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Human Factor Associations with Safety Events in Radiation Therapy

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Human Factor Associations with Safety Events in Radiation Therapy

September 30, 2020

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Abstract

One important connection for all human beings is that we have a shared need for health care and are at some risk of experiencing medical error. Errors documented in the field of radiation therapy have included tragic levels of suffering and even death from preventable mistakes. Efforts to improve patient safety include an approach called incident learning that makes use of information about known errors to inform safety improvement strategy. The complexity of human contributing factors challenges those safety improvements. The problem addressed by this dissertation study is that radiation therapy puts patients at risk, and the incident learning systems designed to inform safety improvements have yet to be optimized through a human factors framework. The Human Factors Analysis Classification System, a validated system utilized to categorize human contributing factors to error, was utilized in conjunction with a radiotherapy-specific list of distinct error types, such as treatment planning and quality assurance to classify a diverse international sample of radiotherapy safety events. The goal of this research was to discover predictive patterns of human factors contributing to radiotherapy incidents. Associations were uncovered between human contributing factors to error. Supervisory failures are linked to erroneous decision making and to unsafe environmental preconditions. Predictive associations between human factors and radiation therapy error types were discovered as well. Treatment-planning errors are associated with a specific kind of skill-based error that involves a lack of mindfulness. Quality assurance events are associated with certain supervisory and decision-type errors. Image-guidance errors are associated with perception failures and to failures at the human-computer interface. These associations incorporate a human factors framework and have direction for effective risk mitigation strategies.

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My family is made up of some very special people who support me, put up with my (sometimes crazy) intensity, and who have been there throughout this lengthy process. Whether offering advice, encouragement, or driving my children to all of their activities, they have truly helped me to reach this milestone. I will always be especially grateful to my parents for making me feel that they are proud.

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Chapter 1: Introduction

Introduction to the Chapter

Cancer patients undergoing radiation therapy should not have to worry about preventable harm, yet accidents happen and improvement strategies have not been optimized with proven tactics from other industries. A series of particularly horrific accidents were highlighted by the *New York Times* in 2010 (Bogdanich, 2010a). Those stories inspired an increased commitment to safety within the field of radiation oncology, including an increased use of knowledge-sharing following erroneous events. This practice, known as incident learning, is not unique to radiation oncology or to the health care field. In fact, using errors as opportunities to develop mitigation strategies and to communicate about risk has had well documented successes in other industries, such as aviation (Mahajan, 2010).

Those successes from incident learning have yet to be fully realized in radiation oncology. One notable difference in how incident learning has been utilized relates to the recognized role of human factors; human factors have been intimately involved in aviation safety strategy but have not been nearly as integral to health care or radiation oncology. Human factors account for the complexity of human interactions, relationships, and communication patterns. Without a purposeful consideration of human factors as contributors to error, the focus of error analysis tends is more on the action taken rather than why it happened (Diller et al., 2014). With an evaluation of human factors contributing to radiotherapy safety events, this dissertation study describes and predicts patterns of specific human behaviors as they relate to error. Study results have fallen short of explaining why radiotherapy safety incidents occur, yet the predictive patterns shown can contribute greatly to efficient and effective safety improvements. A human factors analysis classification system (HFACS) was proposed in 2000 to give structure to a

means of incorporating human factors into error investigation and analysis. With separate

categories for unsafe acts, environmental preconditions, supervisory factors, and organizational

factors (and an additional multitude of subcategories), radiotherapy errors can be associated with

specific human factors. Through this approach, associations between which errors have taken

place and the human factors involved (from the HFACS) show predictive patterns useful to error

mitigation and safety improvement.

<div align="center">**Background to the Problem**</div>

Harm as Part of Medicine

The most basic principles of medical ethics include nonmaleficence, which is the

obligation of medical providers to refrain from intentionally harming their patients. They also

include beneficence or the requirement that providers act in the best interests of their patients'

health and well-being (Emanuel et al., 2008). Despite these basic priorities and intentions,

patients are still being harmed. Medical error is considered the third leading cause of death in the

United States today. This understanding was based on prior studies, such as the one done by the

Institute of Medicine in 1999, one by the Agency for Healthcare Research and Quality in 2004,

and a recognition that human and systems errors are not able to be recognized as official causes

of death on United States (U.S.) death certificates. Official causes of death are selected from the

International Classification of Disease system, which does not include options for human or

systems-based factors (Makary & Daniel, 2016). Without the ability to formally recognize

medical errors as a cause of death, underrepresentation seems inevitable. Detail about the nature

and magnitude of harm in medicine and specifically radiation therapy is explained in Chapter 2.

With the explicitly stated and presumed intention of providers not to inflict harm and the

recognition that patient harm remains a prevalent issue, it is logical to focus some attention on

the fact that an abundance of harm is brought about unintentionally. The Institute of Medicine's (IOM) landmark publication, *To Err is Human: Building a Safer Health System*, indicated that human beings are naturally prone to making mistakes. These mistakes lead to preventable errors that rival some of the more widely recognized diseases as threats to human health and wellness (Donaldson et al., 2000).

Response to a Call to Action

The IOM's publication was effectively a call to action regarding human error in medicine. Part of the response to this call was the Patient Safety and Quality Improvement Act (PSQIA) of 2005. Under this act, federal protections were offered for voluntarily reported patient safety information; medical errors could be shared as learning opportunities with protected confidentiality. The intent of this legislation was to encourage the reporting of medical errors so that safety and quality issues could be addressed (Office for Civil Rights Headquarters, 2017). The potential for shared information about error to enhance safety and quality improvement efforts was duly recognized.

In order to support the PSQIA's offered protections, the act authorized the creation of patient safety organizations (PSOs). These organizations offer a protected space for health care providers to submit information about errors and unsafe conditions. Within this space, data can be aggregated, analyzed, and reported in order to reduce the risk of harm to patients (Agency for Healthcare Research and Quality, 2018).

Harm Specific to Radiation Therapy

One small portion of the vast field of medicine is radiation therapy. Radiation therapy or radiotherapy is a type of cancer treatment that uses high doses of radiation to break down the DNA of cancer cells, effectively killing them or at least slowing their growth. These treatments

can elongate life for cancer patients and in some case even offer cure (National Cancer Institute, 2019). Much like all fields of medicine, however, history has shown that radiation therapy can also result in patient harm.

In 2010, the *New York Times* published a series of articles describing horrific pain, suffering, and death brought about by radiation therapy errors. One such story was the journey of a man named Scott Jerome-Parks who had been treated for a head and neck cancer. When a computer error had gone unnoticed, his brainstem and neck were treated with much higher levels of radiation than were intended. The result of this exposure included intense pain, deafness, near blindness, loss of his teeth, and a progression that eventually took his life at the age of 43 (Bogdanich, 2010a). The personal stories and tragic detail offered in this case and in others presented significant change in how radiation therapy caregivers approached the subject of patient safety. More information about the history of harm in radiation therapy is detailed in Chapter 2.

Why people act and behave in the ways that they do is explained by motivation theory, and a renewed awareness of safety risk and potential disaster had an effect on oncology staff following the *New York Times* publications. The need for personal safety is a fundamental human motivator (Maslow, 1943). It follows reason, then that as caregivers are directly responsible for other people's safety, ensuring that safety would also be a powerful motivator. When drive and commitment to patient safety supersede shame or concern about punitive responses to error, dialog about mistakes and safety improvement becomes possible.

Incident Learning as Part of Radiation Therapy

The safety culture in radiation therapy had new life after 2010, and in 2011, the American Society for Radiation Oncology (ASTRO) partnered with the American Association of Physicists

in Medicine (AAPM) to develop the Radiation Oncology Incident Learning System, or RO-ILS.

Clarity PSO, a federally listed patient safety organization provides the PSO services for RO-ILS,

and the program was officially launched in 2014 (American Society for Radiation Oncology,

2019a). An incident is defined as "an unwanted or unexpected change from a normal system

behavior which causes or has the potential to cause an adverse effect to persons or equipment"

(Ford et al., 2012 p. 7281). This definition contains some amount of subjectivity, which provides

a relatively easy way for those less motivated by patient safety and more motivated by self-

protection (from association with error) to hide mistakes. Incident learning is a means by which

medical errors and narrowly avoided errors can be utilized to better understand the underlying

contributing factors, to develop effective mitigation strategies, and to provide opportunity for

shared knowledge and widespread safety improvements. The very nature of this safety

improvement mechanism is heavily influenced by human motivation. Still, the information

exchanged through incident learning can provide invaluable insight for risk mitigation. When

utilizing information reported through incident learning it is critical to consider the human

drivers for the information reported and for the incidents themselves.

While the RO-ILS system was new for the US-based field of radiation therapy, it was

predated by the Radiation Oncology Safety Information System (ROSIS). ROSIS was launched

in 2001 with similar goals to those of RO-ILS. This system was an international system through

which information about incidents and near-incidents could be voluntarily reported (Cunningham

et al., 2010).

The International Atomic Energy Agency (IAEA) currently offers the Safety in Radiation

Oncology (SAFRON) incident learning system for the same purpose of providing learning

opportunities from voluntarily reported errors and nearly missed errors. Errors reported into this

system are confidential and are protected under federal legislation (IAEA, 2019). SAFRON was launched in 2012 and was authorized to incorporate the more historic ROSIS submissions at that time (IAEA, 2019). The culture of shared learning from radiotherapy errors, therefore, predated the *New York Times* articles from 2010, but the inspiration from those articles fueled the RO-ILS and SAFRON incident learning systems that are significant contributors to the patient safety landscape today.

Information contained in today's SAFRON database provides a wealth of information about radiotherapy errors and the precipitating factors that contributed to them. Those factors include more obvious contributors, such as mechanical failures and more subtle contributors rooted in human interaction. The human component of error affects not only the unsafe acts themselves but also the environmental and supervisory influences that envelop them. Understanding the role that these factors play in radiotherapy safety is critical to safety improvement strategy, yet it is often overlooked.

The role of human motivation within this SAFRON data may present itself with bias. As these data are a quantitative predictive study of error types and human contributing factors, bias is important to acknowledge and understand. Bias and other threats to this study were addressed at length in Chapter 3. The use of SAFRON data as opposed to incident learning data from a single institution or even country does have the advantage of including information from a diverse array of cultures and perspectives. In that regard, this study has benefitted from a potentially minimized bias from any specific source of contributors. That potential aside, geographic information regarding the source of incident submissions has not been provided by the IAEA, so the degree to which this type of bias has been mitigated is unknown.

Incident Learning Systems and Safety Improvement

While the potential for marked safety improvement comes with the opportunity to learn from the aggregation and analysis of reported errors, solid outcome-based data are somewhat limited. Reports of success that do exist take varied forms. Some institutions have cited a reduction in the number of errors that actually reach patients (Chao et al., 2014; Clark et al., 2010). It is important not to equate a reduced number of report submissions to improved safety as reporting for incident learning is voluntary and may increase or decrease for a number of reasons. Other publications have pointed to either the reduced severity of reported incidents or reductions in specific kinds of errors as indications of improvement (Clark et al., 2013; Deufel et al., 2017). The challenges of incident learning in radiation therapy have also been noted in the literature. A lack of communication, feedback, and actionable follow-up have been pointed to as potential limiting factors (Richardson & Thomasden, 2018; Sujan, 2015). There has also been a lack of understanding with regard to why incidents happen as the tendency is to focus more on that which happened and who was involved (Diller et al., 2013). Chapter 2 of this dissertation study includes a robust presentation of incident learning successes and shortcomings, both within and beyond radiation therapy. Alternatives to incident learning were compared and contrasted in terms of their historic effectiveness.

Consideration of Human Factors

In order to optimize the use of information offered through incident learning, it is necessary to take a step back to consider an approach to thinking about error. In 2010, Dekker proposed that people tend to attribute errors and failures to a singular system component. Instead of considering the system itself, blame is assigned to a specific person or thing. This vision aligns with the Swiss cheese model of error propagation proposed by James Reason. Through this model, a single error source may pass through multiple layers of safety barriers before

ultimately reaching a patient (Reason, 1990a). This model was discussed further in Chapter 2.

Dekker went on to hypothesize that errors are more so the result of interactions within complex

systems involving people, relationships, computer systems, and additional influences (Dekker,

2010). Environmental influences and human interaction, such as between supervisors and staff

are included within these complex systems. Dekker's views have been echoed throughout the

literature when errors are discussed in relation to human factors. Human factors are defined as

"the study of the interrelationships between individuals, the tools they use, and the environment

in which they live and work" (Ford et al., 2012, p. 7281).

The limited success has been realized through incident learning and the overall

prevalence of medical errors lend themselves to further work in this area, and this need has been

recognized in published literature. This need was also reviewed in greater detail in Chapter 2. It

has been suggested that health care organizations depend on high-reliability science or the

science for safe, effective, standardized processes. Industries, such as aviation, have earned

recognition as high-reliability organizations (HROs) when they are recognized as being complex,

hazardous, and have achieved safety levels that prevent serious or catastrophic events over long

periods of time (Agency for Healthcare Research and Quality, 2019). The health care industry is

also complex and hazardous. The theories and strategies for HRO safety improvements are,

therefore, of great interest within health care (Chassin & Loeb, 2011).

The pursuit of safety improvement by HROs has historically included a recognition that

errors are brought about by systems and complex human interactions. Landmark fundamentals of

factors associated with error were incorporated into a Human Factors Analysis Classification

System so that these factors could be mapped to a human factors-based schema. With this

system, factors contributing to error could be better understood, and safety improvement efforts

could be more efficient and effective. The system was originally designed to help analyze the causes of aviation accidents but has also been successfully utilized in other HROs and in health care (Diller et al., 2014). To date, the HFACS system has not been applied to error analysis in radiation therapy, and while the importance of human factors have been recognized in this area, a human factors-based aggregate error analysis has yet to be performed. The historic use of HFACS in aviation, rail, and in health care environments outside of radiation therapy were described in the next chapter of this study. For this work, the use of a quantitative approach to evaluating reported radiotherapy errors allowed predictive patterns between radiotherapy errors and human factors to be established.

Statement of the Problem

While complex and hazardous, health care has yet to earn consideration as a high-reliability organization. Other industries that have earned this recognition incorporated a human factors-based analysis into their safety improvement and risk mitigation work. In the health care field patients continue to be harmed by medical errors, which is a leading cause of death in the US (Makary & Daniel, 2016). Radiation therapy is the medical practice of treating cancer patients with high doses of radiation and is no exception to putting patients at risk of harm (Bogdanich, 2010 a or b; Sands, 2017). Efforts to improve patient safety in radiation therapy involve voluntarily reporting information about errors. Information learned from the mistakes of others can inform effective improvement strategies, but error analysis has often focused more on "what" and "who" rather than "why." Historic analysis has also lacked a focus on the complex patterns of human and human-computer interactions that contribute to errors (Diller et al., 2014). Human factors have been shown to exceed others as contributors to certain safety failures in radiotherapy (Huq et al., 2016). By oversimplifying assumptions with regard to the causation of

an incident, mitigation strategies developed from that analysis may be suboptimal. The problem being addressed by this dissertation study is that radiation therapy puts patients at risk, and the incident learning systems designed to inform safety improvements have yet to be optimized through a human factors framework.

The goal of this research is to discover predictive patterns of human factors contributing to radiotherapy incidents. In order to accomplish this goal, a large international database of reported safety events were analyzed with respect to both radiotherapy-specific error categories and human contributing factors. Tests for predictive associations werr run between human factors from a four-tier human factors classification system (tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences) and between those factors and the radiotherapy error types. Results yielded predictive patterns for reported errors and is valuable for prospective safety planning.

Relevance of Incident Learning to Improving Safety

There has been well-documented clinical harm within the field of radiation oncology. Pain, suffering, and even death have resulted over the years from multiple adverse events (Bogdanich, 2010a). Information sharing about errors and narrowly avoided errors can be of great help to safety improvement efforts, and incident learning systems have been put in place to facilitate such sharing (Clark et al., 2013). Reducing the risk of error in complex and hazardous environments through incident learning is not a unique goal for radiation therapy or for the health care environment in general. Significant work and marked success has been well documented in other areas, such as in aviation. Much of that work has centered on analyses of human factors or complex interactions involving people, their relationships, their tools, and their communications (Diller et al., 2014). The purpose of this dissertation study was to explore

reported incident learning data for predictive patterns of factors contributing to unsafe radiotherapy events.

The complexity of involved human factors has challenged this type of analysis in the past and has been underrepresented in published work (Diller et al., 2014). This investigator used a systematic approach to analyze a radiotherapy incident report database through a human factors classification system. Findings may contribute to safety improvement methodology by providing insight into the human contributing factors for an aggregate database of historic errors. The relevance of this dissertation is bolstered by the importance of patient safety and by the need for improvement. It is, however, somewhat threatened by human bias and construct validity involved with incident learning. The voluntary nature of report submission causes human motivation and other biases to affect the data and subsequent analysis. It is also understood that reported events reported make up only a small portion of that which actually takes place. The incident submission process is also somewhat restrictive and could influence that data that is ultimately included.

The event's clinical significance is described in one data field (clinical severity) in the SAFRON report. The majority of submitted incidents were considered minor, yet it is the moderate to severe events that were likely most critical to safety. The focus of the study was only on the reports classified as either moderate or severe so that the more critical events remained a focus. This selection process may influence the results of the data analysis. The incorporation of a diverse data set and required inclusion criteria were utilized to minimize bias and to maximize the quality of the analysis. All threats to this dissertation study were discussed at length in Chapter 3.

Theoretical Framework and Research Question

Theories

Unsafe acts and their contributing factors in the health care setting can be discussed within a number of contexts and theories. The social-ecological model is useful to understand these issues as it provides a four-level framework in addressing some of the involved complexities. Human factors contributing to error are complex and that complexity is part of why they have not been well-studies or well-understood. Their importance to safety improvement successes in high reliability organizations have, however, shown them to be of great value. Social ecological theory describes contributions and influences from individuals, individuals within relationships, from the community at large, and within society as a whole. These four levels of interaction influence one another and ultimately contribute to reality and the human experience (Centers for Disease Control and Prevention [CDC], 2020).

Individual health care workers, patients, and others involved can influence medical care. All involved parties contribute by making decisions, reacting to problems, and by communicating positivity and displeasure. With these influences, they affect relationships with their families, their friends, and their caregivers. Communities are affected by the successes and failures of their local health care environment, and in turn, society is affected by community practices. The tragedies depicted by the *New York Times* in 2010 exemplify these four levels of influence. Each radiation therapy error described caused pain, suffering, and loss for the patients and their families (Bogdanich, 2010a). Involved caregivers were also affected in significant ways. These individuals affected relationships within their personal lives and in their hospital. These events had profound effects on the involved hospitals and their communities.

Social ecological theory also helps explain influences from the community level back down to the individual (CDC, 2020). Using the same example of the accidents from 2010, the

resultant changes to society affected widespread patient safety efforts, especially within the radiotherapy community. New incident learning systems were launched and many practice leaders prioritized safety within their health care systems. Individual providers were affected in different ways, some dedicating their careers to improving radiotherapy safety. Patients were also affected by the increased focus on error prevention.

This dissertation study was focused on human factors as contributors to error in radiation therapy. Social ecological theory helped the investigator to understand how safety issues may propagate from the organization level down through supervisory levels to first line caregivers and to patients themselves. Conversely, it was important to understand how patients and caregivers may influence their departmental environments and their organizational environment.

Motivation and behavior theory is also fundamental to understanding human factor associations with unsafe acts in radiotherapy. Maslow (1943) discussed the motivation of people through a hierarchy of needs in his landmark publication. Maslow explained that in order for people to be motivated by something, the more basic fundamental human needs must first be fulfilled. Physiological needs form the base of this hierarchy followed by safety needs, by love and belonging, by self-esteem, and lastly one can be motived by self-actualization (Maslow, 1943). The philosophy of human motivation was particularly important for this investigation because safety events in this study were voluntarily reported; the presence or absence of event reports is partially based on human motivation to report. For example, health care workers may be motivated to report safety events by their personal patient safety priorities. Similarly, they may be motivated not to report safety events by their fear of negative repercussions.

According to Maslow, personal safety is one of the more fundamental human motivators. In consideration of the safety of others, humans may first consider their own personal safety in

terms of their job security and their reputation. Reporting one's own errors may be hindered by fear of negative repercussions. One of the higher needs on the hierarchy is esteem. If reporting error or taking other steps to ensure the safety of others hurts one's own esteem may be a limiting factor to safety. On the more positive side of motivation and behavior theory, people may be positively motivated by doing good work that protects patients and improves their quality of care. By upholding and improving upon effective safety practices, the risk of harm to patients is reduced. One of the higher needs on the hierarchy is esteem. If reporting error were to ultimately hurt one's own esteem, heath care workers may be reluctant to do so. Workers may be positively motivated to report error if they feel that it would protect patients and improve the quality of care.

Research Question

How are human factors associated with each other and with error types in radiation therapy?

Hypothesis

Human factors contributing to error exist at multiple tiers of proximity to the unsafe act itself. Contributing factors more remote to the unsafe acts will likely have a predictive association to contributing factors closer to the unsafe acts themselves.

The investigator also tested for predictive patterns of human contributing factors as they relate 14 types of radiotherapy errors. Nineteen unique contributing factors exist as subcategories within four tiers of the HFACS. Multiple predictors are expected from this work. Contributing factors at the HFACS tier three supervision level are likely to be related to quality assurance-type errors as quality assurance tasks often performed by a physicist or staff member working alone and often after hours. The physics staff in a radiation oncology department may

also be limited to a single or very few physicists. This environment may lend itself to

insufficient supervision and tier three supervision contributors. Environmental factors under the

HFACS Tier 2 preconditions for unsafe acts are likely to relate to image guidance errors. These

errors depend greatly on imaging software and the human-computer interface, which are integral

parts of the technological environment. Lastly, personnel factors under HFACS Tier 2

preconditions for unsafe acts are likely to relate to documentation-type errors. Personnel factors

include communication, coordination, and planning issues, which may be predictably related to

erroneous documentation.

Definition of Terms

1. Contributing factor. "A circumstance, action or influence which is thought to have
   played a part in the origin or development of an incident or to increase the risk of an
   incident" (Ford et al., 2012, p. 7281).

2. Error. "Failure to complete a planned action as intended or the use of an incorrect
   plan of action to achieve a given aim" (Ford et al., 2012, p. 7281).

3. Human factors. "The study of the interrelationships between individuals, the tools
   they use, and the environment in which they live and work" (Ford et al., 2012, p.
   7281).

4. Human factors engineering. "The study of human behavior, abilities, and limitations,
   and the application of this knowledge to design systems for safe and effective human
   use" (Chan et al., 2010, p. 2).

5. Incident. "An unwanted or unexpected change from a normal system behavior which
   causes or has the potential to cause an adverse effect to persons or equipment" (Ford
   et al., 2012, p. 7281).

6. Near miss. "An event or situation that could have resulted in an accident, injury, or illness but did not either by chance or through timely intervention. Also known as a close call, good catch or near hit" (Ford et al., 2012, p. 7281).

7. Quality of care. "Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Ford et al., 2012, p. 7281).

8. Quality management. "Framework to guide an organization towards improved performance. Quality management includes quality planning, quality control, quality assurance, and quality improvement. Resources are acquired and administered to achieve the desired level of quality" (Ford et al., 2012, p. 7281).

9. Radiation therapy. The field of medicine that utilizes high doses of radiation to treat health conditions, most typically cancer.

10. Radiotherapy. This term is another term for radiation therapy.

11. Safety barrier. "Any process step whose *primary* function is to prevent an error or mistake from occurring or propagating through the radiotherapy workflow" (Ford et al., 2012, p. 7281).

12. Severity. "The extent to which an action causes harm" (Ford et al., 2012, p. 7281).

13. Treatment delivery. "The process of administering radiation to the patient in accordance with a radiation oncologist's prescription" (Ford et al., 2012, p. 7281).

14. Treatment planning. "In the context of radiation oncology, treatment planning refers to the process of translating the physician's prescription into instructions for the treatment delivery device" (Ford et al., 2012).

15. Unsafe act. This term is another term for an incident.

Description of Variables

The dependent variables for this dissertation study are radiotherapy errors. These variables are different categories of reported incidents or deviations from routine and planned behaviors that either cause harm or put people or equipment at an atypically high risk of incurring harm (Ford et al., 2012). These errors have been voluntarily reported into the SAFRON database by an international group of radiotherapy health care workers. The error categories can be found in Table 2.

Independent variables for the study include 15 human factor subcategories all derived from four tiers of the Human Factors Analysis Classification System (HFACS). This system is based on James Reason's four levels of error causation (Diller et al., 2014). The levels are arranged such that influence from one level likely transcends the next one down, and the higher tiers are more progressively remote to the lowest tier. The base tier of HFACS is Tier 1 (unsafe acts), which contains variations of accidental errors and purposeful violations. The next level up is Tier 2 preconditions for unsafe acts and includes preconditions to error or environmental influences. The next tier of human factors is Tier 3 (supervision), and the highest (most remotely influencial) level is Tier 4 (organizational influences; Figure 1). Some modifications have been made from the originally published HFACS. Descriptions of each tier and the sublevels of human factors beneath them can be found in Figures 1 and 3 in Chapter 3.

Rationale for Human Factors Approach to Radiotherapy Safety

Health care is a human need, yet it is an unfortunate reality that patients are sometimes harmed during their course of treatment. Pain, suffering, and even death have been reported as a result of medical error in the field of radiation therapy (Bogdanich, 2010a). The importance of patient safety is, therefore, a widely recognized concept, and one meaningful way to address

safety is to report and learn from mistakes. In order to make optimal use of information about reported radiotherapy errors, the information must be analyzed and communicated effectively. Incident learning systems have a protected environment for such work to be done.

While databases of reported errors exist, safety gains from the incident learning process have been suboptimal (Sujan, 2015; Richardson & Thomasden, 2018). One hindrance to progress may be a disproportional focus on that which happened and who was involved as opposed to contributing factors for why the errors took place. Other industries like health care are both complex and hazardous and have achieved high reliability and successful safety improvement through human factors-based analyses of their errors (Diller, 2014). By analyzing errors in radiotherapy with a human factors-based approach, predictive patterns of factors contributing to error were uncovered. As an understanding of factors contributing to error becomes apparent and predictable, an understanding of why errors occur begins to develop. Radiotherapy errors associated with the human components of unsafe acts or with precipitating human interactions can shed light on and present instructive information about patient safety in radiation oncology. The formality and structure of the HFACS makes this possible. The data uncovered in this study can then be used to inform effective safety improvement efforts and error mitigation strategies.

Study Assumptions

This dissertation study was performed under the assumption that incident reports included within the SAFRON database were submitted truthfully from the perspective of the submitter. It was also assumed that the database supplied by the owner of SAFRON, the IAEA, was inclusive of all reports, complete, and unedited.

Summary of the Chapter

The dissertation study was introduced that related human contributing factors to radiation therapy errors. Patient harm is an unfortunate but ever-present aspect of medical care today, and some of the error is due to human mistakes. The Institute of Medicine's publication in 2000 resulted in federally-backed regulations that allowed health care workers to report errors in a protected environment. The need for such legislation was recognized in 2010 when a series of serious radiotherapy accidents were published in the *New York Times*. In response to these tragedies, the international incident learning system SAFRON was launched in 2012. SAFRON presented an appropriate environment for voluntary error report submissions and also incorporated reported events dating back to 2001 from a legacy system called ROSIS.

Incident learning is used for health care workers to gain insight from unsafe acts and adverse events that have been voluntarily reported. The theory of human motivation has a great contribution as to whether errors are reported and to the factors contributing to those errors. While some quality and safety improvements have been attributed to incident learning, gains have been limited, and the potential for safety improvements has not yet been reached. One theory for this limitation is that the focus of the analysis of errors tends to be more on that which happened and who was involved rather than on the cause of the error and either directly or indirectly help bring it to fruition. Other more highly reliable industries with similar hazards and complexities have had more marked success with safety improvements. Efforts in these other industries have involved more of a focus on human factors. Human factors are the interactions, relationships, and communications between people involved in complex processes. A human factors-based classification system has been utilized for some of that improvement work and has now been utilized within the health care industry as well. The problem being addressed by this study was that radiation therapy involves an inherent risk to patients, and the systems designed to

collect information about error and inform safety improvements have never been analyzed within a human factors classification system. The goal, then, was to perform a study of radiotherapy errors and uncover the human factors that may predictably contribute to them. Error types, such as treatment planning and quality assurance, were identified for each of the included events. Each event was then associated with all reported human contributing factor subcategories from the HFACS. Predictive patterns were developed between contributing factors and between contributing factors and error types. The four tiers of the HFACS are as follows: Tier 1 (unsafe acts), Tier 2 (preconditions for unsafe acts), Tier 3 (supervision), and Tier 4 (organizational influences). This study was relevant to safety improvement work in the field of radiotherapy by clarifying the predictability of human factors as they relate to risk and error.

One theory for safety in radiation therapy and reported error analysis is social-ecological theory. This theory is used to explain how individuals, relationships, communities, and society all affect one another and are affected by one another. Patients, caregivers, health care environments, communities, and society as a whole are all affected by medical errors and by how they are handled. Conversely, the safety practices shaped by the broader societal levels also transcend down to the individual affecting his/her care and experience. Motivation and behavior theory as discussed is also helpful to understand how human factors relate to radiation therapy and to unsafe acts. Maslow's hierarchy of needs depicts how humans are motivated first by more fundamental needs, such as safety, and later by less fundamental needs, such as esteem. These motivations affect human behavior and contribute to if, when, and how errors are voluntarily reported. Motivations and behaviors also drive the human factors for incidents. These theories were utilized in the analysis for this dissertation study.

The research question proposed is as follows: How are human factors associated with error in radiation therapy? It was hypothesized that higher tier human factors from the HFACS were predictably associated with lower tier contributing factors. It was also hypothesized that supervisory factors are associated with quality assurance errors, environmental preconditions for unsafe acts are associated with image guidance errors, and personnel factors are associated with documentation errors. The rationale for the study stemmed from the existence and prevalence of patient harm and the need to make optimal use of reported safety errors. The successful human factors-based error analysis that has been used in other highly reliable industries like the aviation industry has not yet been used with reported errors in radiation therapy. This study used a human factors approach to uncover predictive patterns within human contributing factors to error and between those factors and radiotherapy-specific error types. That information can then inform effective safety improvements.

