Rate your confidence in your ability to

	Not confident at all		Somewhat confident		Very confident
identify **comprehensive** causal factors after an adverse event/near-miss	○	○	○	○	○
identify causal factors that **eschew blame** after an adverse event/near-miss	○	○	○	○	○
design **effective** safety interventions to prevent the recurrence of an adverse event/near-miss	○	○	○	○	○

End of Block: Trainee baseline confidence

Start of Block: Block 3

For the questions beginning on the next page, please rate **whether you agree** with the statements.

End of Block: Block 3

Start of Block: Agree/disagree questions

Safety is increased by increasing system or component reliability. If components or systems do not fail, then accidents will not occur.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

High reliability is neither necessary nor sufficient for safety.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Accidents are caused by chains of directly related events. We can understand accidents and assess risk by looking at the chain of events leading to the loss.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Accidents are complex processes involving the entire sociotechnical system. Traditional event-chain models cannot describe this process adequately.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Most accidents are caused by operator error. Rewarding safe behavior and punishing unsafe behavior will eliminate or reduce accidents significantly.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Operator behavior is a product of the environment in which it occurs. To reduce operator “ error ” we must change the environment in which the operator works.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Major accidents occur from the simultaneous occurrence of random events by chance.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Systems tend to migrate toward states of higher risk. Such migration is predictable and can be

prevented by appropriate system design or detected during operations using leading indicators of increasing risk.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Assigning blame is necessary to learn from and prevent accidents or incidents.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Blame is the enemy of safety. Focus should be on understanding how the system behavior as a whole contributed to the loss and not on who or what to blame for it.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

End of Block: Agree/disagree questions

Learning CAST Analysis - Post-training Survey

Start of Block: Trainee background

How long have you been analyzing adverse events/near-misses?
(Please round to the nearest year)

_____

Prior to this program, were you **aware of** the CAST analysis technique?

- Yes
- No

Prior to this program, had you received training on the CAST analysis technique?

- Yes
- No

Prior to this program, had you used the CAST analysis technique?

- Yes
- No

During the program, were you receiving **any other** training on adverse event/near-miss analysis technique?

- Yes
- No

End of Block: Trainee background

Start of Block: Block 5

Overall, how satisfied or dissatisfied were you with the training program?

- Extremely satisfied
- Moderately satisfied
- Slightly satisfied
- Neither satisfied nor dissatisfied
- Slightly dissatisfied
- Moderately dissatisfied
- Extremely dissatisfied

How interesting was the training program?

- Extremely interesting
- Very interesting
- Moderately interesting
- Slightly interesting
- Not interesting at all

How relevant or irrelevant were the exercises in the training program?

- ○ Extremely relevant
- ○ Moderately relevant
- ○ Slightly relevant
- ○ Neither relevant nor irrelevant
- ○ Slightly irrelevant
- ○ Moderately irrelevant
- ○ Extremely irrelevant

How challenging or not was the training program?

- ○ Extremely challenging
- ○ Very challenging
- ○ Moderately challenging
- ○ Slightly challenging
- ○ Not challenging at all

How much more or less time would you be willing to spend on the training program?

- ○ Much more
- ○ Moderately more
- ○ Slightly more
- ○ About the same
- ○ Slightly less
- ○ Moderately less
- ○ Much less

End of Block: Block 5

Start of Block: Trainee baseline confidence

Rate your confidence in your ability to

	Not confident at all		Somewhat confident		Very confident
identify **comprehensive** causal factors after an adverse event/near-miss	○	○	○	○	○
identify causal factors that **eschew blame** after an adverse event/near-miss	○	○	○	○	○
design **effective** safety interventions to prevent the recurrence of an adverse event/near-miss	○	○	○	○	○

End of Block: Trainee baseline confidence

Start of Block: Block 3

For the questions beginning on the next page, please rate **whether you agree** with the statements.

End of Block: Block 3

Start of Block: Agree/disagree questions

Safety is increased by increasing system or component reliability. If components or systems do not fail, then accidents will not occur.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

High reliability is neither necessary nor sufficient for safety.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Accidents are caused by chains of directly related events. We can understand accidents and assess risk by looking at the chain of events leading to the loss.

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- ○ Somewhat disagree
- ○ Strongly disagree

Accidents are complex processes involving the entire sociotechnical system. Traditional event-chain models cannot describe this process adequately.

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Operator behavior is a product of the environment in which it occurs. To reduce operator “ error ” we must change the environment in which the operator works.

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Major accidents occur from the simultaneous occurrence of random events by chance.

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prevented by appropriate system design or detected during operations using leading indicators of increasing risk.

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- Strongly disagree

Assigning blame is necessary to learn from and prevent accidents or incidents.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

Blame is the enemy of safety. Focus should be on understanding how the system behavior as a whole contributed to the loss and not on who or what to blame for it.

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree

End of Block: Agree/disagree questions

Start of Block: Block 6

Are there any other comments, or suggestions that you would like to provide? Thank you!

_____

_____

_____

_____

_____

End of Block: Block 6