Chapter 2: Review of the Literature

Introduction to the Chapter

In order to understand how human factors are associated with error in radiation therapy and that which may predictably contribute to them, it is critical to understand relevant information in this area that predates this study. From a historical perspective, information about harm in medicine lays the groundwork for why this kind of work is needed. Harm from radiation therapy is even more specifically relevant. The history of safety improvement efforts includes incident learning, an approach that allows many to learn from the mistakes of few. This chapter addresses the strengths and weaknesses of incident learning along with other historic efforts to improve patient safety. It also addresses the safety issues and strategic improvements that have taken place in other industries, such as aviation. Successes in aviation, rail, and other high-reliability industries have earned the attention of safety improvement specialists in health care as they may offer solutions relevant to health care as well. Lastly, this chapter addresses the history and relationship between human factors and health care.

Aside from history, this dissertation study is grounded by relevant theory pertaining to human factors and patient safety. Human behavior is largely driven by motivation, and the landmark theories of A. H. Maslow are reviewed as a presentation of core human drivers. In order to understand human behaviors around error in health care, James Reason's basic theories of human error are discussed. Taking a step beyond baseline human error, the complexities of this error are reviewed with a presentation of Sidney Dekker's views on systems thinking. With all of this historical and theoretical history, a research methodology can be crafted to optimize the value of this study.

Historical Overview

Harm in Medicine

As introduced in Chapter 1, the presence of harm within health care is an unfortunate reality that predicates the need for this study, but determining its prevalence and scope is an exceptionally challenged goal. Harm may have different meanings to different people, and aside from lacking a universally accepted definition, communication and data abstraction methods leave much to be desired. One prominent publication that attempted to quantify the problem and put medical error in the spotlight was the Institute of Medicine's report *To Err is Human* from 1999. Authors quantified the prevalence of medical error by estimating the number of deaths that could be attributed to these preventable mistakes. Their annual estimation within U.S. hospitals was between 44,000 and 98,000 (Institute of Medicine Committee on Quality of Health Care in America, 1999). These numbers were shocking and served as a call to action. Authors encouraged a focused and systematic approach to reducing error, and those recommendations were widely accepted, discussed, and implemented.

The IOM report was based on its lower and upper estimates of error-related hospital deaths from two prominent studies from earlier in the 1990s that utilized similar methodologies. The two-fold difference in their estimates was one indicator of the lack of true understanding and limited accuracy. Another fundamental flaw was that both studies were observational and failed to show true causality with their findings (McDonald et al., 2000).

In 2016, there was another landmark publication in which medical errors were claimed to be responsible for an even larger number of hospital deaths; they estimate was that there were 251,454 annual deaths in U.S. hospitals caused by these mistakes. With that understanding, preventable errors in hospitals would be the third leading cause of death within the US (Makary & Daniel, 2016). It should be noted, however, the researchers offered no discussion of its

limitations, and there is cause to question the validity of the claims. While it may be accurate that some level of error did take place with the number of patients suggested, the researchers again fell short of demonstrating causality. One year later, Shojania and Dixon-Woods (2017) pointed out that hospital deaths cannot be analyzed the same way as deaths from car accidents can; while it is reasonable to assume that lives lost from a car accident would not had been lost without the car accident, one cannot make the same assumption about hospital patients. Patients go into hospitals with illnesses and injuries that leave them at some risk of death whether or not medical errors take place. This fact was not adequately accounted for in the Makary publication (Shojania & Dixon-Woods, 2017).

The prevalence of medical error is important to this dissertation study as it shows the underlying importance for the need for safety improvement. Whether the number of hospital-related deaths in the US are 50,000 per year or 250,000 per year, any preventable death should be avoided, and all of these numbers are high. Contradictions within the published data demonstrate the need for improved and systematic reporting mechanisms. Makary pointed out that coding used to indicate a patient's cause of death on his or her death certificate does not include a selection to indicate unplanned error, which led to a systematic underrepresentation of medical error within officially recognized causes of death (Makary & Daniel, 2016). In order to improve safety in the health care environment, an improved system of understanding the prevalence of harm is greatly needed.

One more important consideration in understanding preventable harm and the need for safety improvement is the fact that prevalence estimations should not be limited to error-related death alone. Safety event reporting regarding non-fatal errors is now required from multiple organizations, such as the Centers for Medicare and Medicaid Services and the Joint

Commission. While these requirements may ultimately be helpful to establishing a database of errors, it may also be detrimental to safety improvement efforts. Reporting requirements have a resource burden on health care settings and may cause health care workers to narrowly focus on key areas that require data submissions (Thomas & Classen, 2014). Still, the need for a better understanding of health care safety is apparent, and some level of systematic reporting is, therefore, necessary. For the purpose of this dissertation study, the published information available to date is sufficient to demonstrate the need for patient safety improvements.

Harm in Radiation Therapy

Given the ambiguity involved determining the prevalence of general medical harm, it is at least as challenging to determine the prevalence of harm in one specific area of medicine, namely radiation therapy. Radiation therapy or radiotherapy is a cancer treatment method that utilizes radiation to damage the DNA of cancer cells. This damage slows down tumor growth and subsequently either shrinks or destroys them. Tumors within the body are often in close proximity to healthy organs and tissues and while the destructive aspects of radiation are helpful to damage cancer cells, they can also be harmful to those healthy tissues. Planned courses of radiotherapy strike a balance between maximizing the amount of radiation given to tumors and minimizing that given to healthy structures (National Cancer Institute, 2019). Radiation errors could upset this balance and inflict harm when exposure was unplanned and unintended. They could also inflict harm by underexposing intended targets.

As introduced in Chapter 1, there have been several well-documented tragedies regarding patients harmed during radiation therapy, but to date, there have not been many published assessments of aggregate harm. Some of the earlier publications from the 1990s were dedicated to more general medical errors. The corresponding focus in radiation oncology came about after

2010, following a series of troubling articles in the *New York Times*. Interest in radiotherapy safety improvements were fueled and invigorated by these articles and brought about a realization that radiation oncology is a particularly hazardous area of medicine. Treating patients with radiation has been recognized as a complex process fueled by a great deal of human interaction and technical sophistication (Hendee & Herman, 2011).

The authors of the *New York Times* publications each focused on singular or small groups of medical errors and depicted the personal tragedies that resulted. The very first publication contained a powerful description of the pain, suffering, and ultimate death of a 43-year-old man who was harmed by a preventable radiotherapy error (Bogdanich, 2010b). Subsequent articles featured additional individual victims and groups of victims, such as 36 who were overexposed at a New Jersey-based cancer center (Bogdanich, 2010a). The author focused on individual stories as a means of personalizing the tragedies. This strategy was ultimately a motivating strategy as the radiation therapy community reacted with a strengthened resolve to improve radiotherapy safety (Hendee & Herman, 2011).

While documentation about patient harm caused by radiotherapy is sparsely understood and published in a seemingly haphazard way, that which does exist is revealing. It has been hypothesized that radiotherapy errors are grossly underreported (Bogdanich, 2010a). Given that which is known about underreported harm in general medicine, it is likely to be the case. It was also pointed out that in order to close the information gap and to learn about errors in a systematic way, heterogeneity within radiotherapy workflows and taxonomy must be significantly reduced. Further, the data that have been reported have yet to be optimally aggregated and studied (Potters et al., 2016). Improvements in communication, data analysis, and

error prevention strategies would all, therefore, be of value to radiotherapy patients. Together these align with the broad goal of this dissertation study.

Improving Safety in Radiation Therapy

The focus on improving patient safety in radiotherapy was started back in 2010 but did not end with the *New York Times* articles. Shortly after radiotherapy safety issues were brought into focus, a meeting sponsored by the American Society for Radiation Oncology and the American Association of Physicists in Medicine was pulled together to address the issues at hand. Attendees included radiotherapy professionals from many areas within the discipline so that diverse perspectives could be accounted for. The end result of this meeting was the publication of 20 recommendations to improve safety. An action plan was also put into place that included creating an anonymous error reporting system, enhancing the practice accreditation program, expanding training, developing communication tools, developing a program to enhance interoperability between equipment vendors, and advocating for new legislation (Hendee & Herman, 2011). Each of these goals was ultimately carried out.

The meeting resulted in some very specific goals that were all achieved, although there was not an especially large emphasis on the issue of safety culture. It may not have been addressed as directly as it is a more abstract concept and was, therefore, easier to overlook. Safety culture encompasses everything from communication patterns, the punitive nature of the environment when mistakes take place, staff empowerment, resource availability, and a host of additional considerations. The meeting participants did seek to establish training, education, and experience requirements for radiation oncology staff, yet even this training falls short of capturing the importance of safety culture (Hendee & Herman, 2011).

There is little statistical evidence that safety culture is tied to patient safety in radiotherapy, yet it has been the expressed opinion of several researchers that it is. One researcher who sough to establish this connection hypothesized that there was an association between safety culture and reported errors, yet there was not enough statistical power within available data to support that conclusion (Sands, 2017). Other researchers have used safety culture assessment tools to tie an institution's culture to actual patient safety. The importance of this need is broadly recognized yet remains unproven, and work in this area is ongoing (Nieva & Sorra, 2003).

Safety improvement efforts in other areas of radiation oncology have taken many different forms over the last decade. The use of big data to fuel this effort has been recognized as having great potential. Information qualifies as big data when the data set is excessively large requiring computer-based analyses and can support solid statistical significance. Radiation oncology is a data-driven medical specialty yet is still challenged to make use of big data analysis techniques; there is too much variation in language and processes between individual departments to run aggregate big-data analyses (Potters et al., 2016).

Another safety improvement strategy proposed was the enhanced use of peer review within radiation oncology settings. Some level of peer-to-peer review is a standard component of best practice standards in radiation oncology. It is required of professional staff, such as radiation oncologists and physicists as part of departmental accreditation requirements. Some programs, however, are far more rigorous than others, and one suggested path to safety enhancement was employing robust peer-review standards (Chao et al., 2014; Marks et al., 2013). In fact, it has been proposed that standardizing all major workflows within radiation oncology is key to optimizing safety (Chao et al., 2014). These suggestions are all sensible, and a common thread

throughout published recommendations is that improved standardization in workflows, taxonomy, and data collection would allow for broad-level aggregate analyses that currently heterogeneous systems challenge. The aim of this dissertation study is to make some progress in this area as it will involve an aggregate analysis of radiotherapy errors that have been reported from a broad international group of contributors.

One more major avenue that has been proposed to support radiotherapy safety improvements was the report of Task Group 100 of the American Association of Physicists in Medicine. A group of professionals met to address radiotherapy failures specific to workflow and process errors. Their ultimate goal was to provide a method of systematic analysis of institution-specific processes. With this understanding, resources available for quality management could be optimally appropriated. The first step in their recommended course of action was to define each and every step involved in a specific radiotherapy process. Potential failure modes would then be defined and rated in terms of the frequency of their occurrence, the severity of consequence that may be involved, and the detectability of the failure. With these ratings, each individual risk could be objectively prioritized. The third recommended step was to map out a fault tree that could aid in determining where within the process things could go wrong. Information from all three components were then recommended to be considered in developing quality management activities (Huq et al., 2010).

AAPM's Task Group 100 (TG100) is methodical, logical, and is well-referenced in the field of radiotherapy safety. Unlike many other safety improvement recommendations, TG100 methodology is a prospective approach; while a department could choose to employ a TG100 strategy in an area where errors manifest, it is a proactive strategy to improve quality and safety. The challenge with TG100 methodology is that is a time consuming and labor intensive process.

Well-resourced departments and academic cancer centers may be more likely to employ these strategies than other smaller more resource-challenged environments. Going back to the previously referenced calls for improved standardization between departments and organizations, if the field of radiation therapy had more standardized processes and nomenclature, work done by the better-resourced institutions would be more applicable to all.

The investigator of this dissertation has established associations between safety events that have been reported by radiation oncology departments and contributing factors that preceded them. While retrospective in nature, predictive patterns were uncovered. Like the failure modes addressed in TG100, this information can be utilized to support quality management and safety improvement activities.

Incident Learning

Incident Learning in Health Care

The AAPM and ASTRO-sponsored meeting back in 2010 was a call to action in response to the *New York Times* publications. The very first point in the resultant six-point plan was to create an anonymous national database through which errors could be reported and analyzed (Hendee & Herman, 2011). An error or incident is defined as an "unwanted or unexpected change from a normal system behavior which causes or has the potential to cause an adverse effect to persons or equipment" (Ford et al., 2012, p. 7281). The opportunity to utilize reported incidents to inform safety improvement strategies is called incident learning and incident learning systems have a rich history both within radiation oncology and beyond.

Back in 2000, the health care industry began more broad usage of incident learning as a methodology for safety improvement. Some of the impetus for this focus was the notable success that other hazardous industries had with similar efforts. In particular, it was understood that

reporting and learning from near-miss events or safety events that were caught prior to reaching a patient were key to the process. By taking advantage of this information, data analysis and the resultant prevention strategies could be more efficient and effective; the inclusion of near-miss data would allow for systems thinking rather than simplistic linear thinking when it came to understanding which factors predictably contribute to error (Barach & Small, 2000).

While this knowledge and awareness was growing, incident learning remained challenged in the health care environment. One major void was information tying safety improvement efforts to improved outcomes. Other industries, such as aviation, had a greater history of success in this regard. With aviation, the frequency of plane crashes was known before and after incident learning-based improvements were implemented. Health care is a much more complex industry in which the number of factors contributing to an incident may be numerous and patient outcomes are confounded by comorbidities. Without enough evidence to demonstrate the effectiveness of incident learning systems, some find it hard to justify the resources required to support them (Benn et al., 2009). One small amount of objective data exists from the Agency for Healthcare Research and Quality. AHRQ survey data shows that larger numbers of incident reports are associated with lower rates of negative indicators that detect adverse events (Ford & Evans, 2018).

Other challenges to incident learning have also been prominently outlined. Voluntary reporting has been challenged for many reasons, such as fear of blame or lack of confidence that reporting will lead to effective change (Health Quality Ontario, 2017; Whitaker & Ibrahim, 2016). This information has confirmed that report databases represent fewer errors and near misses that actually take place. The actual number of errors may never be known with precision but can expected to be significantly greater than that reported. Underreporting has been estimated

to range between 50% and 96% of errors, yet the wide range here is another indication that this information remains unknown (Barach & Small, 2000). Other problems with incident reporting include lacking clarity on that which should be reported, the overall cost burden from these systems, and a lack of visible and effective follow-up (Mahajan, 2010; Stavropoulou et al., 2015). If feedback to report contributors is lacking, report contributors will become disengaged. People must feel that their effort and potential risk of blame or punishment are worthwhile and will be met with improvements to patient safety.

In 2016, 15 years after the landmark publication *To Err is Human*, a qualitative study was performed through which eleven experts in health care safety offered their thoughts regarding the greatest challenges to incident learning. Their findings presented a broader understanding of that which is needed to make better use of incident learning data. They discussed the engagement of reporters, visible action taken following report submissions, and cost. They also discussed the need to take better advantage of health information technology. Finally, these experts pointed to inadequacies in current report processing. Triaging and analyzing report data were felt to be haphazard and suboptimal. Improvements in meaningful analyses techniques should drive more effective follow-up (Mitchell et al., 2016).

The importance of incident learning has been established within the health care environment, but that value is placed more on its potential to improve safety than on solid outcome data. The challenges outlined are fairly consistent between authors. Part of the challenge lies within the stated inconsistencies in workflows, communication patterns, and nomenclature. Another well-established value of incident learning stems from its success in other industries. This investigator employed a methodology that has been used in other industries to find predictive patterns of human contributing factors for reported errors.

Incident Learning in Radiation Therapy

Foundations and Taxonomy. As the focus of this dissertation study is on safety events in the radiotherapy space, it is important to understand the history of and need for incident learning in this area. Ganesh (2014) studied radiotherapy errors between 1976 and 2007 showed 7,741 reported events, 40% of which resulted in patient harm. This result is 16,000 times greater than the risk of injury or death from an aviation accident in the US (Ganesh, 2014). There is no objective data comparing the risk of radiotherapy treatment errors to errors in other areas of health care. It has been noted, however, that radiation oncology departments have particularly complex human interactions and human-computer interactions due to consistently advancing and highly sophisticated technologies (Ganesh, 2014; Spraker et al., 2017). For these complex interactions and other reasons, the need for incident learning in radiation therapy has been emphasized in many forums and is often underscored both with data and individual stories. Professional organizations advocating for its use to improve patient safety are also numerous.

Multidisciplinary authorities, such as the World Health Organization and the Joint Commission for U.S. hospital accreditations, recommend the use of incident learning systems. Within the radiotherapy space, the American Society for Radiation Oncology goes as far as listing incident learning among its standards for accreditation. One of the first shared incident learning systems in this space was the Radiation Oncology Safety Information System or ROSIS. This system was launched in 2001 by the European Society for Radiotherapy and Oncology (ESTRO). In 2012, some of the founders of ROSIS worked with the IAEA to launch the Safety in Radiation Oncology system. ROSIS data prior to 2014 was incorporated into SAFRON, and it is that system that has been used for this dissertation study (Ford & Evans, 2018). SAFRON had over 1,600 incidents in its database as of 2019. Other radiation oncology incident learning

systems include the National Reporting and Learning System (NRLS) in the United Kingdom, the National System for Incident Reporting in Radiation Treatment (NSIR-RT) in Canada, and the Radiation Oncology Incident Learning System (RO-ILS) in the United States (Ford & Evans, 2018).

One of the key challenges to incident learning is the lack of comparable workflows and nomenclature between radiation therapy centers. In 2012, consensus recommendations were published to provide technical guidance for the implementation and use of incident learning systems. Definitions were proposed and are accepted for use in this dissertation study. Standards for process maps, severity scales, report data, and causality taxonomy were also published. Causal taxonomy in this case is meant to describe contributing factors to an incident as opposed to an experimentally determined causal relationship. The rationale for proposing the taxonomy was to allow for increased consistency when interpreting contributing factors to an error. The factors are separated into seven categories and drill down to nearly 100 more specific descriptors of potential root causes (Ford et al., 2012). This published list of factors is thorough and detailed and contain many of the human contributing factors that were used in this study.

A more current study of the AAPM's causal factor taxonomy, again with the term "causal factor" representing contributing factors and not experimentally proven causation, was done in 2017. This taxonomy was more concise having six categories with only 17 individual factors. In the dissertation study, reports were assigned to multiple contributing factors, yet four factors in addition to those included in the AAPM taxonomy were ultimately needed (Spraker et al., 2017).

Reporting Issues. A well-studied challenge to incident learning is insufficient reporting. This issue was eluded to in Chapter 1 when the human motivational component of error communication was introduced. Drivers and barriers for reporting involve personal motivations

as well as environmental influences. Skills that lend themselves to increased reporting include both communication and coping (Schwappach & Gehring, 2015). Motivations to report are typically centered around the desire to improve safety and prevent harm to patients (Okuyama et al., 2014). Additional motivators, such as fear of being caught without having been honest or transparent, have not been discussed. Barriers to reporting are far more numerous and have consistent agreement among published studies. Power dynamics have been cited by several researchers as having influence in this area. When someone of greater stature is present, his/her attitudes, beliefs, and relationships with other staff present have a great impact on whether or not that staff is comfortable speaking up when an error takes place (Morrow, Gustavson, & Jones, 2016; Okuyama et al., 2014; Schwappach & Gehring, 2015). Another commonly referenced barrier is the belief that speaking up would not result in any effective change. Whether due to lack of feedback after reporting or lack of infrastructure, leadership, and resources to improve safety if a person does not believe that his/her reporting will result in change, he/she tend to remain silent (Health Quality Ontario, 2017; Morrow et al., 2016; Okuyama et al., 2014). That which was not mentioned in any of these publications was the effect of flawed analyses. Ineffective incident learning and analysis systems would both cause and then in turn be hampered by reduced participation.

While these researchers provide insight into why incident reporting may be either strong or weak, it is fundamentally challenged with the uncertainty of its potential. In other words, even if the reporting environment was known to be optimal, the number of expected report submissions would still be unknown. This descepancy is due to uncertainty and subjectivity around that which should be reported. People's true reluctance to report is also unknown and

depends on their private feelings and perspective at the time an error takes place. For these

reasons, stated expectations of report volumes are inherently flawed.

Effectiveness of Incident Learning. With nearly 20 years of incident reporting history

in radiation therapy, there are scores of researchers claiming both positive and negative results.

One researcher used a systematic review from 2015 to determine that while process and clinical

settings may be improved due to information garnered through incident learning, no solid

evidence of outcome improvement or culture change was found (Stavropoulouet al., 2015).

While the lack of outcome data is a solid critique of the usefulness of incident learning, some

improvements noted do lend themselves to overall safety culture improvement. The validity of

findings is notably challenged by subjectivity in how both safety culture and improvements are

understood. There was no universally accepted definition of these fundamentals offered.

Other researchers aligned the shortfalls of incident learning to several other factors. A

lack of effective feedback, for example, has been detrimental. If staff members who report

incidents do not see responsive action taken, they will be less inclined to report in the future.

Punitive "shame and blame" cultures have also been problematic. Staff who are made to feel

reckless or unskilled after involvement in an error are strongly discouraged from bringing future

errors to light (Novak et al., 2015). Few researchers have cited flawed analyses or less apparent

reasons why incident learning in radiotherapy has not reached its potential to inform safety

improvements. Most researchers focus on actions taken or not taken, such as report submission

and timely feedback. The quality of action taken, such as the effectiveness of report triage and

analysis, is more challenging to assess due to subjectivity. This finding may be an important area

with opportunity for improvement, however. One researcher who did comment on the

importance of quality work recommended that analyses should be performed by clinically skilled

staff familiar with relevant workflows. Sometimes administrators or risk prevention professionals who do not have experience in a particular specialty perform the analysis work and this lack of experience can be problematic (Richardson & Thomadsen, 2018). Conversely, it could be argued that care providers familiar with clinical procedures may not amply focus on communication breakdowns, environmental factors, poor policy, or understaffing.

A metric that can be viewed very differently by different people, either positively or negatively, is the meaning for fluctuating report volumes. One researcher spoke favorably of his/her incident learning experience and exemplified that by noting a major reduction in report volumes over time (Clark et al., 2010). This finding is in direct contrast to that which was found through the AHRQ study, which showed the opposite that it was greater numbers of incident reports not fewer that should be associated with positive change (Ford & Evans, 2018). The reason for this contradiction makes sense. If one kind of error was reported consistently whenever it takes place, then fewer reports would indeed indicate fewer errors. Incident learning is often not as clean and simple as that scenario, however. There so many factors that contribute to report volumes (as discussed earlier) that an assumption of one error equating to one report is unsubstantiated. More often than not, the opposite trend makes more sense in that larger report volumes, including reports of near misses, indicate a positive safety culture and reduced risk of harm to patients. These are the findings found from the AHRQ study.

Other researchers have used alternative measures to demonstrate incident learning success. A reduced number of incidents that reached patients and a reduced incidence of safety policy violations were two such measures (Deufel et al., 2017). These are valid indicators as they are based on defined standards that can be objectively applied. Even these measures, however, are still reliant on a constant safety culture and consistent reporting by staff. Changes in

departmental environments due to workload, staffing, and resources could threaten the consistency needed as could changes to staff from illness, positive or negative experiences, and so forth. Similar findings from studies over a longer period of time add to credibility. That which has been reported fairly consistently is that departments engaged in incident learning tend to have positive safety cultures. Positive safety cultures in this case include robust engagement by staff, proactivity in quality improvement efforts, and leadership involvement (Clark et al., 2013; Gabriel et al., 2015).

One last research took the approach of isolating one specific kind of treatment within an incident learning database. These were all near-miss events and were rated according to how much harm they would have caused had they not been caught. Contributing factors were assigned using the more abbreviated causal factor taxonomy discussed earlier (Spraker et al., 2017). Rather than concluding that the incident learning process was effective or ineffective in terms of error or reporting trends, reseachers focused on resultant interventions and the reliability of those interventions. They found was that the more harm that an error could have caused, the more likely it was to have had an intervention applied. Those interventions tended to be more reliable when they included automations and forcing functions (unavoidable given routine workflows) when the errors involved human error. In other words, the safety improvement strategies implemented were stronger and more reliable when the errors involved people making skill errors and personal mistakes as opposed to when those errors were equipment related. When errors were due to hardware or software malfunctions, interventions were less reliable as they focused more on rules, procedures, and training (Kim et al., 2017). Techniques used and assumptions made were reasonable, and the data set was used for statistically significant

findings. The difference in intervention approach when human error was involved is noteworthy as human factors are central to this dissertation study.

Human Factors in Safety

Some of the richest research and most supportive data about accident prevention comes from the field of aviation. Targeted safety improvement efforts have been widely acknowledged as being successful. Within the US, there has been a 41% decrease in accidents and a 57% decrease in the accident rate per 100,000 flight hours between 2001 and 2016 (Federal Aviation Administration, 2018). One of the main focal areas for these improvements has been on the human factors component of safety. Human factors are "the interrelationships between individuals, the tools they use, and the environment in which they live and work" (Ford et al., 2012, p. 7281). The complexity of human interaction was introduced in Chapter 1. Incorporation of this issue into safety improvement strategy ultimately had a key role in the approach to aviation safety.

There were several reasons for the advancement in aviation safety, and the initial successes were prominently due to technical improvements. Accident data between 1977 and 1992 showed a declining number of errors, but these improvements were in large part due to improved environmental and mechanical factors; human factors had not been contributing to the noted safety gains. It was recognized at that point that reaching further safety goals would require a shifted focus on human factors. In fact, human factors were responsible at some level for between 70% and 80% of all aviation accidents (Shappell &Wiegmann, 1996). In 1997, one researcher cited multiple sources in his claim that humans had replaced aircraft in being the most dangerous factor in terms of flight risk (Murray, 1997).

The Human Factors Analysis Classification System

In light of the recognized contribution of human error to aviation accidents, there was a need to be able to investigate errors and develop mitigation strategies within a human factors framework. That need was addressed in 2000 with the Human Factors Analysis Classification System (Shappell & Wiegmann, 2000). HFACS was rooted in a widely accepted model for human error called the Swiss cheese model. The Swiss cheese model contains four different levels of human failure with each of the four tiers influencing those below it. Each layer is made up of "cheese," a protective barrier for safety, and "holes," opportunities for human error to occur. When the holes in one layer align with holes in other layers, human error is possible through the successive layers of safety protection. When holes align in all four layers of cheese, there is effectively no safety barrier in place to prevent an accident (Reason, 1990a). The HFACS utilizes the same four levels or tiers of safety with a human factors perspective. The first ground-level tier is the unsafe act itself, including human errors and violations. The second tier contains preconditions for those unsafe acts. These conditions are the operator conditions or practices that fed into the incident. The third tier of the HFACS is unsafe supervision. The fourth tier, most remote to the unsafe act, is comprised of organizational influences (Shappell & Wiegmann, 2000). When flaws in each of the four tiers align, a situation would be at the highest risk for error. In Chapter 1, the Swiss cheese model was presented in contrast to a more complex model of human interaction proposed by S. Dekker in 2010. Dekker's model challenged an oversimplified view of error causation and analysis. Both Dekker and Reason's theoretical framework lay important groundwork for error analysis with human factors and were considered in the discussion of results from this study.

      HFACS Applied to Aviation and Rail. The HFACS is a tool that allows for systematic error analyses within a human factors framework. Before this type of analysis schema was

available, root cause analyses of errors would typically cease once a mechanical or other objective contributing factor was discovered (Wiegmann & Shappell, 2001). This simplistic type of investigation failed to address the more complex nature of that which actually contributes to error. One study of aviation accidents between 1990 and 1996 utilized the HFACS and considered both human and non-human contributors to the safety breakdowns (Wiegmann & Shappell, 2001). The HFACS schema was felt to be appropriate in that no additional causal categories were needed, and all but two were utilized. There was also good inter-rater reliability, which contributed positively to the validity of the work. Specific contributing factors were shown through this analysis, which allowed safety improvement efforts to move forward with very specific and appropriate goals (Wiegmann & Shappell, 2001).

There was another study of military aviation safety events in which the HFACS was utilized to classify 288 incidents (Hooper & O'Hare, 2013). Different kinds of aviation mishaps were evaluated along with their associations with different human contributing factors. Information was learned about the nature of that which led to the mishaps. For example, it was discovered that skill-based errors, those occurring with familiar tasks that typically do not require a great deal of thought, were predominantly responsible for rotary wing incidents. Relationships were also established between these kinds of errors and unsafe supervision (Hooper & O'Hare, 2013). Another study was performed in China that used 523 reported pilot errors. Error types were mapped to the HFACS framework. The subsequent data analysis showed relationships between human contributing factors at the four different classification tiers: tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences. Associations between unsafe acts and contributing factors at both adjacent and

higher level tiers served to demonstrate Reason's belief that latent conditions throughout higher level tiers (tiers two through four) are associated with unsafe acts (Li & Harris, 2006).

Other aviation error studies utilizing the HFACS also had positive results in the sense that the system was found to be a useful tool to analyze human contributions to error. A study of naval aviation mishaps from 2001 showed excellent reliability with consistent application of the system (Schimidt et al., 2001). Contributing factors to error were identified and were felt to be of great value to safety improvement efforts (Schimidt et al., 2001). A study of helicopter accidents in 2011 was similarly successful (Liu et al., 2013). The contribution of higher tier four organizational influences were found to be significantly greater than those of lower tier factors, such as tier two preconditions for unsafe acts. Strategic improvements to the organizational safety culture were then central to their path forward (Liu et al., 2013). A comparative study was done with the HFACS to better understand differences between military and civilian aviation accidents. Learned information was utilized to improve pilot training with targeted skill building in atypically weak areas (Shappell & Wiegmann, 2004).

In addition to aviation, the HFACS has also been used successfully in the rail industry. Researchers applied the HFACS schema to reported rail incidents between 2001 and 2014 (Madigan et al., 2016). The system was felt to work well as the researchers concluded with a risk profile that was helpful at informing improvement strategies. It was noted, however, that information about tier three supervision and tier four organizational influence failures were largely missing from the incident reports (Madigan et al., 2016). The lacking information noted in this study could be a potential problem with any retrospective review of reported errors as error reports are finite. This lack of information does not invalidate patterns of contributing factors discovered through application of the HFACS, but the potential for an incomplete

analysis must be recognized. That issue applies to this dissertation study as well and was discussed as a potential limitation.

Reports regarding utilizing the HFACS are generally positive about the potential of this classification system to show the nature of contributing factors to error. One outlier was about the use of the HFACS for air traffic control errors with the Australian Defense Force (ADF; Olsen et al., 2010). These researchers did some extensive testing of inter-rater reliability and ultimately found the classification schema to be unreliable (Olsen et al., 2010). Other studies showed good to excellent inter-rater reliability. The potential for subjectivity in utilizing the HFACS is duly noted and was considered through this dissertation study.

HFACS in Health Care. Consideration of human factors is newer to safety studies in the health care field. With insight from aviation, one group of health care investigators focused on data showing that most aviation errors had some contribution of human factors (El Bardissi et al., 2007). They hypothesized that it would be the case in health care as well. In order to assess operating room errors from a human factors perspective, they conducted interviews and then classified the resultant transcripts with the HFACS. The classification schema was deemed appropriate and human factor contributions to errors were found. These findings began at the tier four organizational influence level and transcended down through tier three supervision, tier two preconditions for unsafe acts, and tier one unsafe acts (El Bardissi et al., 2007). In another study of surgical mishaps, researchers focused on more extreme or serious surgical errors (Thiels et al., 2015). As soon as an error in this category was discovered, a team was deployed to perform a root cause analysis (RCA) of the situation. Information from that RCA was then analyzed using the HFACS. As in studies done in other industries, use of the HFACS led to the discovery of

predictive patterns of error. The most prominent contributing factors became key target areas for strategic safety improvements (Thiels et al., 2015).

One researcher described how the HFACS could be applied within the health care setting in comparison to more commonly utilized error analysis methods such as RCAs (Diller et al., 2014). It was proposed that RCAs were less effective due to a lack of use standardization, the lack of a standardized taxonomy, and multiple other less desirable features. Researchers claimed that RCAs tended to focus on that which happened and who was involved as opposed to focusing on why an error took place. Lastly, findings from RCAs were said to be too nonspecific to lead to ineffective safety improvements. By comparison the HFACS was described as being standardized both in terms of process and taxonomy. The focus was also directed to that which contributed to error and was used for specific contributing factors to be identified and utilized for strategic improvement (Diller et al., 2014).

While the literature contains examples of how the HFACS has been used to show predictive patterns of contributing risk factors, it was important to consider HFACS alternatives. In 2011, a group of investigators studied 26 different medical error taxonomies (Taib et al., 2011). They found that most lacked an ability to consider theoretical error concepts in addition to the more objective descriptors of that which happened. Human contributing factors tend to fall within a more subjective analytical space and were, therefore, not considered with most of the available systems. The HFACS was among a minority of classification schemas that considered human factors and subjective error theory. Further, this group was found to be more generically applicable to reported errors. Classification tools that were able to capture both system failures as well as psychological failures were found to be more effective in analyzing risk and error (Taib et al., 2011).

There was another valuable study of the HFACS within health care, and the researchers not only pointed to the system's unique value but also to potential challenges applying the system retrospectively to reported medical errors (Diller et al., 2014). Researchers pointed out that information missing from error reports could prevent one or more tiers of the HFACS from being considered in the analysis, which could bias study results (Diller et al., 2014), which was an important consideration for this dissertation study. Positive results from retrospective applications of the HFACS to error reports in other industries were considered as well. Ultimately, the value of considering human factors as an integral part of error analysis was recognized as a priority. In order to mitigate against the challenges of retrospective analysis, error reports were only selected for study inclusion if they contain sufficient information about contributing factors. The specific inclusion criteria was addressed in Chapter 3 and was a part of the study discussion in Chapter 5.

As the HFACS is to be used in this radiotherapy health care study, this section was concluded with a broad critical overview of the published literature. The HFACS system has been used extensively in several industries, such as aviation and rail and more recently in healthcare. Investigators have tested the schema in terms of its applicability and ability to be utilized with limited bias. Results and reviews of experience have been largely positive. That which is missing from the literature are reports of the subsequent safety improvement plan implementations. A complete validation of the HFACS would include not only its usefulness for error analysis but whether or not the strategic interventions informed by the HFACS actually work. Publications of this nature are likely lacking for multiple reasons. First, it is challenging enough to find statistically significant patterns of contributing factors behind error and even more challenging (beyond the scope of this dissertation study) to determine casual explanations

of why errors take place. Showing why errors do not happen would be an even more distant and challenging goal because they are the exception and not the norm. Second, there is so much complexity to the health care environment that aligning a noted risk reduction with one specific safety enhancement is particularly challenging as well. Even given these limitations, there is support in the literature for an expectation that human factors are involved in radiotherapy errors. Reviews of historic error data have not yet been performed from a human factors perspective and the HFACS offers a valid system to show associations between those contributing factors and the reported unsafe acts. As with other studies, predictive patterns can inform safety improvement strategies that have a substantiated expectation for effective results.

Radiotherapy Safety and Human Factors

Without specific inclusion of the HFACS, there is some work that has been done to link human factors-based analyses to safety improvements. Researchers noted that technological advancements in radiation therapy were created to improve efficiency, quality, and safety. In some instances, however, it is the technologic advancement itself that led to errors (Chan et al., 2010). Rapid advancement can leave some staff with insufficient system familiarity, and improved technology can also often come with increased complexity. For these reasons, the very factors that led to some safety improvements could also have led to safety mishaps. In order to reduce unsafe acts in this investigator's institution, a field study was launched to analyze radiotherapy workflows. A number of human factors were identified as sources of potential error. Human-computer interfaces were the redesigned to mitigate those errors. Sixteen radiotherapy students were utilized to test both the original and redesigned systems, and the human factors-based redesigns were shown to (a) reduce error rates, (b) increase the speed of task completion, and (c) improve user satisfaction (Chan et al., 2010). This study had a smaller

scale with insufficient power to experimentally determine causation, but it does reflect positively

on the potential for human factors-based improvements to reduce error and improve efficiency.

Aside from the HFACS studies discussed, there are a number of additional publications

connecting human factors with risk in radiation therapy. One qualitative study was launched in

response to a recognized safety problem concerning radiotherapy communications (Garza

Lozano, 2013). Interviews were used to inform strategic safety culture improvements. Feedback

from staff following those improvements indicated that those improvements helped to improve

communication and enhanced safety (Garza Lozano, 2013). The researcher supported the use a

human factors framework to approach safety improvements but does so subjectively without

strong evidence to support the claims.

There was a more solid study performed in which human factors were linked to safety

risks in radiation therapy (Spraker et al., 2017). The purpose of this investigation was to test a

causal factor taxonomy published by the American Association of Physicists in Medicine. The

taxonomy was applied to 300 randomly selected incident reports from the SAFRON database.

The most common errors involved communication and human behaviors. It was also noted that

reported events involving human factors engineering were associated with more serious or high-

risk issues (Spraker et al., 2017). Multiple other researchers supported this finding; the human-

computer interface in areas of technological growth not only advances the capabilities but also

increases the risk of error (Castro, 2014; Palojoki et al., 2017). Magrabi et al. (2010) offered

different perspective on this issue. The purpose of that study was to analyze safety incidents

related to computer use in order to develop a new classification system. It was shown that only

0.2% of reported studies fit that description. The incident learning system involved had over

40,000 reported events, so the study had a sufficient number of included cases (Magrabi et al.,

2010). This low percentage may not have resulted from a lack of computer use errors but rather the potential for this human factor to be overlooked. As errors are often studied with respect to whom was involved and that which happened, it is plausible that human-computer interactions and other systematic means of communication may be overlooked as contributing factors to error. In the classification system that was utilized in this dissertation study, the investigator considered all possible contributing factors, including poor human factors engineering.

Given the strong presence of human factors in safety risk outside radiation therapy and the high level of human interaction involved within radiation therapy, it is logical to pursue a human factors-based safety assessment of radiotherapy risk. There is more research needed to investigate the link between human factors and radiotherapy errors and ultimately to tie the HFACS schema to outcome data. This dissertation study used the HFACS to serve the former need. This effort contributed to the lengthy but worthy process of improving radiotherapy safety.

Relevant Theory

Radiotherapy errors, like errors throughout health care and other industries, have contributing factors from mechanical failures, human failures, and other types of failures as well. In order to understand predictable contributors to error and ultimately to design optimal safety improvements, it is important to understand the theoretical drivers regarding human error and overall error analysis.

Human Motivation

The foundations of human behavior stem from intrinsic motivations. A. H. Maslow published his theory of human motivation back in 1943, and his understanding remains a well-supported theory today. The theory uses human motivations through a pyramid of needs that has been subdivided into five tiers. The more fundamental tiers are lower on the pyramid. The lowest

tier includes needs that are physiological in nature and include food, water, warmth, and rest. The second tier from the bottom reflects the human need for safety. These first two levels together are basic human needs and must be met before humans tend to focus on the next two levels, which are psychological in nature. The third tier up from the bottom (and first psychological need) includes belongingness and love, which describes the need for relationships and human interaction. The fourth tier from the bottom describes the need to serve self-esteem, to feel accomplished, and to be recognized. Lastly, the top layer of Maslow's pyramid of needs is self-actualization. Maslow describes a human's need for self-fulfillment and feeling accomplished. Maslow did leave some room in his theory for the order of need fulfillment to be slightly altered from how it is laid out in the pyramid. He also noted that human behavior is typically driven by more than one need (Maslow, 1943).

Maslow's hierarchy was described earlier with regard to event reporting because it is helpful in understanding why someone may or may not be willing to report an error. Most people have a desire to be respected and to feel accomplished. These are the two highest tiers of the hierarchy. A more fundamental driver may be someone's need for safety, the second tier up from the bottom of Maslow's hierarchy. If someone feels that the security of his/her employment may be threatened by reporting his/her part in an error (which then affects the ability to provide basic essentials for their family), he/she will most likely stay silent. In contrast in a non-punitive safety culture, health care workers may feel freer to share their errors and allow others to learn from their mistakes. If everyone participates in this kind of communication, the risk of error would be reduced for all.

If most staff members had their most basic needs met, the desire for status, recognition, and respect may also drive safety behaviors. If someone is personally involved in an error, he/she

may not be willing to jeopardize his/her own security in order to protect others. Conversely,

someone who feels he/she is not responsible for an error may feel that he/she would earn status

or respect by coming forward and reporting. These issues reflect human behavior both on an

individual scale and on a broader scale within institutions. Incident learning system

administrators often ask whether participant institutions would like to be listed publicly. Some

institutions see this recognition as an accolade as participation in incident learning can be viewed

as an indication of a positive safety culture. Other institutions wish to remain anonymous and

consider participation as an admission of being error prone. Maslow's publication presents a

framework for how to think about all of these drivers although the order of the pyramid is not

absolute, and multiple factors may play a role in any single motivation. Maslow's hierarchy

should be understood as a framework or a working theory to better understand human behavior.

Human Error

Motivation is an important aspect of human behavioral theory when it comes to

performance and response to stimuli. With regard to error, there is additional relevant theory

available that helps shape the understanding of why humans make mistakes. With this

knowledge, the industry is better positioned to try to avoid errors.

One of the most renowned theorists with regard to human error is James Reason who

published his landmark theories in the early 1990s. A focal point of his ideas was that people

interact with systems in complex ways that sometimes cause weaknesses. These weaknesses can

be thought of as latent failures or failures that lie dormant until something happens to bring about

a more prominent error. The more latent failures there are, the more likely it is to trigger an error.

These failures can be within an end-user environment, at supervisory level, or even at an

organizational level. Reason's well-known depiction of this cumulative failure theory is also

known as the Swiss cheese model. As stated earlier, the holes in the cheese represent latent failures and when these holes align there are no safety barriers left to prevent error (Reason, 1990b).

Reason developed his theories with reference to other historic work in this area. After careful review and consideration, he hypothesized that recurrent types of human error stem from routine human performance mechanisms; Reason felt that more of repeated errors occur when performing normal functions as opposed to when attempting something new. An important contribution from his work was the presentation of three error classifications: skill-based slips, rule-based mistakes, and knowledge-based mistakes (Reason, 1990b). These kinds of errors have been widely recognized in current error taxonomy, including that within the radiotherapy space. A slip is a failure is made while performing a task that requires knowledge and skill but that is performed routinely without error. Rule-based errors are those that stem from either not applying an appropriate rule or from completely misjudging a situation. A knowledge-based error stems from simply not having the information necessary to avoid the mistake (Ford et al., 2012). In the HFACS schema, misjudging a situation is considered a perception error and rule and knowledge based errors are considered decision errors.

Reason's theories present a foundation for thinking about how people act within systems and how multiple unsafe conditions or latent failures can eventually contribute to a more serious error. While this framework is plausible, it is regularly adopted and cited today, and it maintains a somewhat simplistic view of cause (or multiple causes) and effect. A different version of how humans and systems interact with respect to error was presented by Sidney Dekker in 2009.

Human Factors and Systems Thinking

While not entirely contradictory to the theories around human error provided by Reason, Dekker's views go much further to consider the complexities of human interaction; Dekker focused more on the system and how an oversimplified view of human factors falls short of understanding or prevent error. In explaining the system view, the better-understood individual view was clarified. Referred to by Dekker as a Newtonian world view, this individual view is strongly aligned with historic Western thinking. It is linear in terms of cause and effect, meaning that one failure leads to another in a simple linear chain of events. The Newtonian world view also follows the laws of mechanics in that situations are ultimately simple, complete, and intuitive once enough time has been taken to understand them. The assumption is that in time complete understanding will be come apparent with all that took place leading to an error. There is also an assumption about an ontology that if an error has been observed, there must be an action driving it that can be identified as being responsible (Dekker, 2010).

Dekker's explanation of the Newtonian view of error is not often specifically referenced in published accident analyses, but his descriptions of how the root causes of accidents are pursued and understood are recognized within the literature. One researcher compared individual versus organizational perspectives of accident causes (Catino, 2008). Medical accidents were reviewed with regard to that which took place and how situations were ultimately handled. Individual blame was predominant as the researchers focused on tangible and apparent causes. Individual blame is also grounded in personal responsibility, a value that western society has consistently prioritized. While Catino (2008) took a more Newtonian approach to error analysis, he also recognized the value and need for more complex organizational thinking to optimize safety improvements.

Safety protocols and risk reduction behaviors are often aligned with theories around human error. Dekker pointed out that given the Newtonian ontology in that one should be able to foresee harm given a true and complete understanding of our environment, it is considered negligent if steps are not taken to prevent that harm. An example was given of traffic accidents and low speed limits in congested town squares. Given the understanding of increased traffic, parking, and pedestrians, drivers lower the speed limit as a means of lowering the risk of an accident. If someone breaks that speed limit and hits another vehicle, there is an assumption that the accident was due to the person's negligence by going too fast. As Dekker went on to explain a more complex theory of human factors and system complexity, it was questioned whether the accident would have necessarily been due to the person's speed. In the Newtonian theory, there were a finite number of possible contributing factors and so the fault analysis would have been fairly simple. Dekker proposed that this view is oversimplified and further attention paid to gain a more accurate understanding of human error theory (Dekker, 2010).

Dekker explained the alternative to the Newtonian theory with a so-called complexity and systems world view. With this theory, systems are not closed or finite, they are open and very much dependent on interactions within the environment. The added complexity leads to a conclusion that the number of interactions between humans, between humans and computers, and between humans and other aspects of the environment is far too large for people to process. Under this theory, each new computer system set up to mitigate error may reduce some aspects of error but also contributes significantly to added complexity and subsequent error. "With the introduction of each new part or layer of defense there is an explosion of new relationships" (Dekker, 2010, p. 18). The more typically embraced Newtonian view does not account for this buildup of risk or buildup of safety breakdowns that could ultimately lead to error and patient

harm. Dekker's views are not refuted in the literature, but it is notably rare to find researchers who apply the complexity and systems world view to error analysis. In more recent articles, the need for systems-based thinking is acknowledged, but none go as far as to acknowledge the elusive and uncertain nature of error analysis that Dekker proposed. The investigator of this dissertation study found associations between reported safety events and different aspects of the systems that surround them. The goal, therefore, is not to seek a complete understanding or finite explanation of causal factors but rather to establish predictive patterns. With that limited information, safety issues are not likely to be completely resolved but rather to be improved. Safety improvements are considered a worthy goal and are not in contradiction of Dekker's complexity theory.

The complexity and systems theory led Dekker to some final conclusions that are worthy of mention and were incorporated into this study and discussion. It was hypothesized that the truth regarding error causation is not limited to a single explanation. It is incumbent upon safety improvement strategists, therefore, to gather as much information from as many sources possible, but never to believe that the information garnered is complete. It was also advised that strategists be nimble and open enough to reverse prior conclusions when new information suggests that reversal. It should be understood, however, that in those circumstances the initial conclusions leave a fingerprint on the system and change the reality of the system for future risk and error (Dekker, 2010).

Other analysts who presented system-based theories for accident or error analysis are not in contradiction with Dekker though some offer more in the way of solutions. For example, one theorist proposed using the five consecutive "why' questions from Six Sigma methodology. With this approach, a problem is addressed with the question "why," and the subsequent answer

is then also addressed with the question "why." After repeating this process five consecutive times, the depth of the root cause is felt to be adequately approached (Leveson, 2011). This process has a reasonable path forward in addressing error complexity without forfeiting the entire exercise due to the infinite and unsolvable nature to the problem as presented by Dekker.

Several additional researchers offer theories of systems thinking, yet tools available to apply this kind of approach to incident learning data is lacking, which is largely due to the heterogeneity of relevant data sets and to the relatively few number of reports that are voluntarily submitted. It is more likely that progress in this area will be realized through the use of big data from electronic medical records. Once computer-based analyses are able to be performed on these enormous and complex databases, advancing safety in ways that combat the challenges that Dekker described will be likely. Until then and with unique opportunity still available beyond that point, there is valuable insight to be gained through incident learning. That insight was approached in the dissertation study through the analysis of an international database of reported errors. The potential here fell short of that which a computerized big data analysis may someday be able to accomplish, yet it incorporated free text contributions from submitters describing errors and contributing factors. That kind of non-discrete data contributes a unique value beyond that which computerized analyses of discrete data can offer today.

Summary of Literature

There is a rich history of error and safety analysis that predates this dissertation study. That history both substantiated the need for this study and presented a wealth of knowledge and perspective from which further insight was gained. The most basic imperative to improve patient safety in radiotherapy stems from the history of harm in medicine. The Institute of Medicine's report, *To Err is Human*, put the issue of patient harm in the spotlight back in 1999 (Institute of

Medicine Committee on Quality of Health Care in America, 1999). This and other subsequent

reports have highlighted the prevalence of preventable patient harm and also showed that a small

fraction of errors are apparent that actually take place. The same situation exists within the

medical specialty of radiation therapy. This discipline is dedicated to treating cancerous tumors

with high doses of radiation. While radiation is effective at damaging cancer cells, it is also toxic

to healthy organs and tissues that are exposed as part of treatment. The balance of maximizing

dose to tumors and minimizing dose to healthy tissues is delicate, and when treatment errors take

place, patient harm can be devastating. Stories of radiotherapy harm were notably published in

2010 and as with harm in other areas of medicine, known errors are expected to be a gross

underrepresentation of reality (Bogdanich, 2010a).

Following the stories of radiation therapy harm in 2010, the American Society for

Radiation Therapy and the American Association of Physicists in Medicine held a meeting to

address safety and to set appropriate safety improvement goals. Efforts existed beyond those

stemming from this meeting and included making use of big data, enhancing peer review, and

improving standardizations (Chao et al., 2014; Marks et al., 2013). The AAPM also published a

proactive strategy to address workflow and process errors. This publication from AAPM's Task

Group 100 offered the radiotherapy community a logical and potentially effective methodology

to reduce patient risk (Huq et al., 2010). The task group's strategy was notably time consuming

and not able to be easily implemented in all settings.

One important avenue for radiotherapy safety improvement is incident learning. This

practice involves the voluntary reporting of errors so that information regarding that which went

wrong can be used to inform future error avoidance strategies. The history of incident learning is

not confined to radiotherapy or even to health care. For example, it was used successfully by the

aviation industry. In comparison to aviation, however, health care has greater complexity and greater heterogeneities in its technology and communications. With these challenges, incident learning has been resource intensive and by some reports questionably effective (Benn et al., 2009). Published researchers in this area describe problems with report submissions due to several reasons, such as fear of repercussion or disbelief that reporting would result in positive gain (Health Quality Ontario, 2017; Whitaker & Ibrahim, 2016). Other researchers cite the more positive effects of incident learning; the Agency for Healthcare Research and Quality noted a reduced rate of negative safety indicators with an increased volume of incident report submissions (Ford & Evans, 2018).

Specifically in radiotherapy, incident learning has been accepted and promoted as a fundamental means of quality and safety improvement. There has also been a call for a consistent and systematic taxonomy to address the recognized heterogeneity in workflows and communication patterns (Ford et al., 2012). Several incident learning systems have been established for radiation therapy, including the SAFRON system, which is run by the IAEA. Data from this system were utilized for this dissertation study.

As in other areas of incident learning, radiotherapy error reporting challenges have been recognized and discussed in the literature. This issue may introduce an information bias within incident learning databases (Health Quality Ontario, 2017; Morrow et al., 2016; Okuyama et al., 2014). The effectiveness of incident learning is another important topic of discussion in published literature. There are many positive studies showing that a robust incident learning environment promotes a positive safety culture and an improved focus on quality and safety (Clark et al., 2013; Gabriel et al., 2015). Other researchers point to the fact that while cultures and focused efforts may improve with incident learning, there has yet to be solid outcome data

supporting the value and need for incident learning (Stavropoulou et al., 2015). The complexities

of health care and radiotherapy have been noted with respect to the challenge of linking

radiotherapy incident learning to outcome data. Associating incident learning with outcome data

is a lofty goal due to the many confounding factors involved with tying clinical outcomes to

upstream safety improvement efforts.

Human factors have been widely recognized for affecting safety in many industries. The

link between these factors and aviation accidents led to the development of a Human Factors

Analysis Classification System. This system has information from safety errors to be organized

and classified within a human factors framework. The framework consists of four successive

tiers of error, a concept originally suggested by James Reason. The HFACS schema depicts how

human factors can be propagated from the tier four organizational influence level to the tier three

supervision level to the tier two preconditions for unsafe acts level and then to the tier one unsafe

acts level (Shappel & Wiegmann, 2000). The HFACS has been used successfully in both the

aviation and rail industries and has more recently been introduced for use in health care.

Alternatives, such as root cause analyses, can sometimes be too nonspecific and can focus too

much on that which happened and who was involved. In contrast, the HFACS is designed to

focus more on why errors took place (Diller et al., 2014). The HFACS was used in this

dissertation study to show predictive patterns of contributing factors to reported radiotherapy

safety events. While the HFACS has never been specifically utilized in radiotherapy, the need to

focus on human factors has been well recognized in the literature (Chan et al., 2010; Spraker et

al., 2017).

Relevant theory supporting this dissertation study is rooted in human motivation.

Maslow's hierarchy of human need describes those needs that drive motivation. His hierarchy

consists of five successive needs arranged in a pyramid with the most basic and fundamental needs making up the bottom layer. The second most fundamental of the five layers includes the need for safety, which can drive decisions around reporting; the need for job and income security are likely to influence error reporting. The fourth layer, second from the top of the pyramid, includes the human need for recognition and self-esteem, which can also affect decisions about reporting into an incident learning system (Maslow, 1943). Maslow recognized that there is a lack of rigidity in the ordering of tiers in his pyramid. That recognition supports a loose association between tiers of the hierarchy and the relative importance of human behaviors. The hierarchy provides a valuable framework for thought around human motivation.

Theory about human error has been offered by many, and one renowned theorist was James Reason. In the 1990s, Reason described the idea that people interact with systems in ways that bring about weaknesses or latent failures. These latent failures lie dormant but overlap with one another and build until one triggering event may result in a realized error. His popular depiction of this cumulative factor theory is called the Swiss cheese model. The alignment of holes in the cheese are akin to the alignment of latent failures that eventually cause error (Reason, 1990a). Reason categorized errors as (a) skill-based slips, or atypical errors made during routine skill-requiring practices; (b) rule-based mistakes that happen when someone misapplies a rule or misjudges a situation; and (c) knowledge-based errors that occur when someone lacks needed information (Reason, 1990b). These categories and Reason's error theories have informed historic and current thinking about human error and have influenced the HFACS schema that was used in this study.

One last yet important theory addressed human factors and systems thinking. A theorist named Sidney Dekker contributed a fundamental perspective to the literature in 2009. Dekker

first described a historic and more typical worldview of error that was referred to as the Newtonian world view. Within this framework, errors are described in linear chains of cause and effect. These errors are contained within finite systems that are balanced, obey the laws of mechanics, and abide by an understanding that there are always identifiable causal actions for errors (Dekker, 2010). Dekker proposed that this Newtonian framework is oversimplified and inaccurate. As an alternative he proposed a complexity and systems world view that recognized the enormity of interaction between humans, computers, and the environment. With every interaction, Dekker recognized an "explosion" of new relationships that must be factored into the analysis of human error (Dekker, 2010). This worldview involves a much greater amount of uncertainty than its Newtonian counterpart. It is likely a significant factor relating to why the Newtonian theory has persisted for so long. Dekker argued that despite these challenges, it is vital to recognize and attempt to account for the reality of human-system interactions. It can be done by gathering information from a multitude of sources, by being open to changing the direction of thought, and by accepting the inherent uncertainty in analyzing human error (Dekker, 2010). Dekker provided a valuable framework that was utilized in this dissertation study to explore the role of human contributing factors for radiotherapy safety events.

Chapter 3: Methodology

Introduction to the Chapter

This dissertation study is being conducted to find predictive patterns of human factors that contribute to radiation therapy errors. High reliability industries, such as aviation, have made significant safety gains throughout the years and have incorporated an analysis of human factors into their strategic approach for safety improvement. The Human Factors Analysis Classification System has been utilized successfully as part of that effort and has more recently been utilized in the health care industry as well (Diller et al., 2014). The classification schema has rarely been used in radiotherapy. The HFACS contains four tiers of human factors, including tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences. For this dissertation study, the HFACS schema was applied to reported radiation therapy safety events.

Information about these safety events came from reports submitted by radiation therapy staff to the IAEA through its SAFRON incident learning system. The reports include information about safety issues, errors, and their potential causes. Through SAFRON, the IAEA provides a web portal so that radiotherapy departments around the globe can quickly and easily turn their mishaps into learning opportunities for others. The voluntary nature of report submission means that the SAFRON data like all incident learning data may be heavily influenced by human factors and motivations. These human drivers not only can affect that which is reported but can affect the pathways that ultimately led to error. Understanding how people's communications, interactions with their surroundings, response to inadequate supervision, and behavioral connections to culture all contribute to error is important to understanding safety and risk.

This investigator will uncover the relationships between different human contributing factors to error. She also explored different types of radiotherapy errors, such as those that occur during the treatment planning process, the quality assurance process, the treatment set-up process, or a documentation workflow. More specifically, the study included an analysis of how these error types relate to human contributing factors. The human influence on safety and risk is rooted in motivation theory and is, therefore, affected by Maslow's hierarchy of that which drives individuals (Maslow, 1943). From physiological needs to needs for safety, for positive recognition, and for achievement, the fundamental motivators affect the choices made and how tasks are performed. For these reasons, a human factors approach was selected to analyze reported radiotherapy incidents. This methodology had insight to be gained beyond descriptive detail about that which happened; it will allow for the discovery of predictable patterns of human factors that contribute to error and put patients at risk was apparent, which can be utilized to improve safety.

Following the application of strategic inclusion and exclusion criteria, a sample of SAFRON reports were assigned a single (the most appropriate) error type from the list in Table 2. These error types are separate and distinct categories meant to represent the first in a potential series of errors that took place within a single reported event. Each report was also analyzed to determine which human contributing factors from the HFACS were applicable to the described incident. All contributing factors mentioned in the report were noted and utilized. A statistical analysis was then conducted to show predictive patterns of human contributing factors as they relate to radiotherapy errors. This analysis included uncovering predictive relationships between subcategories of higher and lower tiers on the HFACS and predictive relationships between radiotherapy error types and human contributing factors. The value of this study lies with the

application of a human factors-based approach to understanding that which puts radiotherapy patients at risk and that which is likely to contribute to error. With that understanding, future safety improvement efforts can incorporate mitigation strategies that target relevant human factors-based issues.

This chapter addresses the strengths, weaknesses, and threats to the study design. It also had detailed procedures and information about the study data, instruments, statistical analysis and power, reliability and validity issues, limitations and delimitations, and other aspects of the study methodology. The design was a valuable assessment of which patterns of human contributing factors were supporting reported radiotherapy errors. This chapter shall also presented a thoughtful analysis of challenges to this research.

Practical Applications of the Findings

Despite the wealth of knowledge and technology that has developed over time in the field of medicine, patients still remain at risk of being harmed while being cared for. That risk in radiation therapy involves potential radiation over-exposures that can cause intense suffering and even death. It also involves a risk of under-exposures that could compromise the effectiveness of treatment. It has been shown in other industries that human factors, such as decision making, communication, supervision, and human-computer interactions, have a role in the majority of errors. Radiotherapy is not likely to be any different in terms of this vulnerability. In fact, complex and rapidly changing technologies along with a large number of professionals involved in patient care likely increase the risk of human factor-related errors (Cohen, 2017; Diller et al., 2014). By evaluating reported safety events with regard to human factors, awareness of contributing factors can be improved so that patterns associated with error can be avoided and reduce the risk of safety events.

Research Design and Methodology

This investigator utilized a quantitative approach that addressed the following question: How are human factors associated with error in radiation therapy? The IAEA's SAFRON database of voluntarily reported radiotherapy events was utilized to determine these associations. A quantitative approach was used for relationships between variables to be established and with this information, predictive patterns were understood. This information can then inform future safety work so that error mitigation can be strategically optimized.

This approach made use of a representative sample of error data. This error data was not only a subset of the SAFRON database but a small subset of the errors that actually take place in radiation oncology. This reality introduced a potential bias to the study and limited the generalizability of the outcome. A mechanism of full disclosure regarding error does not yet exist and is, therefore, not available to SAFRON or to any other incident learning system. The data utilized had been reported by a diverse population of radiation oncology professionals from around the world. Specific information regarding the origin of any particular report was unknown to the investigator so a distribution of reports by geographic location or even by unique institutions is not available. This lack of information introduced another potential bias to the data, which is discussed in the limitations section. Despite these challenges, the classification and aggregate review of human factors in radiotherapy events has not yet been done and offers unique perspective and value to safety improvement.

The SAFRON data was obtained directly from the IAEA with its express permission for its use. This deidentified data is a non-probability sample as all reports were voluntarily submitted to the system. This sampling method is also referred to as self-selection sampling. With regard to medical error and this kind of study, the sampling method is the only one

available and can ultimately offer a valuable answer to the research question. Limitations from this type of sample were reviewed and discussed. Of over 1,600 reports, a purposive sample of 141 reports was selected for use. This sample was chosen to ensure that sufficient information was available to inform the classification process.

Reports were categorized with error types and with human contributing factors from the HFACS. Error type options were arrived at through the investigator's extensive experience with incident report analysis and with consideration of existing error-type menus (Ezzel et al., 2018). The HFACS has been accepted and utilized widely in published literature, including that in the health care realm (Diller et al., 2014). With these foundations and appropriate inclusion criteria, the classifications performed throughout his study should be reproducible by other researchers. To address potential disparities in the individual report information, events were rated as being of low, medium, or high quality. All of the included reports have met the minimum standard set for quality in that they contain both a narrative explanation of the safety event as well as information regarding perceived contributing factors. Still, the richness of information presented by individual report submitters was variable. Relative quality ratings were used to assess the quality distribution of reports beyond the baseline inclusion criteria, which aided in interpreting the validity and generalizability of the study results.

Study Design

This dissertation used a non-experimental quantitative and predictive study design. The research question was addressed by through an assessment of which relationships naturally exist between human contributing factors to error and also between radiotherapy errors and the precipitating human factors that preceded them. Each included incident report was classified in terms of the involved error type. All involved human factors under the four tiers of the HFACS,

namely tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences, were also specified for each report. Each of the four tiers of the HFACS contain a number of human contributing factor subcategories. After reading through each of the reports, those subcategories that had been indicated were recorded in the database.

Each progressively higher tier of the HFACS represents contributing factors that are more remote to the safety event with tier one representing the unsafe acts themselves and tier four representing the most remote factors that contribute to error through organizational influence. A test for association between subcategories at different tiers was run to determine whether those from higher tiers are associated with subcategories from lower tiers. The Goodman and Kruskal's lambda statistic was utilized to determine whether a proportional reduction in error was present or whether having information about the contributions to error from higher tier subcategories is used to more accurately predict contributions from lower tier subcategories. A chi-square test was then run to determine whether there are significant associations between radiotherapy error types and human contributing factors as represented by subcategories from all four tiers of the HFACS. Predictive patterns were shown and are presented in the results and discussion chapters of this study.

<div align="center">**Rationale**</div>

The need to improve safety for radiotherapy patients is evident from the historic and well-documented patient harm that has existed over the years. While medicine and radiation therapy are not uniquely complex or hazardous, there is a heightened level of both of these factors that puts patients at risk of harm. Other complex and hazardous industries have made significant and successful safety improvements that have earned them recognition as high reliability organizations. Health care has yet to achieve that status.

Tools, such as the HFACS, which have been used successfully in aviation and other high reliability industries, may offer similar safety gains for health care. The human factors approach for evaluating contributing factors that support safety events has not yet been taken with an international database of reported radiotherapy errors. This investigator utilized this approach by testing for predictive associations between human contributing factors and for predictive associations between those factors and radiotherapy error types. The results from this study improve the understanding of that which contributes to error will better position radiotherapy staff to make strategic safety improvements.

Threats

There were a few key threats to the validity of this research study. The first pertains to construct validity. The data that were used is comprised of information reported through the SAFRON incident learning system. Associations made from that data have a presumption that the SAFRON data intake form included all relevant and no superfluous pieces of information. Although it is a given that individual report submitters may have left out relevant information on a case by case basis, it is also possible that key elements regarding either the errors or the human factors contributing to them were standardly omitted from the SAFRON system design. That possibility threatens the validity of the study outcome.

It is also important to consider the fact that the incident learning database is made up of voluntary report submissions. As mentioned earlier, self-selection sampling was used to sample all radiotherapy errors within the SAFRON system. A purposive sampling method was then utilized to hone in on a subset of SAFRON cases. Any distinction that can be made between the reports included in this dissertation study and the complete (largely undisclosed) set of radiotherapy errors that actually take place detracts from the generalizability of this study's

results. The great span of time (2001-2019) and geographic location included in the data set reduce the amount of bias in the data, and the sample was allowed to represent a reasonable approximation of voluntarily reported errors. The extent of any bias that may exist is unable to be accurately determined; radiotherapy errors that are hidden or denied would not be represented in this research and are a threat to external validity. This potential difference in how the study sample compares with all radiotherapy errors is also a threat to internal validity. Again, given the heterogeneity of perspective within the data, the sample was considered reasonable to support the study.

Threats to internal validity are also present with regard to the fact that this study data spans nearly two decades. Over this period of time, technology has changed dramatically, and it is fair to presume that safety cultures and trends have also. Technological advancement has been rapid and palpable over the past two decades with everything from cell phones to the medical technology industry. Radiation therapy has changed significantly with increased automation, increased treatment complexity, and increased electronic documentation. As the environment has changed, it is reasonable to assume that the nature of radiotherapy errors has as well. Given the low percentage of errors that are actually reported and the relatively small sample included in the study, this research is not powerful enough to account for those temporal changes. The lack of ability to consider that confounding variable is a threat to internal validity. Despite these threats, the predictive associations made from this research are powerful enough to inform next steps for informed and effective safety improvements.

Strengths and Weakness of Design

The major strength of this design is that a respected and proven classification system for human contributing factors to error was applied to an aggregate database of radiotherapy

incidents. This approach was taken due to marked successes that have been reported in other high reliability industries. In that respect, this approach was not novel but instead utilized valuable insight gained from success in other areas. Associations between errors and contributing factors can move the understanding about radiotherapy safety beyond a working knowledge of that which radiotherapy errors occur to a working knowledge of the causes.

Weaknesses involved in this research design include those discussed previously in terms of internal and external validity. The voluntary nature of incident reporting into SAFRON introduced a bias threatening both internal and external validity. The sampling method within SAFRON also added bias and detracts from the generalizability of study results. It is also a design weakness that the origin of included reports is unknown. It is possible that few institutions contributed a disproportionate share, which would further degrade the external validity of this study.

Incident learning datasets are challenged in many ways with respect to being a small subset of actual errors. They remain, however, strong opportunities to learn from the mistakes of others. It should be noted also that the more egregious errors that result in patient harm are more difficult to hide than minor errors. With that understanding, it is more likely that reported errors include the more clinically significant of those that take place. From a learning standpoint, it adds to the potential that this study had to produce meaningful results. This dataset is also unique in that it represents radiotherapy errors that happen all over the world. While cultures and geography may differ greatly, human factors are common threads that persist wherever humans live and work. Human factors rooted in fundamentals, such as Maslow's hierarchy, also transcend time and technological change. With that understanding, there was great potential for this study to show predictive patterns of human factors that put radiation therapy patients at risk.

Specific Procedures

The International Atomic Energy Agency's Safety in Radiation Oncology database contains reported events from an international radiation oncology community and was utilized for this research (IAEA, 2019). A subset of the reports with higher severity levels (critical, major, serious, potentially major, and potentially serious) were used for the study sample; events with minor severity levels or an unspecified severity level were not incorporated. Additionally, reports were only included if they contained information regarding contributing factors to the event; incidents lacking information about that which contributed to the error were excluded from the dissertation study.

Each of the SAFRON incident reports has 28 unique data fields. Some of those fields contain information in a free-text format and some have discrete data. The full SAFRON report form can be found in Appendix A with the discrete data options for all of its drop-down fields listed in Appendix B. The focus of report reviews for this study was on the following fields: description of the incident in detail (free text format), clinical incident severity (discrete options), description of the causes of the incident (discrete options), and description of contributing factors to the incident (free text). After careful review, each of the reports was rated as having either a low, medium, or high quality of information so that the investigator could discuss the quality aspect of data incorporated in the analysis. As stated previously, those ratings indicate the richness of information contained in the respective reports above and beyond the minimum quality standard that was set through report inclusion criteria. A rubric for that determination can be found in Table 1.

Table 1

Rubric for Classifying the Quality of SAFRON Reports

Quality Level	Criteria
Lower	Narrative provided minimal information about the event. Information provided about contributing factors left a strong possibility that important factors were missing from the report
Medium	Narrative provided a reasonable description of the event and included some but limited information regarding what happened, who was involved, what the suspected root causes were, and/or what human interactions led to the error. Information provided about contributing factors was sufficient to give the investigator a baseline understanding of significant contributors to the reported error
High	Narrative provided a thorough description of the event and may have included information such as detail around what happened, who was involved, what the suspected root causes were, and what human interactions led to the error. Information provided about contributing factors was extensive and may have included both discrete and free text descriptions

A list of radiotherapy error types was utilized to assign each incident report to a single error category. In reports in which multiple errors were described, the initial propogating error type was selected. Categories were general enough in nature to encompass wide swaths of error descriptions in some basic and typical areas. The investigator's experience reviewing

radiotherapy error both as a clinical physicist and as chair of a radiotherapy incident reporting

advisory council was used to formulate this list. There are commonalities between this list of

error types and those used in published literature, but modifications were made to reduce

redundancy while preserving inclusivity (Ezzel et al., 2018). That list of error types can be seen

in Table 2.

Table 2

Radiation Therapy Error Types

Error Type	Description
Approval	Appropriate approval was missing or something was inappropriately approved
Documentation Incomplete	Documentation was incomplete or missing
Documentation Erroneous	Documentation contained erroneous or inaccurate information
Equipment	Equipment malfunction included software, hardware, connectivity, or networking
Image Guidance	Images were not interpreted correctly, shifts were made in the wrong direction or by an incorrect amount based on a misreading of images, images were accidentally omitted or too many images were taken, image guidance instruction was not followed, there was a failure to assess images based on priority instruction, or there was a lacking skill set in analyzing images appropriately
Treatment Planning	Ex: planner used wrong dose, wrong technique, planner did not account for certain anatomy or implants, prior RT was disregarded, an incorrect target or contours were used, the wrong CT data set was used, etc.
Collision	Either a collision or a potential collision with equipment and/or a patient
Quality Assurance	Quality assurance of a treatment plan, ongoing treatment, or equipment was performed erroneously, was missed, missed a standard component, or was suboptimal with respect to applicable policy or guidelines
Scheduling	Any error around patient scheduling
Simulation	Ex: wrong body part or location simulated, substandard scan protocol, insufficient scan length, incorrect isocenter marked or tattooed, failure to complete the standard simulation process
Treatment Setup	These errors include setup and positioning errors, alignment to incorrect skin markings, forgotten or misplaced bolus, incorrect shifts in setting up the patient for treatment, etc.
Treatment Delivery	These errors include the wrong field treated, a missing treatment accessory, or any other issue that involves an incorrect component of radiation delivery (not setup)
Wrong patient	Patient ID issue
Patient	A patient-related problem occurred such as a significant delay, miscommunication, health problem unrelated to treatment, inadequate coordination with their other care providers, or failure to comply with information in their medical record outside radiation therapy such as allergies or other special care needs

The HFACS system has four tiers of human factors, namely tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences. Each of those four tiers has a sublevel of classification below it, containing a number of subcategories. In total, there were 19 subcategories of human contributing factors throughout the four tiers.

Associations of all HFACS subcategories specified in each report were made and tracked in the study database. Reports were evaluated individually, and all relevant subcategories were included.

The HFACS has been utilized previously in the health care setting and that use was described by Thomas Diller. Diller's version of the HFACS was slightly modified for use in this study so that the classification schema was more appropriately fitted to radiation therapy incident learning data. Modifications included a consolidation of factors within tier two preconditions for unsafe acts; the HFACS presented by Diller originally offered a third more granular level of subcategories under tier two preconditions for unsafe acts. Information contained within incident learning reports was not rich enough to make this third level of subcategories within the HFACS helpful. A diagram of the HFACS utilized for this dissertation study (modified from that presented by Diller et al.) can be seen in Figure 1 (Diller et al., 2014).

Figure 1

The Human Factors Analysis Classification System
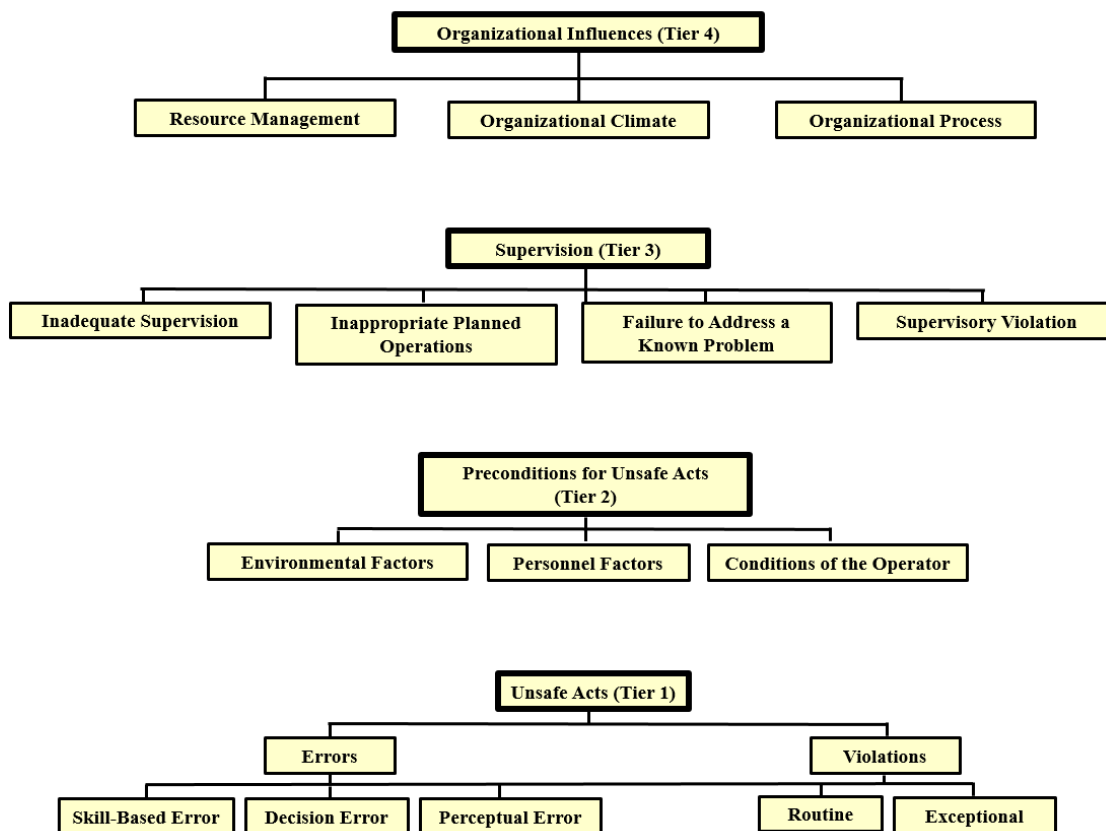
Note. Four tiers of human factors represent distinct categories of contributing factors to error as applied from health care. Adapted from The human factors analysis classification system (HFACS) applied to health care by T. Diller, G. Helmrich, S. Dunning, S. Cox, A. Buchanan, & S. Shappell, 2014, *American Journal of Medical Quality*, *29*(3), 85. Copyright 2014 by Sage.

Coding with Human Factors

Coding individual SAFRON reports with human contributing factors from the HFACS used the systematic application of well-defined factors. The four tiers of factors along with their subcategories and basic definitions are presented in Table 3, and a more detailed description of the coding process is presented here. The progression of tiers from tier one unsafe acts to tier four organizational influences includes a degree of remoteness in which tier one is most proximal to the erroneous act and tier four is most distal.

Table 3

The Human Factors Analysis Classification System Tiers and Descriptions

HFACS TIER	HFACS SUB-TIER	DESCRIPTION
	Tier 1 Unsafe Acts	**Actual actions that take place resulting in an undesirable outcome**
1	Errors - Skill based error	Errors made when performing familiar tasks that are routinely done without a great deal of thought
1	Errors - Decision error	Information, knowledge, or experience is lacking
1	Errors - Perceptual error	Input to any of the five senses is compromised and someone subconsciously fills in missing information
1	Violation - Routine	Disregard for the rules but habitual in nature as "bending the rules" is typically tolerated
1	Violation – Exceptional	Disregard for the rules in a way that is atypical, not done by others and not condoned by leaders
	Tier 2 Preconditions for Unsafe Acts	**Describes the environment and conditions contributing to increased risk**
2	Environmental factors	Physical Environment: Issues with the physical environment such as poor ergonomic layout, lighting, or clutter OR Technical Environment: Issues with equipment, networking, the human-computer interface, or automation
2	Personnel factors	Communication: miscommunication between individuals: information either unavailable or incomplete. OR Coordination: health care providers work independently and do not manage care well between them. OR Planning: patients' needs are not correctly anticipated or for any reason appropriate care plans are not made. OR Fitness for Duty: Care providers have a substandard physiologic state due to issues, such as being tired or being on medication
2	Conditions of the operator	Adverse Mental State: Examples include fatigue, stress, or distraction. OR Adverse Physiological State: Examples include illness, injury, or other temporary incapacitation. OR Chronic Performance Limitation: These limitations are either chronic or long term
	Tier 3 Supervision	**These are issues with front line management who are directly responsible for training, guidance, and oversight**
3	Inadequate supervision	Leadership failure with respect to training, guidance, and keeping up with best practice standards
3	Inappropriate planned operations	Includes scheduling, assigning duties, and keeping staff members aware of the plan so that they are able to execute
3	Failure to address a known problem	Applies when deficiencies, equipment failures, a lack of training, or other issues are known and ignored
3	Supervisory ethics violation	Applies when supervisors allow things to occur that are known to be against policy or regulations

HFACS TIER	HFACS SUB-TIER	DESCRIPTION
	Tier 4 Organizational Influences	**Involve upper level management decisions that affect supervisors and staff**
4	Resource management	Resource allocation and maintenance, including budgets, equipment, and staffing allowances
4	Organizational climate	Describes the safety culture, working atmosphere, chain of command, and values
4	Organizational process	Includes failures of corporate rules that govern everyday activities, such as scheduling and communication

To facilitate an efficient coding process, abbreviations for the HFACS subcategories were utilized on the data collection form. Those abbreviations are presented in Table 4.

Table 4

HFACS Subcategory Abbreviations Used to Classify SAFRON Reports

HFACS Subcategory Tier	HFACS Tier or Subcategory	Description of HFACS
		Tier 1, Unsafe Acts
ES	1	Error–Skill based error
ED	1	Error–Decision error
EP	1	Error–Perceptual error
VR	1	Violation–Routine violation
VE	1	Violation–Exceptional violation
		Tier 2, Preconditions for Unsafe Acts
PE	2	Environmental factors – physical or technological
PP	2	Personnel factors – communication, coordination, planning, or fitness for duty
PC	2	Conditions of the operator – adverse mental state, physiological state, or chronic performance limitation
		Tier 3, Supervision
SIS	3	Inadequate supervision
SIO	3	Inappropriate planned operations
SFP	3	Failure to address a known problem
SSE	3	Supervisory ethics violation
ORM	4	**Tier 4, Operational Influences** Resource management
OOC	4	Organizational climate
OOP	4	Organizational process

As was discussed previously as a weakness of this study, SAFRON reports and all incident reports contain only a finite amount of information; additional information as could otherwise be provided through follow-up interviews was not available here. All SAFRON data had been deidentified and contact with the submitters was not possible. In an effort to minimize investigator bias from presumptions, human factor subcategories from the HFACS were not mapped to a report unless information indicating the presence of that subcategory had been submitted in the report. Even with that caveat, the potential for ambiguity existed within the interpretation of meaning for each human factor. In order to protect against that bias, clear interpretations and definitions were established prior to reading through the reports so that the classification system could be utilized consistently.

Consistency in the coding process was achieved in part by systematically utilizing discrete responses to the SAFRON data prompt "describe the causes of the incident." These discrete options, which would more accurately be termed "presumed contributing factors," were mapped to subcategories in the HFACS. This mapping algorithm can be seen in Table 4. Not all of the reports were able to be mapped this way because some of the discrete contributing factors did not align directly with a single subcategory from the HFACS. The response data that were systematically mapped included multiple subcategories under tier two preconditions for unsafe acts and under tier three supervision.

Table 5

Mapping of Discrete Contributing Factors from SAFRON Reports to the HFACS

SAFRON Contributing Factor	HFACS Tier and Sub-Tier	Code
Lack of communications	Tier 2 Preconditions for unsafe acts, Personnel factors	PP
Inadequate communication of procedure	Tier 2 Preconditions for unsafe acts, Personnel factors	PP
Misunderstood communications	Tier 2 Preconditions for unsafe acts, Personnel factors	PP
Time pressures	Tier 2 Preconditions for unsafe acts, Conditions of the operator	PC
Workload and time pressures	Tier 2 Preconditions for unsafe acts, Conditions of the operator	PC
Fatigue	Tier 2 Preconditions for unsafe acts, Conditions of the operator	PC
Inadequate standard/procedure/ practice	Tier 3 Supervision, Inadequate supervision	SIS
Inadequate training/orientation	Tier 3 Supervision, Inadequate supervision	SIS
Inadequate direction/ information	Tier 3 Supervision, Inadequate supervision	SIS

Continued

SAFRON Contributing Factor	HFACS Tier and Sub-Tier	Code
Lack of or ineffective procedures, protocols, and documentation	Tier 3 Supervision, Inadequate supervision	SIS
Availability (with respect to equipment)	Tier 3 Supervision, Inadequate supervision	SIS
Unclear roles, responsibilities, and accountabilities	Tier 3 Supervision, Inadequate supervision	SIS
Personnel availability	Tier 3 Supervision, Inappropriate planned operations	SIO
Availability (with respect to staff)	Tier 3 Supervision, Inappropriate planned operations	SIO
Conflicting demands/priorities	Tier 3 Supervision, Inappropriate planned operations	SIO
Failure to address recognized hazard	Tier 3 Supervision, Failed to address a known problem	SFP

Aside from the mapping of discrete SAFRON data to the HFACS, a clear and documented interpretation of each subcategory within the classification schema was developed so that they could be consistently applied to the reports. Basic definitions of each tier and subcategory were presented in Table 4. Additional detail for the subcategories is presented here.

Human contributing factors closest to the reported safety event have described tier one unsafe acts. It contains five subcategories, consisting of three kinds of error and two kinds of violations. One error type, skill based errors, refers to errors made while performing familiar tasks without thought. An example of this from the data sample was when a staff member

copied data incorrectly from a treatment planning system into a medical record. In contrast, a second error type called decision errors is used to describe unsafe acts when there was information, knowledge, or experience lacking. An example of this type of error was when a physicist did not understand how to appropriately perform calculations that were required for a radiation-producing machine calibration and then performed those calculations incorrectly. Context of the written narrative describing the event was used to differentiate between skill and decision type errors. Perceptual errors are the third type, and these errors are used to describe unsafe acts when input to any of the five senses is compromised and someone subconsciously fills in missing information. Perceptual radiotherapy errors included the wrong vertebral body being being mistaken for the correct one and an incorrect skin marking being perceived to be the desired positioning mark. Other perceptual errors stemmed from atypical situations when the more common scenario was presumed. These situations included assumptions of no previous radiation therapy, assumptions of a single treatment being prescribed per day, and assumptions of supine feet first positioning. The final two subcategories under tier one unsafe acts were routine and exceptional violations. Routine violations were those that were more habitual in nature and were typically tolerated. Exceptional violations required a disregard for the rules or policy that was not condoned by leaders. The narratives were used to make a determination on which violation had been submitted to SAFRON.

Tier two preconditions for unsafe acts included three subcategories: environmental factors, personnel factors, and conditions of the operator. Environmental factors included both physical and technological components. Some of the earlier reports in the database described egregious equipment issues with linear accelerators that lacked many of the safety features that evolved over the subsequent decades. The more current environmental factors were mostly

related to software errors and human-computer interface issues. Personnel factors included issues of care coordination, planning, communication breakdowns, and substandard physiological states. The final category in this tier, conditions of the operator, included more chronic adverse states and issues, such as fatigue, stress, or distraction. This category was mapped to SAFRON reports that described rushed workflows, time pressures, and instances of employees being worn out or fatigued.

Tier three supervision was the most challenging tier to map as there was a fair amount of ambiguity in how the subcategories could be interpreted. Use of discrete contributing factors from the SAFRON reports were helpful in minimizing bias in the coding process. The first of the four subcategories in this tier was inadequate supervision. This subcategory was used to describe a leadership failure with respect to training, guidance, and adherence to best practice standards. In order for this subcategory to have been assigned, the SAFRON report must have indicated that there was some kind of leadership failure in one of these areas; presumptions were not made unless that information was given. The next subcategory, inappropriate planned operations, was more focused on the day-to-day operations of the clinic rather than general guidance and adherence to standards. This category included scheduling and assigning day-to-day duties. When "availability" was mentioned as a contributing factor, it was considered inappropriate planned operations if the comment was with respect to staff, whereas it was considered inadequate supervision if the comment was made with respect to equipment (which would be more of an issue of general workflow standards as opposed to day-to-day availability for operations).

The final two subcategories in tier three supervision were failure to address a known problem and supervisory ethics violations. In both instances, the problem or issue would have to

have been known and ignored. If the SAFRON event did not explicitly state that this situation was the case, these two subcategories were not selected. Failure to address a known problem included instances of ignored equipment failures and ignored issues with compliance.

Tier four organizational influences included three subcategories. The first was resource management, which was used to address issues with resource allocation, such as budgeting, equipment, and staffing. The second was organizational climate that was used when safety culture, values, or the chain of command were contributing factors to the submitted event. The last subcategory in this tier was organizational process, which included failures of corporate or organization-level rules that govern everyday operations, such as scheduling and communication.

Approach to Data Analysis

Descriptive analytics were used to present key features of the data sample. Graphical representations show the distribution of errors and contributing factors within the data sample; bar graphs were used to present the prevalence of the different error types and of human contributing subcategories within all four tiers of the HFACS. A statistical analysis was performed to determine whether there were significant associations between subcategories of higher and lower tiers of the HFACS. This information led to the understanding of whether and how human factors more remote to unsafe acts may predict the likelihood of other contributing factors closer to them (or more directly involved). The HFACS was based on James Reason's idea that latent errors build and increase the risk of a more apparent and potentially harmful error taking place. This theory was used to support the concept that human contributing factors at higher tiers of the HFACS may increase the likelihood of contributing factors at lower tiers. In order to test this theory, all combinations of higher and lower tier human contributing factors from the HFACS subcategories were tested for significant associations. The higher tier

subcategories were considered independent variables and the lower tier subcategories were considered dependent variables for these tests. For each combination, an analysis for proportional reduction in error between the two subcategories was performed using the Goodman and Kruskal's lambda test statistic. When significant associations were found, it was understood that the dependent variable (lower tier subcategory from the HFACS) could be better predicted if the independent variable (higher tier subcategory) was known. Lambda values below 0.1 were considered weak associations, those between 0.11 and 0.30 were considered moderate, and those above 0.31 were considered strong. The significance of each lambda value was also assessed, and all results are presented in Chapter 4. While a significance of $p < .05$ was desired, lambda values with $p < .20$ were reported. This dissertation study included 141 SAFRON events and smaller subgroups contained specific subcategories from the HFACS. With that data limitation, results with confidence levels greater than 80% were found to be worthy of discussion and were, therefore, included in Chapters 4 and 5. Each significant human factor association was further explored through the calculation of an odds ratio, which showed the relative odds of the dependent variable existing with the presence of the independent variable versus without the presence of the independent variable.

Additional statistical analyses were used to evaluate associations between radiation therapy error types and human contributing factors from the HFACS. This analysis was accomplished with the chi-square test for independence. Each subcategory within the HFACS (at all four tiers) was tested against all error types. The p values below .05 showed that there was at least one significant association between the tested human contributing factor and an error type. An evaluation of adjusted residuals was then done to determine which specific error types had that significant association. Adjusted residuals greater than 1.96 demonstrated that

significance with 95% confidence. Significant results are presented in Chapter 4 and discussed

in Chapter 5.

Subjects

Subjects involved in this dissertation study were the staff members whose interactions,

relationships, communications, and other human factors have contributed to the safety incidents

reported into the SAFRON incident learning system. The source of information for this study

was SAFRON incident learning reports. As the data was secondary in nature and had been

deidentified, specific patients and staff involved in these incidents were unknown to the

investigator and shall, therefore, remain anonymous.

Power

It was the goal of investigator to analyze associations between radiotherapy errors and the

human factors that contributed to them. Statistical testing to show predictive patterns between

these variables needed to be both accurate and reliable. The strength of study results was

dependent upon several factors and power of those tests determined the likelihood that

significant associations (below the threshold for an acceptable p value) would be discoverable if

they in fact existed (Statistical Solutions, 2020). Association between variables was tested

through two different means. A proportional reduction in error test was performed with the

Goodmand and Kruskal's lambda test statistic to determine how useful it would be to know

about the presence of a higher-tier subcategory (human contributing factor to error) from the

HFACS in predicting the presence of a lower-tier subcategory. A finding of zero would indicate

no usefulness and a finding of one would mean that we could make the prediction with one

hundred percent accuracy. A power limitation from this kind of test rests with the fact that if the

modal category was the same for both crosstab cells pertaining to the independent variable, the

lambda test statistic will be zero (Goodman & Kruskal, 1979). In other words, if testing for an association between the higher-tier subcategory "inadequate supervision" and the lower-tier subcategory "decision errors," the lambda statistic could be zero even if the presence and absence of the supervision error with decision errors had vastly different report volumes. With the data from this study sample, it was not the case and the power limitation from this test was not an issue. Odds ratios were calculated for all associations having significance level of at least .05. These measures of relative effect size allow for a further discussion of power associated with these tests.

The second test of association, a chi-square test, was used to determine whether or not there was a predictive relationship between any of the HFACS subcategories and a specific kind of radiotherapy error. There were 141 events included in the study sample but as each was assigned to only a single radiotherapy error type, there were ultimately some error types with relatively few data points. Work was done to pool data in order to avoid having crosstab cells with expected counts less than five but ultimately those pooled categories were not used. While this served to improve the power of the chi-square testing, it washed out the meaning behind associations with specific error types. Power from chi-quare tests is also affected by significane level (as represented by the *p* value) and effect size. Results were considered significant if their *p* value was less than .05. Odds ratios were calculated in order to address relative effect size. All these components of statistical strength were used to support the findings from this study and the recommendations made to mitigate radiotherapy error.

Sample Size

The full database of SAFRON incident reports was provided by the International Atomic Energy Agency in 2019, and it contained 1608 reports dating back to 2001 with the exception of

one additional report, which had been submitted in 1986. After careful selection of appropriate

cases with the exclusion and inclusion criteria described below, and 142 incident reports made

up the sample for this study. One of those cases was ultimately found to be the duplicate of

another entered in the same timeframe so the final sample size was 141 cases.

Inclusion Criteria

SAFRON reports were included in this study if they had been submitted to the IAEA's

web-based report intake platform prior to prior to February 2019. They were also included if

they had been incorporated into SAFRON from the legacy ROSIS database, which was described

earlier. This incident learning system is international, so contributors work in radiation oncology

departments all over the world. Reports shared with the investigator for use in this dissertation

study lacked any information about the origin of the reports; all reports contained only

anonymous de-identified data. Every report in the SAFRON database was submitted voluntarily

although reporting may have been influenced by departmental policies or safety cultures.

The SAFRON report contains 28 response items 28 opportunities for contributors to input

data. Some of those fields have drop-down menus with discrete data options, and some allow for

free text. A blank report and a listing of all dropdown menu options can be found in Appendix A.

A report was only able to be submitted to SAFRON if all required data had been entered by the

contributor. All data fields were reviewed by the investigator although a select few response

items were particularly critical to the study analysis. Those were as follows: clinical incident

severity, detailed description of the incident, description of the incident causes, and the

description of contributing factors to the incident.

Exclusion Criteria

In order to improve the quality of analysis for this dissertation study, certain exclusion criteria were applied. While it is important to report about and learn from all radiotherapy errors whether or not they resulted in clinically significant harm to patients, only reports of higher clinical severity were included. These reports tended to contain more detailed information, which was used for a more thorough analysis. There were six options in the drop-down menu under clinical severity. The selections of critical severity, major severity, potential major severity, potential serious severity, and serious severity were all included. Cases that had either minor severity selected or no information provided were excluded.

As the focus of the investigator was on predictive patterns of human factors that supported radiotherapy errors, it was important that studies be excluded if they did not contain information about contributing factors or perceived causes. One data field in the SAFRON report offered a drop-down menu of potential causes of the reported error. The question on the report says "Describe the causes of the incident." Any report that had "other" or a blank response to that question was excluded from this study.

One of the most important data fields from the SAFRON report was the detailed description of the event. Reports with no entry for this data field were also excluded from this study. The three exclusion criteria described reduced the initial 1608 events to 142 and 141 after exclusion of one duplicate entry. Of those 141, 96 had additional free text information offered to describe contributing factors to the incident.

Characteristics

The 141 reports that have been included in this study were submitted between 2001 and 2019. They were submitted from undisclosed radiation therapy clinics around the world. The commonalities these clinics have is that they treat cancer patients with high doses of radiation.

The radiation producing devices and the planning, calculation, quality assurance, and communication systems that support them are complex in nature and there is a requirement for highly trained staff. The treatment of cancer patients also has a requirement for communication between a number of specialists, such as radiation oncologists, nurses, physicists, dosimetrists, radiation therapists, administrators, social workers, and other multidisciplinary medical teams. These complexities are important as they contribute to the human factors and safety cultures for these reports.

Each report described a safety event or error that occurred in a radiation therapy department and was voluntarily entered into the SAFRON incident learning system. The content of each report was unique and contained a mixture of standardized discrete data responses and free text descriptions of the incident. The amount of information offered varied from report to report.

Recruiting Procedures

There was not any recruiting requirement for this dissertation study. The IAEA had provided incident reports from the SAFRON incident learning system for use. There was not any involvement of individuals or data outside of these reports.

Formats for Presenting Results

A unique identification number was assigned to each report. A sample table has been presented in Chapter 4, showing a distribution of human contributing factors that were selected for each of those reports. Graphs were also utilized to depict frequency patterns of how well or poorly different categories of human factors (subcategories from the HFACS) were represented in the data set.

Tests for significant associations were run to determine whether predictive patterns existed between higher and lower tier subcategories from the HFACS. Results of these tests, presented with the Goodman and Kruskal's lambda test statistic, significance levels, and odds ratios, are presented in Chapter 4. Significant associations between radiation therapy error types and subcategories from the HFACS (at any of the four tiers from the HFACS) were also uncovered. These results were presented with the chi-square test statistic, significance levels, adjusted residuals, and odds ratios. Predictive patterns of human contributing factors associated with one another and associated with radiotherapy error types are discussed in Chapter 5.

Resource Requirement

The incident report data for this dissertation study came from the SAFRON database. As described previously, the analysis was performed by associating each included report with a number of human factors that had been organized through HFACS. The HFACS was originally introduced by Shappell and Wiegmann (2000) for use by the United States (U.S.) Navy and Marine Corps and was first modified for use in health care in 2007 (El Bardissi et al., 2007). That system was further modified for use in health care and for use with the radiotherapy data in this study (Diller et al., 2014). All other supportive literature came from scholarly publications.

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Reliability and Validity

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A fundamental challenge to reliability and validity comes from the voluntary nature of incident learning submission. With all report submission, there is a potential bias to the data; submitters fit a profile of being informed about the reporting program and of being willing to report. Not all radiotherapy staff fit that description, so contributors to the SAFRON database may have a stronger commitment to patient safety than others in the field. As more severe incidents are typically more difficult to hide, the selection of higher severity events for this

research partially limited the bias regarding willingness to report (Morrow et al., 2016). The reports themselves may also have reflected a biased view from their contributors.

A modified version of the Human Factors Analysis Classification System was utilized to analyze reported incidents. This system incorporated four tiers of human factors: tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences (Shappell & Wiegmann, 2000). The retrospective nature of incident learning limited the extent to which information was available in any or all of these areas. An analysis of both free text response information and discrete data concerning contributing factors was conducted during the classification process. A standardized system with clear definitions was applied in order to identify involved human factors at each of the four tiers. While steps were taken to minimize investigator bias, this process was a manual process, and so some amount of subjectivity could not be avoided.

Regarding the time component of the report submissions, it was possible that reporting volumes were influenced by factors other than the prevalence of errors. The difficulty or ease of submission, publicity around other adverse events, leadership or safety culture changes, and variable staffing levels are just a few examples of that which may have influenced the volume of report submissions over time. Lastly, due to the de-identified secondary nature of the report data available to the investigator, there was no way to understand where reports were submitted from; it was not known how geographically diverse the report origins were nor was it known if a smaller number of institutions had contributed a disproportionate share of the reports.

Ethical Considerations and Review

The investigator utilized reported information about various unsafe acts that had been reported by staff members in radiation oncology clinics. Relationships between unsafe acts and

the human factors that contributed to them showed predictive patterns and was used for an actionable understanding of risk. The involvement of radiotherapy staff in these errors presented a type of human research warranting ethical consideration and protections. This research and any kind of human research have a requirement that the principles of justice, autonomy, beneficence, and nonmaleficence are upheld and respected.

The reports utilized by the investigator contained secondary deidentified data. The IAEA had primary ownership of this data and had not disclosed any information from which the identity of involved parties could be shown; the report data was completely anonymous. This anonymity had both security and confidentiality for this research. As outlined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), patients have a right to their privacy as part of their health care process. The act has standards for the protection of information, and those standards were upheld throughout this study to make sure that patient rights were amply respected and protected (Office for Civil Rights Headquarters, n.d.). If confidential patient information is ever disclosed through the incident learning process, involved patients could potentially be adversely affected and future patients may refrain from seeking care. Under these circumstances, patients may also become distrusting of their health care providers and may seek care elsewhere (which could adversely affect participating institutions). Due to the anonymous nature of this study, none of those concerns had materialized.

Aside from sensitivities around patient information, it is also important that privacy be maintained for radiotherapy practices contributing incident learning reports. Error is an inherent part of any human process (Reason, 1990a). It is, therefore, part of any health care practice, radiotherapy included. Reporting unsafe acts is used for preventable errors to become opportunities for learning; involved and uninvolved health care practices can analyze that which

happened and use that information to improve safety. However, there is still a stigma around reporting error. It seems to be an irrational but ever-present concept that the best health care practices operate without error. Public disclosure of institutions that submit incident learning reports may put those institutions at risk of having their reputations tarnished. While participation in incident learning should rightfully improve these reputations, public perceptions of incident learning have not yet aligned with safety culture realities. For these reasons, it would be important to protect the privacy of contributing institutions. The IAEA had supported this need by providing data for this study in a deidentified state.

In order to ensure that the ethical considerations described above were supported, several layers of security were involved in the dissertation process. A research committee was established and served to oversee the study. A committee chair, a second University advisor, and an expert in the field of radiotherapy incident learning were all part of this committee. They had been recognized by the University as having the experience and ability to oversee an ethical process.

Following a formal and accepted research proposal defense, this investigator sought approval from Nova Southeastern University's Institutional Review Board (IRB). Detailed information about this study was submitted as part of that IRB application. The submission included goals and justification for the research, information about proposed variables and participants, a full description of potential risks and protections, and specific steps being taken to ensure confidentiality. The study was initiated after the IRB had reviewed and approved the proposed research and ethics practices.

Funding

This dissertation study was unfunded.

Study Setting

As this study involved a review and analysis of secondary data reports, it was conducted on the investigator's personal computer at the investigator's residence in Massachusetts, USA. A backup of the study information was retained on a single encrypted drive, which was secured in a locked drawer when not in active use. Interaction with the committee was largely remote through email and phone call communications.

Instruments and Measures

The primary instrument utilized for this study was the SAFRON incident report. This instrument was the data collection form that had been filled out by staff from radiation therapy centers around the world. A blank copy of the report can be found in Appendix A. The report contains question prompts for both both discrete response options and for free text responses. Reports had been submitted online through the IAEA's SAFRON web portal.

The instrument begins with questions about the kind of treatment the safety event is associated with, the phase in the workflow process it is associated with and how the incident was discovered. It also contains a response prompt regarding clinical incident severity. Defined options for severity include critical, serious, major, and minor clinical significance. The instrument has a prompt for the contributor to classify incidents that were caught before they reached a patient, which was accomplished with the inclusion of options, such as potential serious incident and potential major incident. The instrument additionally has prompts for the submitter to include information about whether or not the incident reached the patient, whether any part of the prescribed treatment was delivered incorrectly, and if anyone was affected by the incident.

The reliability and validity of this information depended in part on the contributor and in part on the incident itself. Radiation therapy incidents have some unique complexities; clinical harm from a radiation error may not be apparent for weeks, months, or even years after an error takes place. When effects are temporarily distanced from an error, there are additional confounding variables that complicate the understanding of cause and effect. In order to optimize the quality, reliability, and validity of SAFRON data, the instrument contains help buttons that define selection options within the report.

Because of several data fields on the instrument, the contributor is able to enter free text descriptions of the incident. With this format, each report offers a narrative description of that which is being reported and a separate description of that which is understood to be contributing factors. There is value to most if not all of the data fields although the free text narratives were particularly informative and typically made for a solid understanding of that which took place. As with any free text descriptions, the level of quality and detail varied by report. Also, while containing some of the more valuable information from reports, these free text narratives were also notably vulnerable to reliability and validity issues. Reporters may have had biased understandings of that which took place, and they may have presented a flawed representation of the incident.

The instrument contains prompts for the contributor to offer information about that which they believed contributed to the safety incident. This information could be offered through free text descriptions or through a selection of discrete data options. A selection of discrete options was utilized to obtain information about safety barriers that failed, worked, and may have worked. The instrument contains a request for information about the equipment that was used, the treatment method associated with the incident, whether or not the incident occurred on the

patient's first day of treatment, and whether or not a risk assessment had been completed. Again, all of this information had been contributed to a SAFRON report by a radiation oncology staff member. Submitted information was, therefore, vulnerable to reporter bias and potential issues of reliability and validity. With the optional and voluntary nature of this reporting, however, it was reasonable to presume that reporters had done their best to offer valid information with minimal bias.

In summation, the SAFRON incident submission form is a tool available to all radiation therapy sites who choose to use it. The form has been structured to allow the contributor to supply relevant information about the unsafe act that took place. The format of the data collection contains both free text descriptions that allow the contributors to communicate their own perceptions and menus of discrete data options. This blended format was used to support a meaningful analysis.

Data Collection Procedures

SAFRON data was collected for this dissertation study directly from the IAEA. The investigator contacted the IAEA employee responsible for oversight of this data and a formal request was made for the data to support this dissertation study. The request was granted and the entire database was electronically transmitted to the investigator.

Data Analyses

The goal of the investigator was to determine whether human factors are associated with unsafe acts in radiation therapy. Associations found through this study were positioned to show predictive patterns useful to inform effective safety improvements and error mitigations. Associations between human contributing factors to error were determined by evaluating proportional reductions in error with Goodman and Kruskal's lambda statistic. These tests

evaluated the relationships between subcategories at higher tiers on the HFACS schema and subcategories at lower tiers (which they may or may not predictably influence). Chi-square tests were then utilized to determine whether or not there were statistically significant relationships between radiotherapy errors and associated human contributing factors, namely those falling under tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences. The significance level for all tests was noted as were odds ratios.

Format for Presenting Results

Descriptive statistics were utilized to present frequency distributions of both error types and of assigned human contributing factors from the HFACS.   Associations between higher and lower tiered subfactors from the HFACS were presented with Goodman and Kruskal's lambda statistic. The *p* values for these associations were presented and odds ratios were calculated for all significant relationships. Significant relationships between human contributing factors to error (presented as subcategories from the HFACS) and specific radiotherapy error types were determined and presented with chi-square test results. Data tables are presented in Chapter 4 showing significance levels and adjusted residuals for those relationships. Odds ratios were also presented.

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Summary of the Chapter

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Human beings are naturally prone to error, and in the field of health care, it puts patients at risk. Within the radiation therapy specialty, there is ongoing work to reduce that risk by improving safety. This dissertation study was used to aid in that effort through a quantitative analysis of human contributing factors to error. A non-experimental quantitative and predictive study design was utilized for that work.

Human factors contributing to reported radiotherapy incidents were ascertained from reports to the IAEA's SAFRON database. A representative sample of reports was selected for this research. These voluntarily submitted reports showed information about radiotherapy errors yet contained some amount of inherent bias; contributions were offered through self-selection sampling. This bias is addressed and does not overshadow the potential for this research to contribute to safety improvement strategy.

The goal of this research was to determine the nature of associations between radiotherapy errors and the human factors that precede them. Each incident report in the included sample was reviewed and assigned to a single error type as well as to all applicable human contributing factors from a well-established human factors classification system. Within this system, human factors exist at four levels or tiers, including tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences. An analysis was done to determine whether there were significant predictive associations between human contributing factors at higher tiers of the HFACS and factors at lower tiers. The Goodman and Kruskal's lambda statistic was utilized to assess that significance. Statistical tests for association between human contributing factors and radiation therapy error types was then performed. The chi-square test with an assessment of adjusted residuals was used for this assessment.

Threats to this study included construct validity with the SAFRON incident learning report. Radiotherapy incidents are complex, and it is possible that (as would be the case for all incident learning reports) the standard SAFRON intake form did not let information to be shared optimally. The voluntary nature of the reports and the purposive sampling method used to include only a sample of reports also detracted from overall generalizability. The lack of

generalizability detracted from external validity. Internal validity was affected by a 20 timespan over which the reports were submitted to SAFRON. Changes in technology, communication patterns, and workflows were not able to be accounted for with the given sample size.

An important strength to this dissertation study is that validated human factors classification system was utilized to better understand how and which human factors contribute to error in radiation therapy. This approach has achieved success in the aviation industry, in other high reliability industries, and has recently been used in health care. The approach is new, however, to radiation therapy incident learning. Associations between human factors and error types were made systematically in a valid way that could be reproduced by another researcher. One weakness of this study design was the inclusion of voluntarily submitted incident learning reports. It is understood that the reported errors are only a subset of the actual errors that take place.

The SAFRON database contributed to this study by the IAEA contained over 1,600 reports. This database included reports that had originally been submitted via the ROSIS database described in Chapter 2; reports were included in the database if they were submitted through either the ROSIS or SAFRON web-based intake forms. Events were excluded from this study if they were labeled with either minor or unspecified patient harm or if they were missing information in key areas, such as the incident description or the presumed causes of error. Ultimately, 141 reports were included, which allowed for reasonable power and statistical certainty from the analysis. Results from this study are presented in Chapter 4 with graphs and with relevant statistics. Reliability and validity issues were assessed, and quality ratings for the reports were presented to aid in that discussion.

Incident report data utilized for this study contained sensitive information about radiation therapy safety events. The data as supplied by the IAEA had been deidentified such that all parties were anonymous. This step was necessary from an ethical standpoint and is required by the Health Insurance Portability and Accountability Act (Health Insurance Portability and Accountability Act, 1996). High ethical standards were upheld throughout this dissertation study to insure that involved parties were respected with appropriate privacy and confidentiality. Both the Nova Southeastern University IRB and the appointed dissertation committee served to ensure that these ethical standards were preserved.

Data for this study were provided by the IAEA as a database of SAFRON incident learning reports. As stated, all of those reports had been voluntarily submitted over the past two decades. Following the mapping of each report to an error type and to the specified human contributing factors, tests were run to find associations and predictive patterns. Those results are presented in Chapter 4 and are discussed in Chapter 5.

Chapter 4: Results

Introduction to the Chapter

The purpose of this dissertation study was to uncover predictive patterns of human factors contributing to radiotherapy errors. An evaluation was done from an international sample of reports submitted to the SAFRON incident reporting and learning system. The HFACS was utilized to map each of the reports to as many human contributing factors as were noted to be relevant. Those factors spanned four distinct tiers with tier one unsafe acts being closest or most proximal to the noted error and tier four organizational influences being most remote. Radiation therapy-specific error types were also assigned to each of the reports.

A Goodman and Kruskal's lambda test statistic was used to measure the proportional reduction in error between all combinations of subcategories from higher and lower tiers on the HFACS. For example, each of the three subcategories from tier four organizational factors was tested for an association with every subcategory within each of the lower three tiers, and each of tier three supervision subcategories was tested for an association with every subcategory from tiers one and two. Results are presented to show that there are predictive associations between some of the higher and lower tier HFACS subcategories. These significant associations indicate that the lower tier factor can be better predicted if the higher tier factor is known. Additional analysis was done to determine whether there were significant associations between human contributing factors to error (as represented by subcategories from the HFACS) and specific error types. Chi-square testing with an analysis of adjusted residuals was utilized for this determination. Odds ratios were calculated for all associations as a measure of relative effect size.

Data Analysis Results

One hundred and forty-one SAFRON incident reports were analyzed for this dissertation study. As incident learning report submissions are always voluntary, the SAFRON data were voluntarily submitted by the international population of radiation therapy workers who chose to participate, which resulted in variable report quality. In order to assess this variability, the quality of each report was assessed using the algorithm presented in Table 1, and the distribution of report qualities is presented in Figure 3. Approximately one half of all reports, 70 in total, were of high quality. Another 46 reports (33%) were of medium quality, and the final 25 reports (18%) were of lower quality.

Figure 2

SAFRON Report Quality
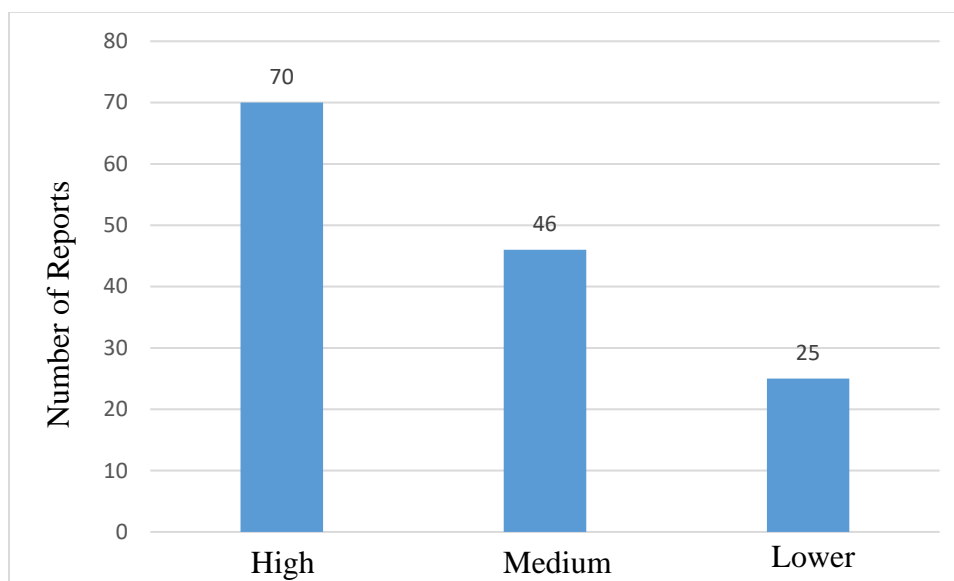
This investigator focused on 14 different types of radiation therapy error, which were defined in Table 2. A single error type was assigned to each of the 141 SAFRON reports. The error type assigned was the one that best fit the main error described in the report. If multiple errors of equal significance were described, the first or precipitating event was used for the error categorization. Each of the categories was utilized at least once within the data sample, and the

distribution of assignments is shown in Figure 4. As a means of assessing the impact of report quality on error type, Figure 3 shows this distribution both with and without inclusion of lower quality reports. The comparison is discussed further in Chapter 5.

Figure 3

Error Type Distribution of SAFRON Reports with and without Lower Quality Reports
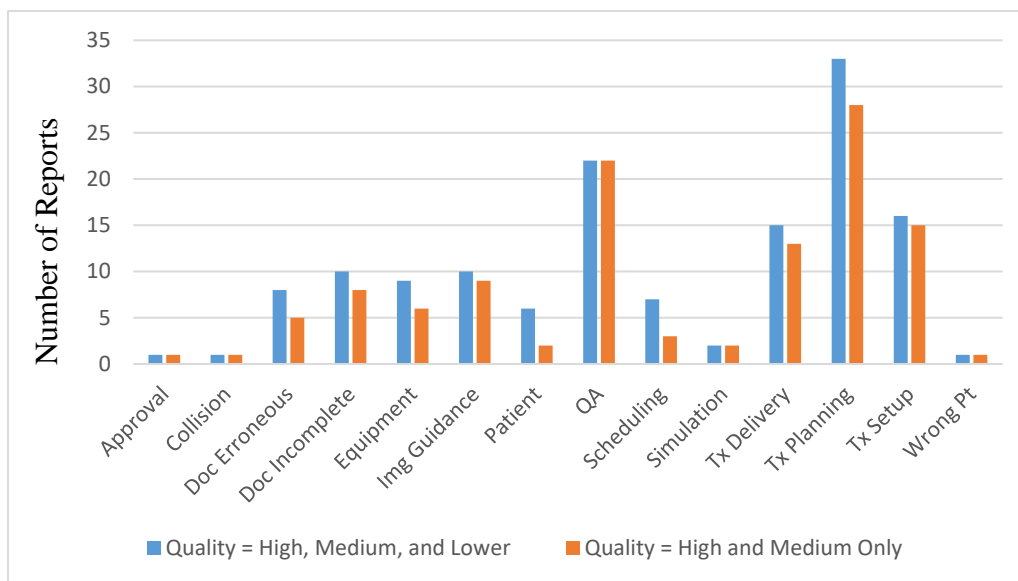
Note. This graph shows the error type distribution from 141 SAFRON event submissions of all quality levels and 116 from high and medium quality SAFRON events (with the exclusion of 25 lower quality submissions).

Coding Human Contributing Factors to Error

In addition to being assigned a single radiotherapy error type, each of the 141 SAFRON reports was assigned a number of human contributing factors from the HFACS. A sample data collection form that was used to organize the process is presented in Figure 4. Each report had at least one HFACS subcategory assignment and there were 564 assignments in total.

Figure 4

Sample Data Collection Form

Report ID	Quality	Error	HFACS Subcategories														
			1 ES	1 ED	1 EP	1 VR	1 VE	2 PE	2 PP	2 PC	3 SIS	3 SIO	3 SFP	3 SSE	4 ORM	4 OOC	4 OOP
1	H	Tx Planning	ES			VR											
2	H	QA		ED			VE				SIS	SIO	SFP		ORM		OOP
3	H	QA		ED							SIS						
4	H	Tx Delivery	ES					PE									
5	H	Tx Delivery	ES					PE	PP								
6	H	Tx Setup		ED	EP												
7	H	Tx Delivery			EP				PP		SIS						
8	H	Tx Setup		ED	EP				PP								
9	M	Tx Delivery			EP				PP								
10	H	Tx Setup			EP	VR			PP								

Note. Report quality abbreviations are as follows: "H" corresponds to high, "M" corresponds to medium and "L" corresponds to lower. Codes representing the HFACS subcategories can be found in Table 4. The presence of a code in the body of this table indicates the presence of that contributing factor in the corresponding report. An example of coding from 10 reports is shown.

Descriptive Statistics around Human Contributing Factors to Error

Among the 141 SAFRON reports, each with a single error type, there were 564 relevant human contributing factors assigned. The average number of factors or subcategories within the HFACS that were assigned per individual event was 3.84. The mode within the event sample was 3. The standard deviation was 1.83 and the variance was 3.36. The minimum number of human factors assigned to an individual case was 1 and the maximum number was 11. The distribution of these assignments per SAFRON event can be seen in Figure 5.

Figure 5

Volume Distribution of Human Contributing Factors Assigned to SAFRON Reports
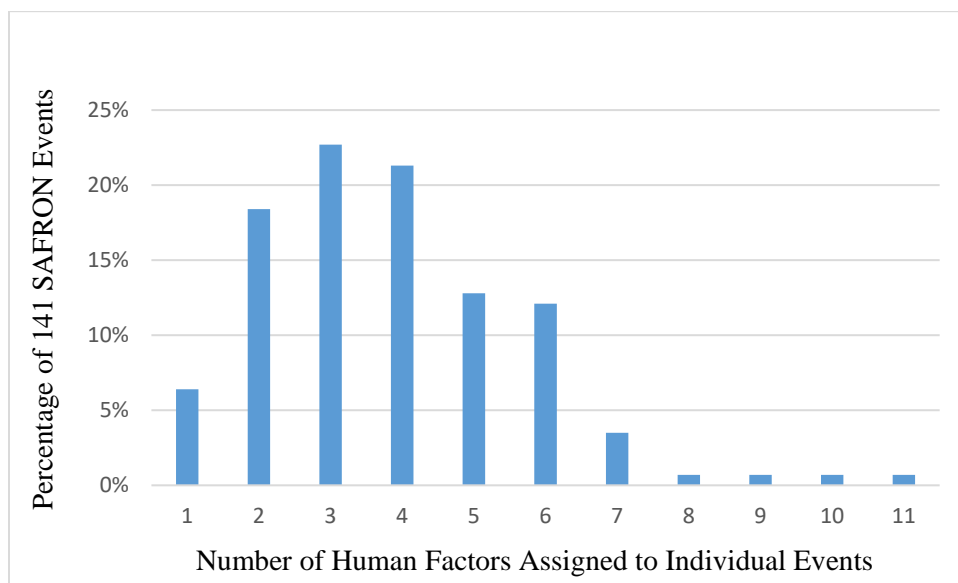
Within four tiers of the HFACS, the 564 subcategory assignments were predominantly made in tiers one through three; there were relatively few assignments made to tier four organizational influences. The relative distribution of assignments between the four tiers can be found in Figure 6.

Figure 6

Subcategory Assignments within the Four Tiers of the HFACS
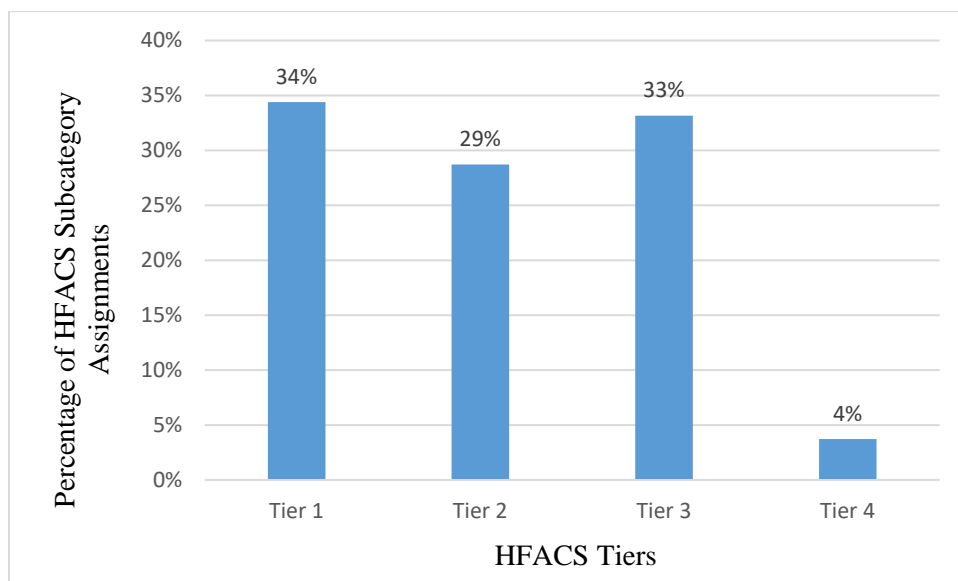
Note: The distribution of subcategory assignments from all four tiers of the HFACS is presented in Figure 7.

Figure 7

Prevalence Distribution of Human Contributing Factors
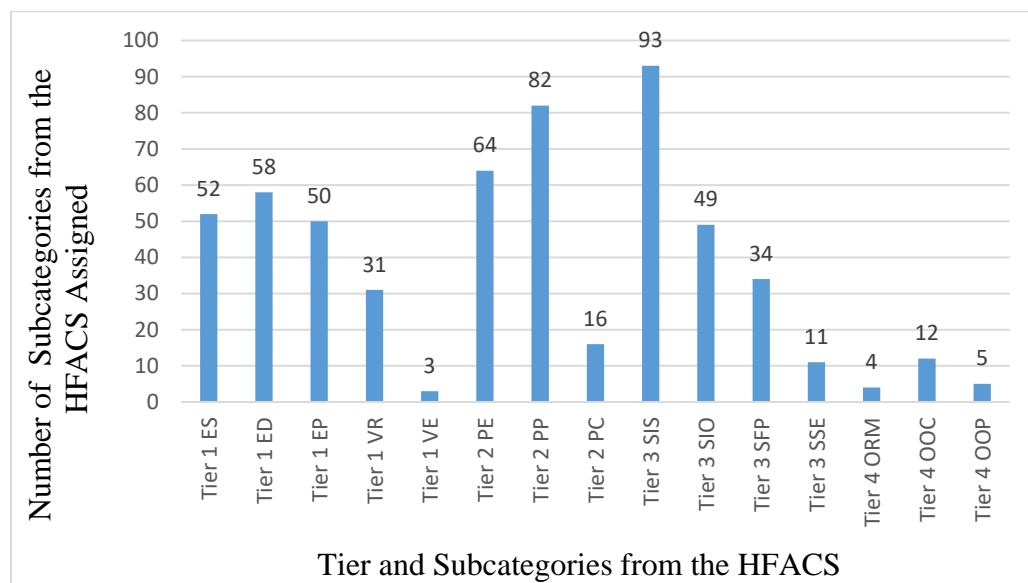
Note. This graph shows the distribution of 564 human contributing factors from all four tiers of the HFACS. The assignments were distributed among 141 individual SAFRON incident reports. Codes used to define the HFACS tiered subcategories can be found in Table 4.

As can be seen in the figure, the most frequently assigned contributing factor (with 93 assignments) was the tier three supervision subcategory called inadequate supervision. The second most common contributing factor was the tier two preconditions for unsafe acts subcategory called personnel factors. These involved communication, coordination, planning, or fitness for duty.

Volume distributions have now been presented as radiotherapy-error types and for human contributing factors to error (subcategories from the HFACS). Figure 8 shows a comparison of the relative volume of assignments made in these two areas. The graph shows the relative prevalence (percentage distribution) of the 141 error type assignments. For each of the error types, it also shows the percentage of the total 564 factor assignments were allocated to that error category. This graph does not distinguish between human factor subcategories in any way.

Figure 8

Distribution of Error Types and Human Factors Assigned to SAFRON Events
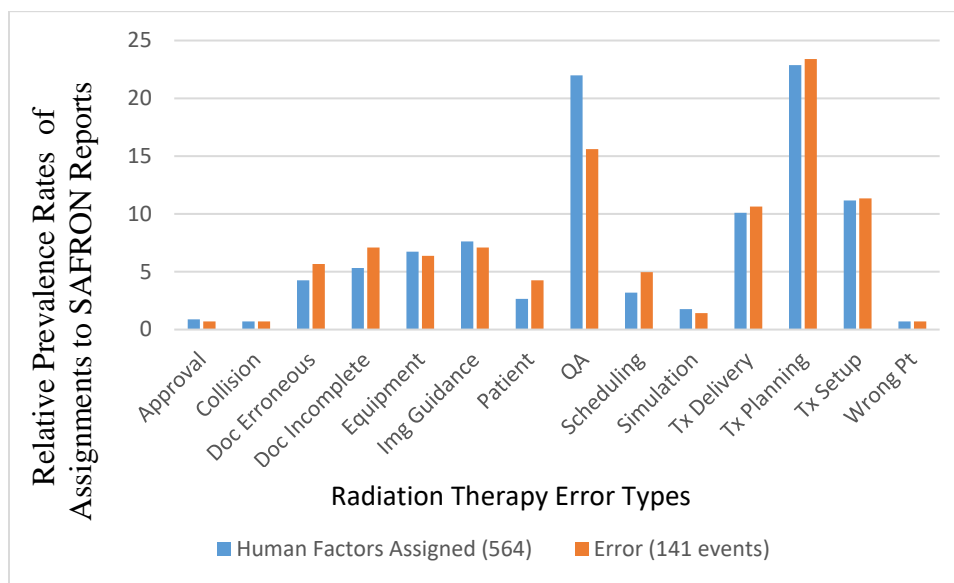
Note. This graph shows the prevalence rates for 141 errors and for 564 human contributing factors assigned to the SAFRON events. Rates were calculated as a percentage of the total number of assignments multiplied by 100.

Associations between Tiered Subcategories of the HFACS

James Reason's original Swiss cheese model of error was based on the theory that latent errors increase the risk of a serious error actually taking place (Reason, 1990b). Similarly, contributing factors to error, which are in a sense latent errors or suboptimal conditions, increase the risk of an error or unsafe act. The HFACS schema is tiered in order to incorporate the concept remoteness. Human contributing factors closest to the safety error fall under tier one unsafe acts and factors most remote or indirectly influential to the safety error fall under increasingly higher tiers. The schema culminates with tier four organizational influences. It follows in theory that that contributing factors from lower tiers would be dependent on those from higher tiers; contributing factors close to the unsafe acts would be dependent on other contributing factors more remote to those unsafe acts.

Testing was done for significant associations between all combinations of subcategories from higher and lower tiers. For each test, the lower tiered subcategory was considered the dependent variable. Significant associations along with their significance level and strength of association (as given by Goodman and Kruskal's lambda) are presented in Table 6. Odds ratios were also calculated and presented as a means of understanding relative effect size.

The strengths of the associations have been described as proportional reductions in error (PRE). They describe predictability of the lower-tier contributing factor given the presence of the higher-tier contributing factor. A lambda (or PRE) value of zero means that the higher-tier contributing factor would be of no use in trying to predict the lower-tier contributing factor. All non-zero lambda values show some level of predictability. A 5% threshold, a minimal lambda value of 0.05, has been used in other publications for reporting, and greater lambda values would indicate stronger predictability (Hooper & O'Hare, 2013). The p values for the findings ranged from .07 to .16 Odds ratios ranged from .37 to 6.26.

It was found that decision errors from tier one unsafe acts can be predicted from inadequate supervision. With a lambda value of 0.25, reports of inadequate supervision have a 25% reduction in error when predicting decision type errors. In the study sample, decision errors were over six times more likely to be reported when inadequate supervision had been reported.

Reported failures to address known problems from tier three supervision have improved predictability of three different lower-tier contributing factors to error. When these supervisory errors are known to be present, the predictability of decision errors is improved by 14%, the predictability of environmental factors from tier two preconditions for unsafe acts was improved by 12%, and the predictability of personnel factors from tier two preconsitions for unsafe acts was improved by 13%. Odds ratios from the data sample showed that decision errors were

reported nearly four times more often and environmental conditions were reported 2.8 times more often when supervisors failed to address known problems.

The odds ratio for tier three supervision failures to address known problems and tier two preconditions for unsafe acts personnel factors was 0.37. Personnel factors were less likely to be reported when supervisors failed to address known problems. This is discussed in more detail in Chapter 5.

Table 6

Significant Associations between Human Contributing Factors to Error

Human Contributing Factor Subcategories from the HFACS

Higher-Tier Factor	Lower-Tier Factor	Lambda (PRE)	*p* value	Odds Ratio
Tier 3 SIS	Tier 1 ED	.25	.08	6.26
Tier 3 SFP	Tier 1 ED	.14	.16	3.95
Tier 3 SFP	Tier 2 PE	.12	.16	2.80
Tier 3 SFP	Tier 2 PP	.13	.07	0.37

Note. This table displays higher-tier subcategories from the HFACS that are associated with lower tier subcategories. Goodman and Kruskal's lambda values less than 0.10 are considered weak associations, values 0.11 to 0.30 are considered moderate, and values greater than 0.31 are considered strong. Tabled associations have a minimum of five SAFRON events in each cross tabulated category and a *p* value of up to .20. Abbreviations for subcategories from the HFACS are listed in Table 4.

Predictive Associations between Radiotherapy Errors and Human Factors

The distribution of subcategories from the HFACS with respect to their corresponding error types are presented in Figure 9. Several combinations of error type and subcategories from the HFACS have either zero or very few instances.

Figure 9

Human Contributing Factor Prevalence for 14 Error Types

	Tier 1 Unsafe Acts					Tier 2 Preconditions for Unsafe Acts			Tier 3 Supervision				Tier 4 Organizational Influences			
	1 ES	1 ED	1 EP	1 VR	1 VE	2 PE	2 PP	2 PC	3 SIS	3 SIO	3 SFP	3 SSE	4 ORM	4 OOC	4 OOP	TOT
Approval		1		1			1	1		1						5
Collision			1			1	1	1								4
Doc Erroneous	5		3			2	7	2	4		1					24
Doc Incomplete	2	1	1	2		5	8	1	5	1	1			1	2	30
Equipment		4	4	3		7	3		6	5	2	2		2		38
Img Guidance	3	6	8	1		8	4	1	5	1	5	1				43
Patient	1	2	3			1	4	1	2	1						15
QA	2	20	4	8	3	7	10		22	19	12	5	4	6	2	124
Scheduling	4		1			1	6	1	4	1						18
Simulation	1	1	1			2			2	1	2					10
Tx Delivery	8	3	6	3		7	9	2	10	3	5			1		57
Tx Planning	18	11	10	9		16	18	4	22	11	5	3		1	1	129
Tx Setup	7	9	7	4		7	10	2	10	5	1			1		63
Wrong Pt	1		1				1		1							4
TOTAL	52	58	50	31	3	64	82	16	93	49	34	11	4	12	5	564

Note. There were 564 Five hundred and sixty-four human contributing factors spanning the four tiers of the HFACS were assigned to 141 SAFRON incident reports. Abbreviations for the HFACS subcategories can be found in Table 4.

Chi-square tests were performed to uncover predictive associations between radiotherapy error types and human contributing factors to error (subcategories from the four-tiered HFACS). The significant associations are presented in Table 7. Significance was defined with *p* values less than or equal to .05. For each significant chi-square test, adjusted residuals were analyzed to determine which of the error types tested had a significant association. Adjusted residual values greater than 1.96 indicate the presence of those significant associations. Those values are also

presented in Table 7 and are described in the following paragraphs. There were no more than two significantly associated error types for any of the HFACS subcategories.

When evaluated in combination with all involved error types from the SAFRON reports, a significant difference in frequency was found within the subset of reports containing skill-based errors from tier one unsafe acts. In other words, the spread of reported skill-based errors among the different radiotherapy error types was not the same for all error types [X^2 (13, $N =$ 141) $= 26.88$, $p = .01$]. Post hoc testing showed that the statistical difference was with treatment planning errors, which were more frequently associated with skill-based errors than the other error types. This determination was made based on an evaluation of adjusted residuals. Values over 1.96 were significantly greater than the expected number of these errors given a significance level of .05. The adjusted residual for treatment planning errors was 2.1.

Similarly, a significant difference in frequency was found within reported decision-based errors from tier one unsafe acts [X^2 (13, $N = 141$) $= 52.86$, $p < .01$]. Post hoc testing showed that this difference was with quality assurance errors. The volume of quality assurance errors reported with the decision error contributing factor was significantly greater than expected with an adjusted residual of 5.5. Perception errors from tier one unsafe acts were also shown to have a statistically significant difference among its association with the radiotherapy error types [X^2 (13, $N = 141$) $= 24.67$, $p = .03$]. Post hoc testing showed that the image guidance error type stood out as being reported significantly more frequently than expected. Its adjusted residual was 2.0. Environmental factors under tier two preconditions for unsafe acts had a statistically significant finding within its error type associations [X^2 (13, $N = 141$) $= 24.84$, $p = .02$]. Post hoc testing for this subcategory showed significant associations with both equipment errors and with image guidance errors. Both error types had adjusted residuals of 2.4. Lastly, a significant finding was

uncovered within failures to address known problems from the HFACS' tier three supervision $[X^2 (13, N = 141) = 26.67, p = .01]$. Post hoc testing showed that both image guidance and quality assurance errors were significantly more prevalent than expected within this data set. The adjusted residuals were 2.8 and 2.6, respectively.

Odds ratios were once again calculated and presented (in Table 7) to show the relative effect size of each finding. The smallest odds ratio was 3.67 and showed that image guidance errors were 3.67 times as likely to occur when the tier one unsafe acts subcategory of perception errors was present than when it was not. The largest odds ratio showing a large effect size involved the tier one unsafe acts subcategory decision errors and the quality assurance error type. The value of this odds ratio was 25; it was 25 times more likely to have reported a quality assurance error when erroneous decisions were made than when they were not.

Table 7

Significant Associations between Error Type and Human Contributing Factors to Error

HFACS Tier and Subfactor Code	X^2	*p* value	Associated Error 1	Adjusted Residual 1	OR 1	Associated Error 2	Adjusted Residual 2	OR 2
Tier 1 Unsafe Acts, ES	26.88	.01	Treatment planning	2.1	2.33			
Tier 1 Unsafe Acts, ED	52.86	<.01	QA	5.5	25.0			
Tier 1 Unsafe Acts, EP	24.67	.03	Image Guidance	2.0	3.67			
Tier 2 Preconditions for Unsafe Acts, PE	24.84	.02	Equipment	2.4	5.81	Image Guidance	2.4	5.81
Tier 3 Supervision, SFP	26.67	.01	Image Guidance	2.8	5.56	QA	2.6	3.74

Note. Significant relationships between error types and human contributing factors are listed if their chi-square value is significant with a *p* value less than .05, with an *n* greater than 5, and with an adjusted residual greater than 1.96.

Each of the significant error type and human contributing factor combinations are presented below as prevalence graphs; for each significant association, graphs show the percentage of assigned human factors (among the 564 assigned subcategories from the HFACS) for each radiotherapy error type so that significant differences can be seen graphically. The graphs are used to aid in the discussion following in Chapter 5. Figure 10 shows the prevalence distribution of skill based errors (a human contributing subfactor from the HFACS' tier one unsafe acts) across all error types. Similarly, Figure 11 shows the prevalence distribution of decision based errors, and Figure 13 shows the prevalence of perceptual errors. These are subcategories from the HFACS' tier one unsafe acts. Figure 14 shows the distribution of environmental contributing factors (from the HFACS' tier two preconditions for unsafe acts), and Figure 15 shows the distribution of unsafe supervision with a failure to address a known problem (from the HFACS' tier three supervision). Again, each graph shows the prevalence distribution of the HFACS subcategory across all error types.

Figure 10

Prevalence Distribution of Skill Based Errors across All Radiotherapy Error Types
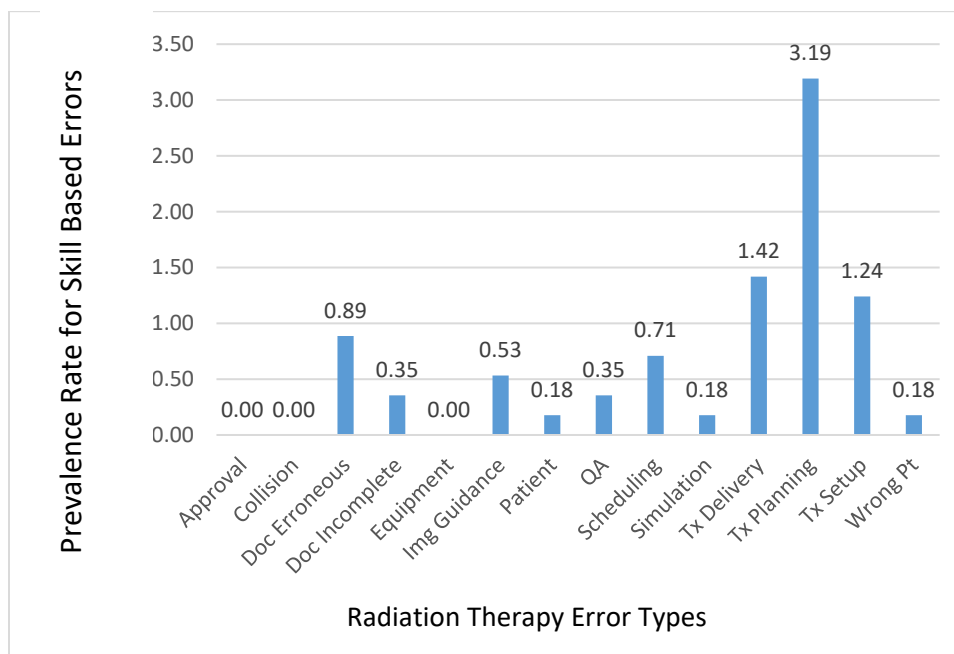
Note. This graph shows the prevalence rates for skill-based errors. Rates were calculated as a percentage of the 564 human contributing factors assigned multiplied by 100.

Figure 11

Prevalence Distribution of Decision Errors across All Radiotherapy Error Types
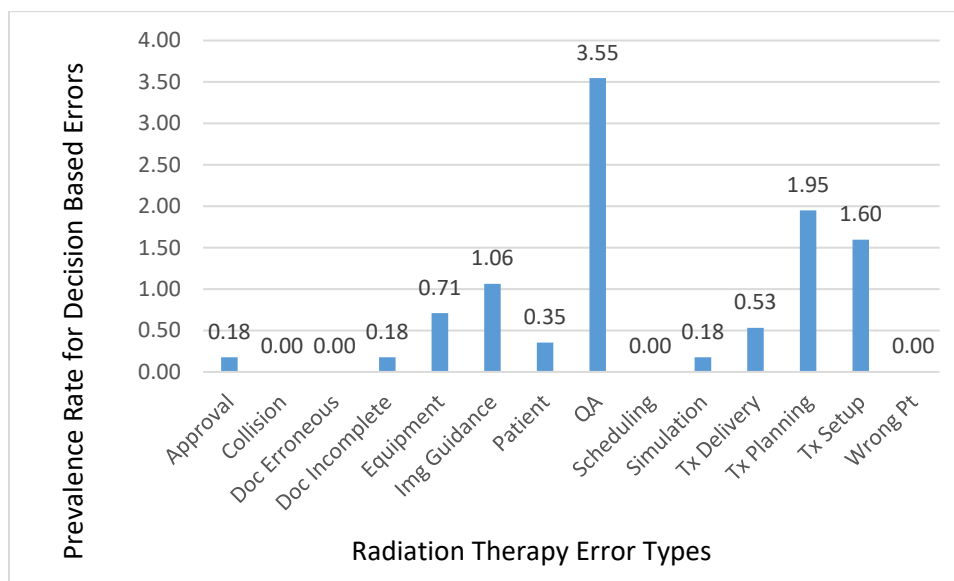
Note. This graph shows the prevalence rates for decision based errors. Rates were calculated as a percentage of the 564 human contributing factors assigned multiplied by 100.

Figure 12

Prevalence Distribution of Perception Errors across All Radiotherapy Error Types

Note. This graph shows the prevalence rates for perceptual errors. Rates were calculated as a percentage of the 564 human contributing factors assigned multiplied by 100.

Figure 13

Prevalence Distribution of Environmental Contributing Factors across All Radiotherapy Error Types
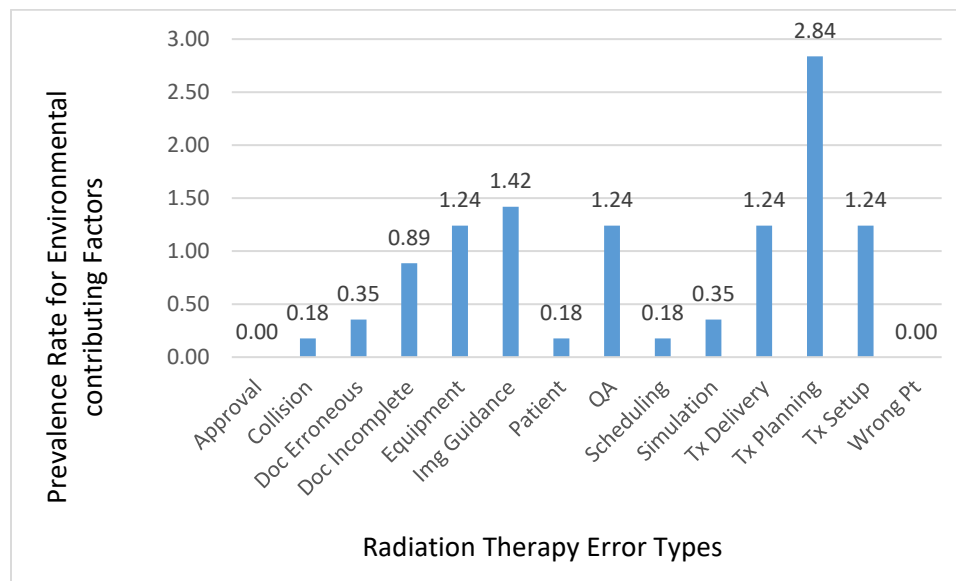
Note. This graph shows the prevalence rates for environmental factors contributing to reported error. Rates were calculated as a percentage of the 564 human contributing factors assigned multiplied by 100.

Figure 14

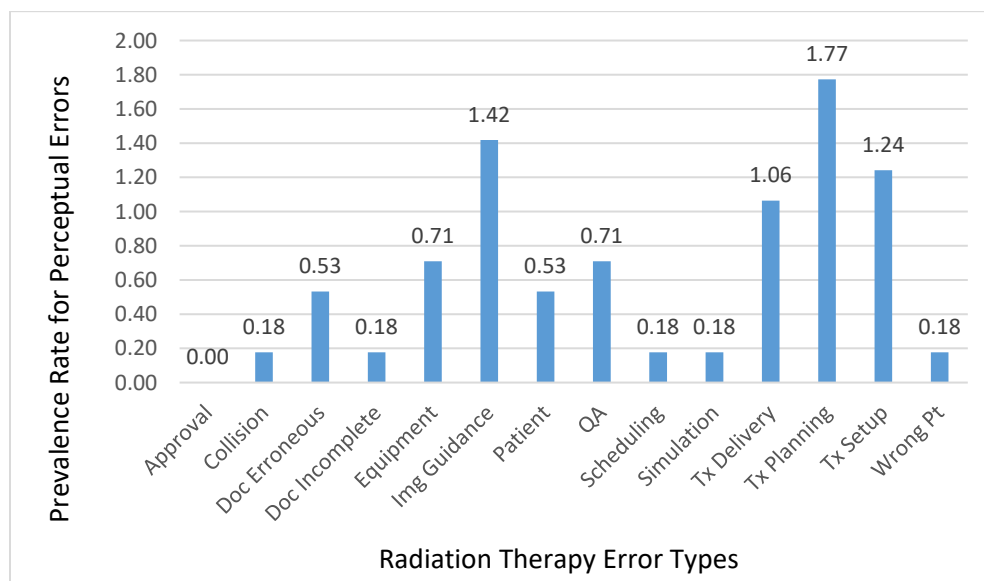*Prevalence Distribution of Unsafe Supervision with a Failure to Address a Known Problem*

across All Radiotherapy Error Types
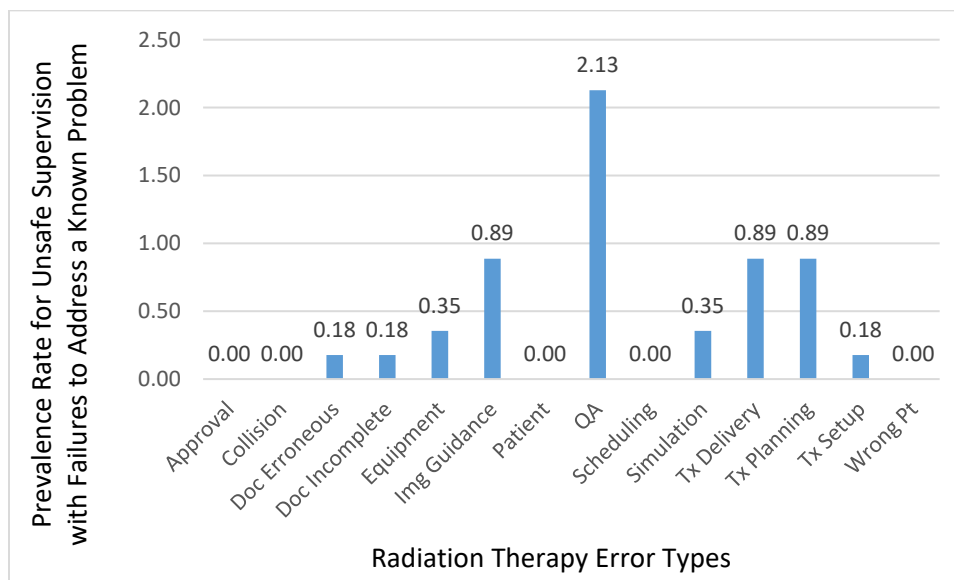
Note. This graph shows the prevalence rates for unsafe supervision factors with a failure to address a known problem. Rates were calculated as a percentage of the 564 human contributing factors assigned multiplied by 100.

Summary

A sample of 141 reports to the SAFRON incident learning system were analyzed in order to uncover predictive relationships between human factors contributing to error and radiation therapy error types. Approximately half of these reports contained high quality information, approximately one third were of medium quality, and the final 18% were of lower quality yet still met the minimum inclusion criteria and was of value to this study. Each of the SAFRON reports was assigned a single radiotherapy error type, indicating the nature of the error described in the report. Descriptive statistics were presented with treatment planning errors being the most

prominent followed by quality assurance errors. The presence of lower quality reports did not significantly affect the prevalence distribution among error types.

Each SAFRON report was coded with as many applicable human contributing factors as were indicated in the report. Human factors assigned were subcategories from the four tiers of the HFACS. Descriptive statistics of human factor prevalence were presented with the tier three supervision subcategory called inadequate supervision being the most frequently involved. The second most frequently involved subcategory from the HFACS was the tier two preconditions for unsafe acts' personnel factors.

The HFACS schema contains four tiers, namely tier one unsafe acts, tier two preconditions for unsafe acts, tier three supervision, and tier four organizational influences. The concept of tiers in the HFACS represents the degree of remoteness to the erroneous act with tier one unsafe acts being closest to the error and tier four organizational influence being the most remote. Each tier contains a number of relevant subcategories. Testing was done to determine whether there were significant associations between subcategories from higher and lower tiers. All combinations of subcategories were assessed with the Goodman and Kruskal's lambda statistic. Tier three supervision's inadequate supervision subcategory had a moderate association with the decision error subcategory from tier one unsafe acts. That moderate association was determined with 92% confidence (*p* value of .08) and had an odds ratio of 6.26. Tier three supervision's failure to address a known problem subcategory was also found to have a moderate association with the decision error subcategory from tier one unsafe acts. That determination was made with 84% confidence (*p* value of .16) and had an odds ratio of 3.95. The tier three supervision subcategory failure to address a known problem also had a moderate association with the environmental factors subcategory from tier two preconditions for unsafe acts. That

finding had an 84% confidence level (*p* value of 0.16) and an odds ratio of 2.8. Lastly, the tier three supervision subcategory failure to address a known problem had a moderate association with the personnel factors subcategory from tier two preconditions for unsafe acts. That finding had a 93% confidence level (*p* value of .07) and an odds ratio of .37.

Human contributing factor subcategories from all four tiers of the HFACS were analyzed with respect to radiation therapy error types to determine if there were predictive associations. Chi-square testing with an analysis of adjusted residuals was utilized to make this determination. It was found that skill-based errors from tier one unsafe acts were associated with treatment planning errors. It was also determined that decision-based errors from tier one unsafe acts were associated with quality assurance errors, perceptual errors from tier one unsafe acts were associated with image guidance errors, and physical or technological environmental factors from tier two preconditions for unsafe acts were associated with both equipment errors and image guidance errors. Lastly, failures to address known problems from tier three supervision were associated with both image guidance and quality assurance errors.

Each of the significant associations between a human contributing factor and a radiotherapy error type were further explored with graphs. These graphs showed frequency distributions of the HFACS subcategories across all error types and is referenced for further discussion in Chapter 5.

Chapter 5: Discussion

Introduction to the Chapter

The problem being addressed by this dissertation study is that radiation therapy puts

patients at risk, and the incident learning systems designed to inform safety improvements have

yet to be optimized through a human factors framework. Incident learning, a system through

which mistakes and nearly missed incidents are used as learning opportunities, has been utilized

both within and external to radiation therapy. In high reliability industries, such as aviation,

incident learning work has incorporated a focus on human contributing factors to error. That

human factors framework has not yet been applied to analyze national or international

radiotherapy incident learning databases. The purpose of the dissertation was to apply the

human factors framework with the IAEA's SAFRON system by uncovering predictive patterns

of human factors contributing to radiation therapy safety events.

The research question addressed was as follows: How are human factors associated with

each other and with error types in radiation therapy? In order to answer this question, a validated

schema for the classification of human factors, the HFACS, was slightly modified for use with

radiation therapy incident learning reports. The system contained 19 human factors describing

potential contributions to error. They were organized as subcategories under a total of four tiers.

Tier one, unsafe acts, included the subcategories that had the closest involvement with the

erroneous acts themselves while tier four organizational influences included the subcategories

that had the most remote or indirect contributions to error. Each of the 141 reports included in

the SAFRON database sample was assessed. For each report, as many of the 19 contributing

factor subcategories were mapped to that report on a data tracking spreadsheet. Additionally,

each report was assigned an error category; 14 radiation therapy error types were utilized for this study, and the single most relevant error type was mapped to each report.

In order to better understand the relationship between human contributing factors (represented by subcategories under the four tiers of the HFACS), a test for proportional reduction of error was performed. This test was used determined whether there were predictive associations between higher and lower subcategories of the HFACS. A Goodman and Kruskal's lambda test statistic was used to show significant associations. When a human contributing factor exists and has a known association with a lower tier factor, purposeful and proactive steps can be taken to protect against error. It was hypothesized that these relationships could be uncovered through analysis of the SAFRON report data, which was indeed the case. A detailed discussion of the analysis follows later in this chapter.

Testing for significant associations between human contributing factors and specific radiation therapy error types was also performed. This test, too, showed predictive patterns that can be helpful in making strategic safety improvements. It was hypothesized that there would be an association between a tier three supervision subcategory and errors relating to quality assurance testing, which was found to be the case for the subcategory failure to address a known problem. There was an additional predictive association between quality assurance errors and the tier one unsafe acts subcategory called decision type errors, which had not been included in the hypothesis.

It was hypothesized that environmental factors under tier two preconditions for unsafe acts would show a predictive association with image guidance errors and that was found to be the case. It was additionally determined that image guidance errors were related to perception errors (which within the HFACS fall under tier one unsafe acts) and were related to failures to address

known problems (under tier three supervision). Lastly, it was hypothesized that there would be a predictive association between personnel factors from tier two preconditions for unsafe acts and documentation errors. While this hypothesis made sense in theory, it was not found to be the case in these data sample. An analysis of these and findings will be presented in this chapter.

Discussion and Interpretation of Results

Quality Distribution of Reports

Unlike a qualitative study involving interactive interviews, this quantitative dissertation study utilized data extracted from deidentified incident reports. The reports contained a finite amount of information and the level of detail offered was variable across the sample. In order to ensure that the data utilized in this study contained an acceptable amount of relevant information, inclusion criteria were specified that ultimately reduced the total SAFRON report count from over 1,600 to 141. The included reports were of at least moderate clinical severity, contained a free text description of the event, and contained information about factors believed to have contributed to the event taking place.

A quality rubric was utilized to categorize each of the reports as containing either low, medium, or high quality information. Given the inclusion criteria applied, however, even the lower quality reports contained descriptive information about the event and about contributing factors. The amount of and/or quality of information presented by reports labeled lower quality was lacking in that important factors could possibly have been excluded. It was important for this study that the investigator not add her own bias to the human factor classification process; human contributing factors to reported errors were only assigned if they were specified in the reports, even for reports labeled lower quality.

Figure 3 showed that 18% of reports were found to be of lower quality while 82% were of either medium or high quality. Information submitted through the included SAFRON sample was, therefore, largely inclusive of rich and detailed information. It is also important to note that while the data included an international sample of experiences and human contributions to radiation therapy error, incident learning databases only reflect a very small percentage of actual safety events. Incident learning, therefore, serves more to direct meaningful and effective safety improvement strategies rather than to identify universal truths. That value was felt to be realized through the course of this study.

The data presented in Figure 4 went further to show that the lower quality report information was similar to the medium and high quality reports in terms of error report distribution. The data sample with all three levels of quality was compared with the sample with only medium- and high-quality reports included. The relative report volume distribution among 14 error types was notably similar. Had it not been the case, results would have had a greater bias due to report quality. If, for example, reports about quality assurance errors had mostly lower quality reports while other error types had mostly medium- or high-quality reports, conclusions about quality assurance errors would be more apt to lack reliability and accuracy, which was not the case, however. The comparison in Figure 4 has given credibility to the findings of this study.

Human Contributing Factor Assignments

Factors thought to contribute to reported errors were described by those who submitted reports to the IAEA through SAFRON. Not all were human factors, but all events had at least one contributing factor that was able to be appropriately mapped to a subcategory on the HFACS. It is important to note that these factors were interpreted as contributors to the reported safety events as opposed to causes. The report submission form has a prompt that says "describe

the causes of the incident," which offers a menu of discrete options. In order to more accurately represent the true meaning of causation, these selections have been interpreted as contributing factors. Other contributing factors were described in a free text section of the report submission.

Each of the four tiers of the HFACS represent a different commonality and the progression of factors from tier one to tier four represents an increase in remoteness relative to the unsafe act. Tier four organizational influence subcategories were, therefore, the most remote or indirectly related to the errors. Tier one unsafe act subcategories were the least remote or the most directly related. Each of the subcategories within a tier were related to one another (as they were described by the tier heading) but were also unique and distinguishable from one another. Those distinctions were used for clear and systematic assignments.

Several of the discrete SAFRON contributing factor options closely aligned with specific subcategories on the HFACS. The assignment of those subcategories was, therefore, able to be mapped systematically. The detail of those assignments was described in Chapter 4. Other contributing factors offered in the SAFRON reports, both discrete and in free text format, were assigned using clear definitions of the HFACS subcategories. These subcategory definitions were presented in Chapter 4. It was important for the integrity of this study that the assignments of human contributing factors were clear and systematic such that they could be repeated by a different investigator.

Even with the variable level of detail offered in the reports, most reports had between two and four human contributing factors mentioned. The higher quality reports tended to have more robust descriptions and to offer as many as 11 different factors. The majority of human contributing factors were assigned to three tiers namely tier one unsafe acts (34%), tier two preconditions for unsafe acts (29%), and in tier three supervision (33%). Tier four organizational

influences represented only 4% of the contributing factors submitted. This investigator believes that the underrepresentation of organizational influences reflects not that organizational culture and policies do not impact safety events but rather that radiation therapy workers do not routinely consider their relevance. In fact, the Goodman and Kruskal's test for association found that organizational climate (under tier four organizational influences) had a weak association with physical or technological environmental factors (under tier two preconditions for unsafe acts) with a p value of .08. The odds ratio showed that physical or technological factors were 8.6 times as likely to occur with the presence of organizational climate factors contributing to error than they were without. The test also showed a moderately strong association between organizational climate and inadequate supervision (under tier three supervision) with a p value of .007. Both of those results were excluded from presentation in Chapter 4 due to having only seven events with contributing factors regarding organizational climate. These results do indicate that tier four organizational influences may very well be relevant to safety events in radiation therapy, which is still unknown and could be a worthy focal area for safety improvement.

With the understanding that human contributing factors to the 141 SAFRON events were concentrated in tiers one through three, it is important to evaluate further at the distribution of subcategories assigned. As was likely true for the lack of reported tier four organizational influence factors, it is possible that the underrepresentation of a subcategory represents a lack of consideration by the submitter rather than a lack of relevance. However, when a diverse international group of submitters share the same or similar trends in data, there is likely a valid reason. In the case of lacking tier four data, this investigator speculated the reason was that this catagory is the most remote category relative to the unsafe act and is, therefore, the most likely to

be overlooked for risk contribution. The other three tiers of the HFACS are closer to the unsafe

act and share relatively similar contributions to the 564 contributing factors mentioned (and

assigned); contributions in each of the first three tiers fell within a 5% spread of one another. It

is, therefore, presumed that volume trends within subcategories of the first three tiers of the

HFACS represent reasonably accurate distributions.

Within tier one unsafe acts it is noteworthy that of 194 contributing factors, there were

only three exceptional violations. As compared with errors, violations are defined by a willful

neglect for the rules. Exceptional violations were those that were atypical and were not

condoned by leaders. It is expected that these violations would be few and far between, yet there

were still three reported in the sample. It is important to acknowledge that with all safety events,

there are far more instances that actually take place than are reported into incident learning

systems. Exceptional violations, therefore, exist and can cause great harm to patients. In all

three circumstances reported in this sample, a complex technical issue (such as a radiation output

calculation) was handled incorrectly and had significant clinical ramifications on a patient

population. When discovered, the issues were buried rather than being corrected. Eventually,

following additional and avoidable patient harm, the issues were shown more publically and

were ultimately corrected. Without enough volume for statistically significant findings, it can be

reasonably well understood from these submissions that disastrous problems likely come with a

perceived threat (by those involved) to the safety and security of those who made the errors.

From Maslow's hierarchy, there is understanding that people require safety and security to

satisfy their most basic human needs. When those needs come under extreme threat, there is an

enhanced risk that personal protections will be prioritized over more typical goals around patient

safety. For safety strategists, it is important to recognize the human factors at play in these

scenarios and to promote safety cultures that reduce the security threat to workers. By protecting the basic needs of providers and staff, the likelihood of transparent communication about errors is enhanced. If known errors from the three reported exceptional violations had been transparently communicated when discovered, lives could have been saved and negative clinical outcomes could have been avoided.

Within tier two preconditions for unsafe acts, there were 162 human contributing factors assigned. Of those, approximately 40% were due to issues with the physical or technological environment, half were due to personnel factors (communication, coordination, planning, or fitness for duty), and about 10% were due to conditions of the operator. Environmental issues were mostly having to do with the human computer interface and other issues involving technology and automation. This area is an one that was affected by the large two-decade timespan through which reports had been submitted; technological advancement has had a significant impact on both safety provisions and safety challenges over the decades of data included in this study. There were no reported factors involving clutter, ergonomics, or lighting. If these issues did increase the risk of safety events, they were not recognized by report submitters. Communication breakdowns in comparison were widely recognized as contributing to error. In fact, over the 564 contributing factors assigned in total, 15% fell under this subcategory (it was the second most popular contributing factor). Current technology has the opportunity for an increased use of electronic medical records and for the more systematic use of enhanced communication tools. Using these tools to further improve personnel factors could reduce the risk of safety events and improve patient care.

One hundred and eighty-seven human contributing factors were assigned to subcategories under tier three supervision. Half of those were inadequate supervision, which was the most

highly assigned subcategory in the HFACS. It includes failures with staff training, guidance, and keeping up with best practice standards. Insufficient equipment and having inadequate standards were both mentioned frequently in the reports. This category is a broad one as it incorporates an expected adherence to best practice standards. In that sense, this category had a lower threshold in that risks contributing to suboptimal care were recognized here (as compared to risks of catastrophic and life threatening failures).

Incident learning and the more broad commitment to safe and effective radiation therapy address a number of important safety goals; these goals include an avoidance of catastrophic error as well as an avoidance of miscommunications and other more minor safety blunders that chip away at the potential for optimal outcomes. In some instances, a single contributing factor can lead to an egregious patient error, and in other instances, a contributing factor can lead to something with more minor impact. The ultimate fate of a more minor latent error is determined by the environment and which other latent errors have also taken place. It is important, therefore, to evaluate each of these human contributing factors as potential contributors to all kinds of error and to recognize the importance of each of them. Inadequate supervision is important not just because it could contribute to a life threatening error but also because it is the human factor that may contribute most prominently to a broad array of patient safety events in radiation therapy.

Another important subcategory under tier three supervision is the failure to address a known problem. In this data sample, there were 34 instances reported, whereby deficiencies and failures were known and were purposefully ignored. It is reasonable to assume that people who work hard to gain the education and skills needed to work in radiation therapy do not intend to cause patient harm. In fact, they likely work hard to protect against it. When this number of

instances of failure to address known problems are reported (and again understanding that this is only a percentage of the issues that actually exist in the field), there is something that warrants further attention. There were two general trends recognized regarding issues reported under this subcategory, and both were affected by the investigator's preception of time pressure. First, there were a number of reported instances in which a hazard was recognized but due to a complex set of confounding issues (such as problems with image interpretation), that hazard was given less attention than was required. Erroneous decisions were then made. The second trend, which was even more prevalent in the data set, involved historic problems that were relatively minor in nature. If, when these issues arose, it were plausible to deny the existence of the recurrent nature, the issue was ignored in order to bring a task or treatment to completion. Again, there was a time-pressure component to these circumstances. The findings indicate that a reduction in time pressure, either through more efficient workflows or by some other means, may reduce these failures to address known problems.

Radiation Therapy Error Type Assignments

Assigning a single error type to each reported event had a requirement for a clear definition of which error types were intended to describe. Reported events are typically complex and include a number of errors made by a number of different people. There was variability in the level of specificity provided, and there is typically no single mistake that by itself results in an unsafe act. Instead there are a larger number of latent errors and unsafe conditions that increase risk to the point that an event takes place and is reported. The error types assigned to each event reflected the best overall label (of the 14 options provided) that described the reported event. If the reported event had a series of cascading errors, the event type was used to describe the first one.

There are several radiation oncology publications that include a similar menu of event types, and those were reviewed and considered for this study. The investigator's experience with optimizing event type options for alignment with reported events (in clinical settings and for a national database) was utilized to improve upon existing options. That work was done prior to reading through the study sample. After completing the review of all study data and making the assignments, the list of event types was found to be appropriate. All event types were assigned at least once, and the distribution among 141 events was reasonable.

Figure 9 shows the prevalence rate distribution of both error types and human factors (subcategories from the HFACS) that were assigned to reports. There were 564 human contributing factors assigned and 141 event types. For each error type, the graph shows the percentages of total error types assigned as well as the percentage of all human contributing factors assigned. The most commonly reported event type was treatment planning followed by quality assurance (QA) type errors. Larger numbers of an event type, such as treatment planning events, which had more opportunity for human factor assignments; if the same number of human factor contributors had been assigned to each case, the relative prevalence displayed in Figure 9 would be the same for each error type, which was not the case, however. Treatment planning events occupied the largest percentage of error type assignments (23.4%) and had nearly the same percentage of the human contributing factors (22.9%). Quality assurance events, however, had a relatively larger proportion of human factor assignments; 15.6% of all errors were of the quality assurance type as well as 22% of all contributing factors assigned. With that understanding, it will be important to look at quality assurance type events as having a larger opportunity for safety improvement. None of the other error categories had the same disproportionality either with excessive or lacking numbers of contributing factors assigned.

Associations between Tiered Subcategories from the HFACS

In order to uncover predictive associations between human contributing factors and radiation therapy errors, it was important to understand the relationships between the human contributing factors themselves. When significant, proportional reductions in error (as expressed by a lambda value) demonstrated an increased ability to predict the involvement of a lower tiered HFACS subcategory from a higher tiered one. For example, a significant lambda value of 0.10 between a tier three supervision subcategory and a tier four organizational influence subcategory indicates a 10% improvement in the ability to predict a supervision problem from an issue with organizational influence. Prior publications of similar work have used a threshold of 5% when reporting useful proportional reductions in error (Li et al., 2006). The same requirement was utilized in the presentation of calculated lambda values in Chapter 4. In addition to these lambda values, odds ratios were calculated for all relationships in which the lambda value was greater than 0.05 and the *p* value was below .20. The *p* value limit of .20, indicating an 80% confidence level, was utilized because moderately strong lambda values were uncovered with *p* values greater than .05 and up to .16. This study of 141 incident reports was important for uncovering associations and opportunities for further study; a much larger study would likely result in findings with lower *p* values. The confidence levels of 84% to 93% were considered strong enough for this study to show relevant associations worth consideration for safety improvement.

Inadequate Supervision and Decision Errors. The first relationship presented was between the tier three supervision inadequate supervision subcategory and the tier one unsafe acts decision error subcategory. This relationship was a moderately strong relationship with a lambda value of 0.25, which means there is a 25% increase in the ability to accurately predict decision errors when information about inadequate supervision is known. There was a 92%

confidence in this finding, and the odds ratio was 6.26; it is 6.26 times as likely to make a decision error when inadequate supervision is involved as opposed to when it is not.

Decision errors are those that are made when information, knowledge, or experience is lacking. They are errors that involved thought as opposed to carelessness or insufficient attention. The opportunity to decrease the risk for these errors, therefore, lies in strengthening the knowledge and skills that workers have. Inadequate supervision is a contributing factor that involves failures of leadership with respect to training, guidance, and keeping up with best practice standards. It is sensible that these two issues go hand in hand; if department leadership is not offering training and implementing standards that keep up with best practice standards, their employees will fall short of having the knowledge and skills to perform at that optimal level. It is logical that these two human contributing factor subcategories are associated, and there is credibility with the report data that they do in fact have a significant association.

While the link between these two subcategories seems less than revolutionary, it is an important distinction to highlight and to show a statistically significant association between them. If reported errors can be categorized as being decision type errors, risk mitigation strategies can then be developed around training, education, and the establishment of best practice standards. Without making such a distinction, these very specific kinds of errors can be easily lumped into a more generalized category of blunders that is not strategically addressed. Further, when errors are not recognized as being linked to other latent risks, the shame and blame culture tends to creep in and safety issues go unaddressed and unreported.

Failure to Address a Known Problem and Decision Errors. A second association involving decision type errors was also found, which was with the tier three supervision subcategory of failure to address a known problem. Those supervisory failures result when

equipment failures or deficiencies in staff knowledge, training, or awareness are known to leaders but are ignored. This association was also a moderate association and was found with a *p* value of .16 or with 84% confidence. The odds ratio was 3.95, so it was roughly four times more likely for a decision-based error to take place when there was also a known and ignored issue at the supervisory level.

From a data analysis perspective, it made sense that these two subcategories were related although with a lower odds ratio than was with inadequate supervision. Some of these supervision failures involved known deficiencies with staff knowledge and training. The association between these issues and decision-based errors would follow the same logic as was discussed above for inadequate supervision errors. This category also involved issues of known and ignored equipment failures, however, and these issues would be less apt to be associated with a decision error. The lesson to be learned from this association is that when decision errors are found to be an issue, human contributing factors at the supervisory level should be evaluated. Inadequate training and staff knowledge may be problematic and if that is the case, leadership awareness should also be explored. Conversations with supervisors may show barriers to safety improvements, such as insufficient time, resources, or a safety culture problem.

Failure to Address a Known Problem and Environmental Factors. A third association that was uncovered when testing for proportional reductions in error between tiered subcategories from the HFACS was between the same tier three supervision factor of failure to address known problems and the tier two preconditions for unsafe acts subcategory of environmental factors. This environmental factors subcategory includes issues with the physical or technological environment. In this study sample, it applied mostly to reported issues with

equipment, automation, networking, and the human-computer interface. There were very few references to ergonomics, lighting, or clutter.

Over the past several decades, there have been dramatic advancements in the use of software to improve the safety, accuracy, and precision of radiation therapy. The use of redundant safety interlocks on linear accelerators to improve the reliability of radiation delivery, the use of computerized real-time imaging to more accurately align radiation targets, and the use of electronic record and verify systems to improve the reliability of treatment plan execution are just three of those more impacting advancements. While these changes had significant gains in safety and treatment accuracy, they reduced the amount of critical thinking and manual participation that is routinely involved in patient care. Radiation oncology staff likely became more reliant on the optimal design and function of computer systems and human-computer interactions became a new source of safety risk.

Accessing an incorrect patient in the electronic medical record system, misunderstanding how to properly use a treatment planning system, inadequate testing of a new system, and the misinterpretation of imaging information used for patient alignment are just a few examples of equipment and human-computer interface issues that fell in the environmental factor subcategory. These kinds of issues are not always easy to resolve by supervisors in a radiation oncology department. The computer systems that drive radiation oncology are purchased from external vendors and have limited flexibility in their use. They are also extremely costly. If issues with these systems are known to be problematic, supervisors may feel ill-equipped to do much about them, which could be one reason that a failure to address known problems is associated with the environmental factors subcategory from the HFACS. Another reason could be that these equipment challenges happen so regularly that they are considered standard; when

human-computer interface challenges occur systematically and frequently, leaders may become complacent and fail to seek safer alternatives. Lastly, it should also be noted that the complex nature of these systems may lead to suboptimal commissioning and and customization. That could further exacerbate the problem.

Failure to Address a Known Problem and Personnel Factors. The final significant association between higher and lower tier subcategories from the HFACS was between the tier three supervision subcategory failure to address a known problem and the tier two preconditions for unsafe acts subcategory describing personnel factors. The tier two subcategory includes breakdowns in communication between individuals and between different health care departments. It also includes issues around patient care needs not being adequately anticipated and planned for. As was the case with the human-computer interface and equipment issues described above, planning and communication issues are also very common. In fact, most safety events that are reported have some relevant communication breakdown that contributed to error. It was for that reason that communication errors were not listed as a separate radiation therapy error type for this study. There was a moderate association between the two subcategories, and the *p* value was .07. The odds ratio for this association was .37, showing that when supervisors fail to address known problems, communication, coordination, planning, and fitness for duty are less likely to be reported as a contributing factor. The result may reflect a natural relationship; if a safety risk is known and transparently ignored, staff are less likely to value communication and planning breakdowns as relevant contributing factors. In this scenario, the finding seems more indicative of how radiation therapy staff perceive and report about contributing factors; it is not likely that failures to address known problems has an actual protective relationship regarding communication break downs.

Predictive Associations between Radiotherapy Errors and Human Factors

Associations between human contributing factors to safety events are helpful in understanding risk environments. Understanding associations between these contributing factors and specific error types within radiation therapy can also have an important role in mitigating risk and improving patient safety. Fourteen different error types were used to categorize reported radiation therapy events. A single error type was assigned to each and represented the best overall label to describe the nature of the event. There were 141 error types assigned in total. As described earlier, each event also had a number of human contributing factors assigned to it. Those assignments were made if and only if they were mentioned as contributing factors by the submitter of the SAFRON report. There were 564 human contributing factors assigned. After all assignments were made, the distribution of error types and contributing factors were evaluated to discover predictive patterns.

Each of the 19 human contributing factor subcategories from the HFACS was tested against all 14 error types to determine whether or not there was a statistically significant relationship between any of the variables. The p values less than .05 were considered significant. When a significant relationship was discovered, adjusted residuals were calculated to determine which specific error type had that significant relationship. The null hypothesis was that there were equal numbers of error type and contributing factor combinations (for all error types). An adjusted residual greater than 1.96 indicated that the null hypothesis could be rejected in favor of the alternative with 95% confidence (p value of .05). Human contributing factor and error type combinations with adjusted residuals greater than 1.96 had a significantly greater number of instances than other combinations. In total, there were seven associations between radiotherapy

error types and human contributing factors that were found to be statistically significant. Each are discussed below.

       Skill-Based Errors and Treatment Planning. Skill-based errors are unique in that they are errors made while performing familiar tasks that are routinely done without a great deal of thought. These are errors that often take place when focus and concentration are somehow compromised. Treatment planning in radiation therapy is used to determine how a prescribed radiation dose is to be delivered for a specific patient. It typically involves a computed tomography (CT) image set and a sophisticated planning system that contains detailed information about the radiation source and how that radiation will interact with the patient's anatomy. A specially trained group of individuals will often spend several days designing the geometry, technique, and customized plan that will optimally target the patient's tumor while sparing their healthy organs and tissues to the greatest extent possible. In this way, the cancer has the greatest likelihood of being destroyed while the patient is spared harmful radiation side effects. Treatment planning involves the appropriate set up and use of multiple computer systems and calculation protocols. There are industry standards for independent and redundant checks so that errors can be caught and rectified. Still, treatment planning is highly complex and mistakes often slip by even the most robust safety management systems. Errors involved with any step of the treatment planning process were considered treatment planning errors in this study.

       Treatment planners, dosimetrists, and physicists spend their time at a computer and work largely independently. They usually work on multiple patients at a time, and most will run hundreds of treatment plans per year. While all patients are unique, the process of treatment planning, calculation, software utilization, and data transfer are somewhat routine. For that

reason, it was not surprising that an association between treatment planning and skill-based errors was uncovered. Treatment planning was the error type that had the highest volume among all reports, and this association was the only statistically significant association that it had with an error type. Similarly, skill-based errors only showed a statistically significant association with treatment planning errors. The relationship was found with a chi-square value of .013 and the adjusted residual was 2.1. With that adjusted residual greater than 1.96 it was understood that the number of cases in which involving both skill-based errors (human contributing factors) and treatment planning errors was significantly larger than would be expected if there were no association. The confidence behind that determination was 95% (significance level of .05) and the relationship can be seen graphically in Figure 11.

Over the years, radiation therapy treatment plans have become increasingly more complex. Radiation delivery machines and linear accelerators became capable of reliably delivering radiation with more customization, with steeper dose gradients, and with increased modulation. With better precision and with improved accuracy, radiation oncologists were able to increase doses to tumors while decreasing doses to healthy organs and tissues. These advances were revolutionary in the field of radiation oncology. In order to make use of the advancing capability of linear accelerators, radiologist oncologists used treatment planning systems to be able to design plans that made use of that which became possible in terms of treatment. Planning algorithms were advanced as were treatment techniques themselves. Part of the nature of these advancements was an increase in planning automation; the treatment planning process still required planners to have an awareness of anatomy and the dose tolerances of individual organs, but the manual design component of treatment planning was partially replaced by a computer-driven process. Manual calculations were largely replaced by computers as well.

These changes were great steps forward for patient safety in that they reduced errors that often came with the more manual processes. It seems logical, however, that the reduced need for critical thinking and increased need to guide a computer program through a more automated process caused skill-based errors to increase. The nature of these errors should be considered when safety improvement strategies are being considered for treatment planning.

Digging deeper into the narratives of events that shared this error type and human contributing factor was used for a better understanding of the specific kinds of mistakes that were more prominent. One area that seems to be especially at risk for these kinds of errors is dose fractionation. Radiation therapy prescriptions specify a dose per fraction, a total number of fractions, and a total dose. There is variability in those prescriptions between patients and to some extent between different medical practices. There were several instances reported in which an incorrect dose was used for calculation. Verbal communication and manual data entry were two risks that contributed to these errors.

A second commonality with these errors concerned manual processes in general: manual calculations have been performed incorrectly, data have been entered incorrectly, and specific steps in the treatment planning process have been performed incorrectly. In many of these instances, more robust automated checks could have been utilized to catch the mistakes. For example, one incident involved the unintentional assignment of different isocenters for different radiation beams within the same plan. As it is not a standard practice, it is something that a treatment planning system could flag as an error. Enhanced automated checks of more standard or expected information could help in other areas as well. The needs of typical treatment planning, such as non-standard treatment distances, were reported and could easily be flagged for confirmation by a computerized system.

A third major issue found in this area was the human computer interface. The enhanced safety that computers and automation have is well documented, yet the potential to optimize that safety enhancement is limited in part by the human computer interface. Computer systems must be developed and then improved upon to eliminate safety barriers that are found to be problematic. The SAFRON events reported in these categories had information about these barriers. In multiple instances, different layouts or the ordering of discrete data fields being different in different views (either within the same computer system or in two different software programs) has led to incorrect data entry. It would seemingly be more problematic when one view is predominantly utilized; a data entry error in a different view is more likely when someone is trained to expect the layout of data to be different than it is. Second, dose and fraction information have been entered incorrectly for a multitude of reasons. An improved human computer interface could eliminate the need for redundant data entry and could flag likely errors if an expected data range was referenced.

Lastly, there seems to be a consistent pattern of failure with independent redundancy checks. It is a standard practice in radiation oncology for dose calculations to have a second independent check and multiple other checks throughout the course of a patient's treatment. This work is done through computer systems and by additional dosimetrists and physicists. On many occasions, these redundancy checks failed to catch even the more apparent errors reported, which could be due to a lack of attention, fatigue, rushed or overloaded schedules, or a multitude of other reasons. These may be the least likely issues to resolve completely, yet communication, awareness, and responsiveness to identified stressors could lead to safety improvements. Improvement made at the human-computer interface could also serve to improve efficiency and reduce time pressures.

Decision-Based Errors and Quality Assurance. Decision-based errors are dissimilar to skill-based errors in that they involve a purposeful erroneous decision as opposed to a mindless error made while distracted. When thoughtful decisions are made erroneously, there is a knowledge or awareness that is lacking, which can stem from inadequate experience, training, or from a number of other reasons. Safety improvement strategies to reduce the risk of decision errors are, therefore, markedly different than those meant to address skill-based errors. The chi-square testing done through this study showed a statistically significant association between decision-based errors and QA-type errors. The chi-square value was less than 0.001, meaning that the finding was made with at least 99.9% confidence. The adjusted residual was 5.5, which shows that decision-based errors of the QA-error type are higher in volume by over three standard deviations as compared with decision-type errors across all other error types. Figure 12 shows this distribution of decision errors, and it can be seen that the volume of QA errors is much higher than comparative volumes with other error types. Treatment planning errors show the second highest volume of decision errors, but they had the highest reported volume of error types overall and the strength of association with decision errors was not as strong.

QA work is that which is done to ensure the safety and accuracy of patient care. In radiation oncology, the term is typically used to describe the work done by physicists to make sure that radiation producing machines, treatment planning systems, imaging systems, and many other peripheral hardware and software systems work accurately and reliably. Organizations, such as the American Association of Physicists in Medicine publish protocols and best practice standards that have been incorporated into the expectations of accreditation and certification bodies. This kind of work is unique for two main reasons. First, this work is performed by a relatively small group of individuals as compared with nurses, doctors, therapists, and other

members of a radiation oncology department. In fact, many departments have only one single physicist. Even when a department has multiple physicists, quality assurance work is often done by one person working alone outside of standard treatment hours, which is a necessity because work done on a linear accelerator or other treatment machines must be performed when there are no patients occupying the equipment. The second distinguishing characteristic of QA work is that it is highly complex and technically specialized. That fact further isolates this work from that which is routinely reviewed by many people.

A review of the SAFRON reports containing QA-type decision errors was performed and showed multiple commonalities. As knowledge was lacking in each of these cases, education and training may have helped to prevent the mistake from occurring. It is noteworthy that education and training have historically been less effective than other safety improvement strategies, such as automated safeguards (American Society for Radiation Oncology, 2019b). An increasingly automated process for quality assurance, including calibrations, would likely be highly effective here as well. Still, the knowledge and skill of trained physicists is important for safety and ongoing learning and routine knowledge assessments may help mitigate against the deficiencies uncovered with this association.

Incorrect treatment machine calibrations and treatment planning system commissionings were the most common mistakes falling into this category. Unlike other more stand-alone kinds of errors, these errors affect larger groups of patients; when a planning system or treatment machine has incorrect information and is used to plan and treat a patient population, the entire population is affected until the error is caught and corrected. The next most frequent issue reported with this error type and human contributing factor was the inappropriate use of equipment. The use of a large ionization chamber to measure a small radiation field, for

example, will result in the collection of bad data and can have catastrophic effects on patient treatments. These errors would not be apparent to the user unless he or she had the proper training, knowledge, and experience. Also, as mentioned, radiation therapy physicists often work alone or in very small groups. This environment lacks an abundance of opportunity for erroneous practices to be noticed and corrected by those who may be more knowledgeable.

The issue of isolation around QA work has been addressed in many reports. Physicists were often working alone and were unchecked by others. It is not uncommon for this situation to be the case, and there are guidance documents drafted especially for solo physicists so that they can address riskier parts of their job through periodic external reviews and other forms of redundancy checks (Halvorsen et al., 2003). In some cases, physicians and other staff may step in to try to cross check a physicist, yet without proper training, this situation has led to overlooked errors or additional errors. Again, an appropriate knowledge base is critical in this area.

Department standards and leadership protocols were often lacking in the reported SAFRON events. In one case, two different and conflicting data tables were being used by staff within the same department. In another situation, there were conflicting data sets measured by a consultant physicist (brought in to do a one-time commissioning on a new piece of equipment) and the on-site physicist. The risk for such interdepartmental conflicts necessitates proper oversight, which could be accomplished through one designated person responsible for cross checks of work done by multiple people. In most situations when that oversight was lacking, the errors were not caught until an external review or independent check of some sort ultimately was done. In some cases, it took years. These findings show the importance of external audits.

While it is easy enough to state that independent checks are necessary, they often require time and expense, which can be challenging as the human contributing factors described in these narratives often convey a sense of extreme pressure. The pressure could come from senior leadership, from the staff members themselves, or from any aspect of the clinical work environment. That which is more consistently expressed and understood is that the commitment to start and treat patients with high safety and quality standards is stressful for workers; time pressures are not uncommon. One reported example of the pressure was at a site where a new treatment machine had been commissioned with independent testing done by an external body. Unfortunately, clinical treatments began before test results were returned, and the errors that were uncovered had already affected several patients. Independent verification typically takes some time as the testing material often needs to be mailed to an off-site location for analysis, and those results can take several weeks. Another example was when a physician noticed a clinical outcome difference between his patients at two different oncology centers within the same organization. Instead of pausing treatment, informing others, and looking into the error, he adjusted his prescriptions at one center and allowed the root cause of the problem to continue to affect other physicians' patients.

The intense pressure felt by radiation oncology workers to continue treating without calling attention to their failures was also exemplified through reports of staff who went to extreme measures to mask error. In one case, a physicist falsified records so that an independent reviewer would not uncover his mistake. In other cases, patients were treated on machines that had their safety interlocks overridden. By overriding the interlocks, staff prevented any treatment interruption that would have been required to resolve the machine malfunction. In hindsight, these actions are understood to be reckless and dangerous to patients, but in the

moment workers likely felt that the risk taken through their actions was minimal in comparison with alternatively stressful treatment delays. These priorities are likely not uncommon given the learned experience of risky behavior with positive outcomes and the rarity of reported treatment errors. Education and a positive safety culture are necessary to ensure that safer decisions are made.

While these issues may have been addressed within the individual clinics they were discovered in, it is critical to safety that these situations also be looked at in aggregate. Striking commonalities can then be worked into strategic safety planning. It is important to understand that typical time pressures and workload stresses are exacerbated when new equipment needs to be commissioned or whenever the workload is higher than normal. Quality assurance work is often complex so risk mitigation requires time efficient workflows and both the equipment and education required to support them. As education and training cannot be expected to prevent all errors, it is even more important that redundancy and independent verification be an integral part of any quality assurance program. This independent verification must take place prior to the clinical use of new equipment and prior to any change from existing systems. The time and expense requirements required for independent verification are high, yet the cost of serious treatment errors affecting large populations of patients is much higher.

Perceptual Errors and Image Guidance. Perceptual errors are a human contributing factor on tier one unsafe acts from the HFACS. These errors result when any perceptive ability (through any of the five senses) is compromised and missing information is subconsciously filled in. Expectation bias often has a role in these kinds of errors.

One radiotherapy error type with more prominent perceptual errors was image guidance. Image guidance is a process through which two- and three-dimensional imaging systems are

utilized to align a patient properly for radiation therapy treatment. The central point in space

thorough which therapeutic radiation is to be directed is called an isocenter and each patient's

planned isocenter must be aligned to the treatment machine with precision. A high level of

accuracy and precision around patient alignment is used for planned radiation fields to be

minimal in size, which in turn minimizes radiation exposure to healthy organs and tissues.

Image guidance is a critical component of radiation therapy.

In order to perform image guidance on a linear accelerator, a set of reference images is

used to define optimal alignment; the goal of image guidance is to align the patients for treatment

the same way that they were aligned on the reference set of images. Reference images are

typically obtained through a CT scan. Images used for treatment alignment are taken on a linear

accelerator and are compared with the reference set of images as part of that image guidance

workflow. Computer systems are utilized to match the two sets of images together and to

determine the positioning adjustments required. These adjustments fine tune the patients'

alignment so that they are positioned and aligned according to the treatment plan. Patients are

positioned on a motorized treatment couch that is utilized to drive the patient into that proper

position based on the adjustments calculated from the image guidance system. While this image

guidance process is mostly automated, it still requires oversight and some manual operation from

the patient care team. If an image and referenced anatomical location are perceived incorrectly, a

patient could receive treatment to the wrong area.

The association between perceptual errors and image guidance errors was found with a

confidence level of 97% (p value = .03) and an adjusted residual of 2.0; the contribution of

image guidance errors to perceptual errors in radiation therapy is two standard deviations above

other error categories, which can be seen graphically in Figure 13. There was actually a higher

rate of prevalence with treatment planning errors although the statistical association was not as strong. The baseline number of reported treatment planning errors was far greater than that for image guidance but did not have as strong of an association. As image guidance has become a largely automated process, the use of critical thought and manual analysis has become less intensive. This change may have lead to a reduced level of skill and may, therefore, have increased the risk for these perception type errors.

One kind of image guidance error that was reported multiple times was a misaligned spinal treatment in which the perceived alignment to one targeted vertebral body was actually aligned to a different vertebral body. Without solid landmarks to anchor a spine image, it can be difficult to differentiate between certain vertebral bodies. This ambiguity increases the risk for an error. Prior to being imaged, radiation patients undergoing image guidance are roughly aligned with external skin markings. Then their treatment images are taken. With an expectation that the patient will be aligned to the correct vertebral body, a focus on intravertebral alignment as opposed to intervertebral alignment can lead to perception images. Expectation bias can similarly affect other kinds of radiation therapy errors when a more typical scenario is presumed but is not the reality. Examples of this expectation bias include assumptions that a patient has not received previous courses of radiation therapy and expectations that treatment prescriptions are for a single fraction of radiation daily (as opposed to one every other day or two per day, which are sometimes prescribed).

Other perception errors in radiation therapy are at increased risk when multiple software systems are brought together in a mixed vendor treatment environment. While there are work groups and efforts underway to specifically protect against the safety risks that can result from these multi-vendor environments, the risks are still present. In one reported case, two involved

software systems utilized different coordinate systems. A patient's entire course of therapy was delivered to an incorrect area because coordinates from the wrong system were used. This case involved a perception error because the clinical team took images of the patient's position daily and analyzed them. While aware of where the patient was planned to be treated, multiple people assumed that the positioning shown on the daily images was correct as it was aligned to the coordinates within the system. These multi-vendor environments must be recognized for their increased risk to safety, and care must be taken to adequately mitigate against them.

One last commonality found with image guidance and perception errors was the presence of an atypical high-pressure situation. It is not uncommon in radiation therapy for time pressures to be felt, but it is noteworthy that in several of these events, the patient was reported to be in extreme pain. The tables used for patient treatments must be hard due to the need for precise and reproducible positioning. When patients have bone metastasis or other painful conditions, they may be in serious pain as they attempt to lie still for their radiation treatment. Being keenly aware of this situation and sympathetic to patients, radiation therapists can feel pressured to quickly analyze images, make the required adjustments, and complete the treatment. These tense situations would amplify the risk for perception-type errors.

More so than in other areas of radiation therapy, image guidance workflows have been shown to be particularly susceptible to perception-type errors. In order to strategically mitigate these issues, those involved can be made aware of the increased risk so that they can pace themselves and make sure they are doing their best to avoid such errors. More importantly, software vendors can take these issues into account when designing safer systems. Automated recognition of vertebral body alignment, for example, could be a growth area for image guidance that would greatly improve these kinds of errors.

Environmental Contributing Factors and Equipment Errors. An association was found linking the tier two preconditions for unsafe acts environmental factors subcategory to equipment related errors. The environmental errors subcategory on the HFACS includes human contributing factors dealing with either the physical or technical environment. Physical environment issues would include ergonomic issues, poor visibility, inefficient space layouts, and other such problems. Those issues were very rarely mentioned in the SAFRON reports. The focus of more typical environmental factors from the reports was on equipment problems, networking, and issues with the human-computer interface. The equipment error type includes issues with radiation therapy hardware, software, connectivity, and networking. Radiation therapy has the requirement for the use of radiation treatment devices, treatment planning systems, a multitude of imaging systems, quality assurance equipment, and other highly specialized pieces of equipment. This equipment is manufactured and supported by a variety of vendors and often has a requirement for interconnectivity. Due to the sensitive nature of radiation therapy and the need for high levels of accuracy and precision, equipment errors must be handled safely, timely, and effectively.

The environmental factors subcategory on the HFACS showed a significant association with equipment errors. The p value from the association was .02, and the adjusted residual was 2.4. Figure 14 shows the prevalence rates of environmental contributing factors for all error types. The largest volume of environmental contributing factors was submitted for treatment planning errors, yet as explained earlier, the large number of reported treatment planning events does not necessarily translate to a significant association. In this case, the association between environmental contributing factors and equipment errors was more than two standard deviations stronger than the association with other error types.

Information in the SAFRON reports showed that the presence of environmental factors often having to do with the human computer interface was a good indicator that equipment-related errors would also be present. It should be noted that reported equipment errors almost always included some measure of patient harm or nearly missed patient harm. It is understood and expected that all equipment will malfunction or be mismanaged at one point or another, but in a safe environment, those hurdles can typically be managed safely. The SAFRON reports in this category were largely those that were not handled safely and ultimately increased the safety risk to patients.

Several reports that have barred this association have described major errors with the radiation-producing devices used to treat radiotherapy patients, mainly linear accelerators. Recent decades have brought about major advancements in the area of linear accelerator safety. Reported events from the earlier years of the study sample include issues in which severe injury took place, and lives were lost due to machine malfunctions that simply do not exist today. While technical advances afford protections that we now benefit from, the human contributions to error are still quite relevant and offer opportunity for growth. One factor described in several of these reports was that despite ongoing machine malfunctions, patient treatments continued. Reasons for this factor were not offered, but in the field of radiation oncology, there is a fairly consistent pressure to continuously provide daily radiation therapy treatments to those needing care. There is a time sensitivity to the radiation treatment of cancer, and equipment downtime can threaten the continuity of care. The financial component of treatment would hopefully not be as much of a driver, yet in some environments, the financial component, too, could have a factor. Additionally, patients who have cancer and the families who care for those patients are often eager for treatments to proceed as planned. Coping with a life-threatening illness can be

challenging, and receiving treatment on schedule is often strongly desired. When equipment malfunctions occur, therefore, there can be a fair amount of pressure to resolve them quickly and to proceed with treatments as scheduled. With the knowledge of serious harm can and has come to patients when health care providers give in to this pressure prematurely, and they can move to ensure that safety goals dominate in these situations.

With other associations between contributing factors to error and the error types themselves, the contributing factors typically preceded and increased risk for the error. In this case, the equipment malfunctions have amplified environmental risk and led to errors, such as those at the human-computer interface (a form of environmental precondition for unsafe acts from the HFACS). For example, in cases in which equipment malfunctions were known, staff moved quickly to implement a work around. A work around was the case in multiple situations in which linear accelerator engineers implemented non-standard "resolutions" with system overrides for operational errors. These situations resulted in patient harm as there were no independent checks or verifications (as would be standard physics protocol today). In a more recent example, a multi-leaf collimator system, a motorized radiation beam shaping device, stopped functioning correctly. The complexity and network connectivity involved with this system made it difficult for the clinic staff to understand whether steps taken to resolve the problem actually worked. They had not, and patients were harmed. Pressure to resume treatment quickly may have had a role, and once again had a role. This investigator believes that external pressures increase the likelihood that workers misinterpret their equipment failures and then fail at the human-computer interface to rectify those problems. The association uncovered by this investigator showed that complexities at the human-computer interface challenge people's abilities to effectively mitigate the environmental safety risks at hand.

Environmental Contributing Factors and Image Guidance. The HFACS subcategory of environmental factors from the tier two preconditions for unsafe acts was not only significantly associated with equipment errors but also with image guidance errors. Both the environmental contributing factor and the image guidance error type were described previously. Chi-square results had a *p* value of .02. With these results and an adjusted residual of 2.4, it can be understood that environmental factors can predictably contribute to errors having to do with image guidance. Again, the rate of prevalence for environmental contributing factors among all error types can be seen in Figure 14.

One issue that was discussed previously and was reported with this association was that of treating the wrong vertebral body. Given the displays and functionality of the computer systems involved, challenges of identifying the correct vertebral body were noted. From a human-computer interface perspective, it was noted that the length of the spine and inclusion of identifiable landmarks were both lacking. Improved contrast, resolution, and scan length (potentially through scan protocols) would have improved patient safety in these cases. It was also noted that systems were not equipped with tolerance tables to flag atypical couch positions when aligning patients on the treatment machines.

Another issue with software systems and image guidance errors occured from the fact that different vendors utilize different coordinate systems. Even when data transfers were set up correctly to allow for this situation, the situation was confusing to staff. On more than one instance, manual corrections were made when those corrections were felt to be necessary. They were not necessary, however, and resulted in incorrect patient alignment.

One last error that was reported multiple times in this area involved not only the environmental human-computer interaction and incorrect image guidance, but a reluctance for

radiation therapy staff members to believe that which they were seeing. When patient

positioning looked incorrect on images or had changed significantly from day to day (which is

not planned or expected), staff were too quick to accept the discrepancies. The reason was

because patients who are in pain or who cannot lie still for other reasons will have an

unavoidable amount of interfraction motion (meaning it is understood that they will set up

slightly differently day by day). When a patient had actually been set up to the wrong site,

however, therapists misinterpreted that which they were seeing as that acceptable interfraction

variability. In multiple reported cases, that discrepancy was actually more significant. This

issue resulted from a combination of expectation bias and a failure of the human-computer

interface to make the error more clear. Challenged human-computer interactions and other

environmental preconditions can lead to error, which is statistically more likely in the area of

image guidance. Safety improvements for image guidance hardware and software would be a

strategically effective area to align resources.

Failure to Address a Known Problem and Image Guidance. The human contributing

factor of failure to address a known problem falls within the HFACS' tier three supervision. As

discussed earlier, this failure includes deficiencies, either with equipment or staff knowledge

being known and ignored. A significant association was found linking these contributing factors

to image guidance errors. The chi-square result for these findings had a *p* value of .01 and an

adjusted residual of 2.8. Figure 15 shows the relative prevalence of supervisory failures to

address known problems among all error types. Notably, the prevalence of this contributing

factor is greater with quality assurance errors than with image guidance errors. Still, based on

the number of each error type submitted, the observed number of associated contributing factors

and error types for this association exceeded that expected by over two standard deviations.

There was also an association with quality assurance errors that are discussed in the next section of this chapter.

Many of the issues that have been previously discussed in this chapter were relevant to this association as well. For example, there were reported issues of falsely identifying a vertebral body and then treating it, and issues of incorrect localization coordinates in an imaging system. It took reading through descriptions and narratives in these cases to understand why there would be a link between image guidance errors and failures to address problems once they were known. In several cases, it took multiple days and multiple treatments for errors to be addressed. If one were to presume that there was no actual ill intent of the involved staff, it would be reasonable to conclude that it took that amount of time for staff to think and rethink situations that did not seem right and to gain confidence in their need to address it. Internal communications about the issues may have transpired and improved the level of clarity around these situations, which may potentially have increased the pressure for transparency. Without access to report submitters to ask follow up questions, this study fell short of offering a deeper level of certainty for that which drives the hesitation to confront and address these known issues. The information reported, however, is a pattern of taking several days to rise to that point of confrontation.

With the issue of incorrect anatomy being treated, especially the repeated false identification of vertebral bodies, the concept of failure to address known issues is less than clear. In some of these cases, staff members suspected that the identification was aligned to the wrong vertebral body, but with other team members more confident that they were aligned correctly, there was a failure to speak up and express concern. With this issue, there is also a problem of failure to recognize repeated issues with the same image guidance problem. If

individual cases are corrected but action is never taken to reduce risk within the workflows and computer systems, it could also be reported as a failure to address a known problem. This issue may be improved through retraining or through the establishment of protocols to include specific landmarks in spine images. It could be, however, that current image guidance systems are not suitable to support safe workflows for these specific issues. Safety initiatives and substantial effort by radiation oncology supervisors and staff may just not be enough.   The ultimate approach to safety will likely have multiple prongs and awareness is a critical step towards improvement.

Failure to Address a Known Problem and Quality Assurance. This next association that was discovered, a link between QA-type errors and supervisory failures in addressing known problems, is understandable given the kinds of errors described in the prior sections. The association found through a chi-square test had a *p* value of .01 and an adjusted residual of 2.6. Figure 15 shows a graphical representation of this contributing factor as it relates to all error types. As previously mentioned, the number of cases in which there were both failures to address known problems and quality assurance error types was the most prominent for this contributing factor. There were statistically more associated cases observed than would be expected by more than two standard deviations.

Events involved in this grouping overlapped to some extent with the decision error association. Errors were more critical in nature (more severe in terms of patient harm), affecting large groups of patients. Most reported errors in the study sample affected only a single or small group of patients, so this distinguishing feature is an example of quality assurance type events. The increased severity and broader impact is then linked to the gravity and pressure that is felt by staff. The larger and more catastrophic the event, the more desperate some staff members might

be to cover it up, which ties back to Maslow's theory of human need. Protection of one's job

safety is critical as is the need to protect one's reputation. In one report, a physicist reported to

his/her department's physician that a 21% error was discovered in the treatment planning system,

which would have affected many if not all patients treated in the clinic. Instead of accepting the

gravity of the meaning and implementing a correction for moving forward, a decision was made

to ignore the error completely and to continue to treat without change. Assuming there was no

malicious intent, the pressure and ramifications that would be incurred by showing and working

through the error were felt to be worse than ignoring the error completely. That mistake was

eventually discovered by an external source and was reported.

Supervisors may ignore known safety issues for a multitude of reasons, but it was not

surprising that ignoring quality assurance issues would stand out as being uniquely associated. It

was for that reason that this particular association was hypothesized. The technical complexity

and reduced number of people aware of QA errors make this kind of mistake easier to hide. The

gravity of consequence that can be associated with these kinds of errors likely also has a role in

why they are sometimes ignored; the stakes are higher when confronting mistakes that have

affected multiple patients. Lastly these issues may occur and be ignored due to people being

overworked, rushed, or even just lacking the drive to see things through. Awareness of problems

that would take a great deal of time and effort to resolve (such as intercomparisons of equipment

or investigations of suspected issues) may be tempting to put off or disregard completely.

As with other kinds of improvement efforts, these situations call for strong leadership and

clear protocols. Quality assurance programs should be designed with the specificity to address

these issues. When problems do arise and have the requirement for resources and capital to

address, they should be discussed in this frame of reference with those who have the ability to

make a decision and execute it. Safe patient care is a universal goal in radiation oncology, and

quality assurance work has some unique aspects that put that goal at risk. With appropriate

foresight and recognition of these weaknesses, safety cultures, and quality assurance programs

can be designed to minimize that risk.

Literature Review

Going back to the literature that laid the foundation for this dissertation study and the

relatively recent use of the HFACS in medicine, the usefulness and applicability of the HFACS

for radiation oncology incident learning is now better understood. Use of this classification

system for a more qualitative or mixed methods study involving interviews would have taken

even greater advantage with that which the system has to offer. The upside to this study,

however, was the large number of reported events and perspectives that were incorporated.

Participation from radiation oncology staff around the world was used for a true study of human

factors, which has a commonality that all cultures share. Diller pointed out that a main benefit of

the HFACS is that it strategically directs attention to why incidents and reported events take

place as compared with who and that which was involved with any particular case. Diller also

pointed out that missing information could unknowingly bias results and both of those points

were relevant to this study (Diller et al., 2014).

The usefulness and relevance of the HFACS as compared with previously published

studies is interesting, given the different industries that have made use of this schema. Lui et al.

(2013) noted the prevalence of tier four organizational influences as compared with lower tier

factors, such as tier two preconditions for unsafe acts regarding helicopter accidents. The

opposite was true of the dissertation study; report submitters rarely mentioned the involvement

of organizational influences. The helicopter studies may have involved follow-up and personal

interviews, which could have intentionally addressed the presence or absence of organizational influences, whereas the dissertation study did not. It should be understood that the absence of tier four organizational influences in the results of the dissertation study may be more due to a lack of focus or awareness of this potential contributing factor. A study of rail accidents was more in line with the dissertation study in that tier four contributing factors were missing. Tier three supervision factors were also missing while they were frequently reported in the radiation therapy incident learning reports (Madigan et al., 2016).

Other health care studies that used the HFACS to evaluate human contributing factors to safety events focused more on the feasibility of the system rather than the findings themselves. One rare exception was the study of emergency room safety events, and El Bardissi et at. (2007) concluded that all four tiers of human contributing factors were involved. In terms of feasibility for the dissertation study, the HFACS was found to be well suited. Involved limitations and delimitations are noted later in this chapter, but after a small modification, all four tiers and all subcategories were utilized over the 141 events (to varying degrees). Shappell and Wiegmann (1996) found that only 80% of safety events involved human factors in an aviation study (Shappell & Wiegmann, 1996). It is plausible, however, that in that aviation case, human contributing factors were indeed involved and were not considered. There is some subjectivity to this analysis and subsequent conclusion. It is also noteworthy that the classic HFACS was modified slightly for better alignment with radiation therapy incident reporting.

Prior to analyzing relationships between human contributing factors and radiotherapy error types, an analysis of the HFACS tiers was done to determine whether or not there were relationships between subcategories at the different tier levels. Other researchers had performed similar tests with their own study data. Li and Harris (2006) found associations between the

different tiers the researchers used this information to confirm Reason's belief that latent errors at all four tiers ultimately increase the risk for safety events. Similar associations were found with the dissertation study. It can be understood that in radiation oncology there are associations between human contributing factors at different levels of remoteness to the unsafe act. Specifically, tier three supervision contributing factors were found to be associated with (a) tier one unsafe acts decision type errors, (b) tier two preconditions for unsafe acts environmental conditions, and (c) tier two preconditions for unsafe acts events involving personnel factors. Similar associations with tier three supervision were also found in an aviation study of military flight safety (Hooper & O'Hare, 2013). As this dissertation study included a finite number of events with limited information contained in each report, these findings should be considered a handful of significant relationships among that which is likely a larger set of others. An equally important takeaway, as Reason pointed out, is that different kinds of contributing factors contribute to the increased risk of a safety event; contributing factors remain dormant as latent errors until gaps or holes in safety barriers align in such a way that safety events occur.

Another important finding from the dissertation study was that there was an increased number of studies in the literature, which demonstrates the importance of human factors engineering to safety. The dangers associated with suboptimal human-computer interfaces were noted in several prior publications (Castro, 2014; Palojoki et al., 2017). In the dissertation study, links between tier two preconditions for unsafe acts environmental factors and both equipment and image guidance errors showed issues with the human-computer interface. Almost all of the environmental contributing factors mentioned in the SAFRON report sample involved issues with human computer interaction. The dangerous side of technological advancement and its association with error was noted in 2010 along with an acknowledgement that this issue can be

improved when human factors are considered during software design (Chan et al., 2010). This issue has also captured the attention of ASTRO and the AAPM; both organizations have noted the need for improvement in this area and the need for improved interoperability between software vendors (Hendee & Herman, 2011).

As the dissertation study and other studies advance awareness and understanding of safety risks and the importance of human factors engineering, it is helpful to re-evaluate the safety risk and error philosophies proposed by Reason and Dekker. As mentioned above, Reason proposed a theory that is well-explained by the Swiss cheese model of risk. Latent errors or safety risks are like the holes in Swiss cheese. When the layers or errors are aligned in such a way that the holes align, errors make it all the way through to cause safety events before being caught (Reason, 1990b). If one thinks of the four tiers of the HFACS as different layers of safety mitigations and the holes in these safety barriers as latent errors, one can be well served by understanding the relationships between them. The uncovered associations between tier three supervision risk factors and both tier one unsafe acts and tier two preconditions for unsafe acts, presents the opportunity to design more robust safety barriers that are less likely to have their vulnerabilities align.

Sidney Dekker posited that James Reason's error theory was overly simplified. He felt that assuming a more linear or causal relationship between contributing factors and safety events underestimated the complexities that human interaction imposes on these relationships. Dekker theorized that every human interaction results in an "explosion of new relationships" that must be accounted for in order for error threats to be neutralized. Human-computer interactions further complicate these issues by reducing error and increasing complexity (Dekker, 2010). Findings from this dissertation study specific to the human-computer interface have shed some light on

specific areas within radiation oncology that offer opportunity for safety improvement. Examples include the opportunity to decrease perception errors and to improve human-computer interactions with image guidance. The misidentification of vertebral bodies is one example of an error that has been repeatedly reported in this area. Treatment planning errors are another focal area that would be well served by improved software design. The skill-based errors that occur without thought and purposeful decision may be able to be countered by targeted interface enhancements. While there is a noteable focus on improving this area and evidence of progress, the continued reporting of safety events shows that there is still a lot of work that needs to be done.

Implications

Implications for Practice

The findings from the dissertation study are characterized by the nature of and associations between human contributing factors and error in radiation oncology. Given a validated human factors classification system and its applicabitly to every SAFRON report included in the sample, it is fair to say that human contributing factors have a very real role in radiotherapy safety issues. There were some significant associations between factors at different tiers of remoteness to the unsafe act that were shown through this work. The tier three supervision subcategory failure to address known problems was involved in multiple associations.

Supervisory factors with failures to address known problems had a significant association with personnel factors under tier two preconditions for unsafe acts. Personnel factors can be broad, and communication alone is a factor that is commonly involved in clinical workflows. It is not surprising, therefore, that it is an issue that often remains unaddressed, despite leadership's

awareness of its problematic nature. One aspect of this association that may be better suited for strategic advancement involves communication and coordination of care between medical disciplines. Many radiation oncology patients are also patients of medical oncology, and almost all of them require coordinated care with other specialty practices. The use of electronic medical records has improved the ability to coordinate multidisciplinary care, but as widespread adoption of electronic charting is fairly recent, it will likely take several more years for that system to improve these kinds of reported issues.

Failure to address known problems was also associated with decision errors. The involved staff is required to knowingly and purposefully make a mistake based on lacking skills or knowledge with decision errors, which is very different than skill-based errors that occur when people are simply not paying attention or are rushed. The association shows a need for improved knowledge and awareness in some key areas. If expanding knowledge and improving skills are not specifically targeted for improvement and other avenues, such as policy changes or punitive action are taken instead, the errors will not subside. Safety improvements made through automation while effective would also not improve decision-type errors. These improvements could be reasons why decision errors are perceived as being ignored.

The prominence of decision-type errors begs the question of whether maintenance of certification and ongoing education programs adequately ensure that radiation oncology staff acquire knowledge with regard to current issues and do not regress with regard to knowledge gained through initial training and education. Advancements have been made in recent years requiring self-assessment components of continuing education, which may ultimately lead to more effective learning although will still likely require further tweaks. Participation in incident learning is another way for systematic knowledge deficits to be uncovered and addressed.

Currently, however, participation in RO-ILS and/or SAFRON is not required, and its use is variable within the field. Another potential reason for decision-type errors is that the field of radiation oncology has become increasingly more automated. Automation has contributed to significant advancements in safety, yet it also has the potential to erode skills that would otherwise be exercised on a regular basis. These trends beg the question of whether additional effort is needed in order to sharpen the clinical and critical thinking skills that were required of radiation oncology staff prior to the technical automation advancements.

One specific error type for which failures to address known problems and decision errors were linked was quality assurance. Quality assurance involves a wide array of activities performed by radiation therapists, dosimetrists, physicists, nurses, and physicians but most all of the quality assurance errors reported were with physics testing. Physics quality assurance testing may be particularly susceptible to decision errors due to the issues noted above regarding continuing education, awareness of systematic errors throughout the industry, and increased automation. Additionally, physicists often work in small groups or solo environments that would challenge the transparency around these safety issues. Even when there are other physicists in an oncology group, work is often done alone after hours when patients are not scheduled to be in the clinic. For example, if a physicist were to be using an erroneously large ionization chamber for small field measurements, it would be harder to catch than an error that was made with other staff present. The relatively small number of physicists in a department is also problematic because they have such a unique skill set. If a clinical oversight error were to be made by a radiation therapist, it is plausible that a nurse or physician or another clinical team member may catch it. If a physicist makes a calibration calculation error, however, there may be few or no staff within the department who are capable of discovering that error, which is likely a key

reason why failures to address known issues are associated with decision errors and with this error type.

In order to address the issues above, it is incumbent upon department leaders to ensure that robust education and continued learning are incorporated into job descriptions. Recent advancements in maintenance of certification programming offered by the American Board of Radiology may help. Specific areas that are requiring growth and education could be highlighted through participation in a national or international incident learning program. Intradepartmental incident learning could be helpful as well. Improvement in automation may help address some specific areas, such as using automated independent check systems. A strategic focus on areas with higher numbers of reported errors (such as treatment planning, quality assurance, and image guidance) would be impactful. It is also important to ensure that networking for physicists working alone or with very few associates is included in cultures of safety, which could be done through national and local chapters of radiation oncology organizations, through audits, or through other professional networks.

A third association that was found with failures to address known problems was with environmental contributing factors, mostly involving the human-computer interface. Any failure to address a known problem could occur from pressure to continue treating patients, rushed timeframes and workflows, or a perceived inability to affect change. The dissertation study showed more specific findings in this area that have implications for safety improvement efforts.

The field of radiation therapy is reliant on sophisticated technology, including radiation-producing linear accelerators, treatment planning systems, and electronic medical records. Change and advancement within this technological space has been noteworthy and fast paced throughout the last decade. Adaptation and an evolution of the human-computer interface is

required for these changes. As Sidney Dekker pointed out, human contributing factors to error have a high level of complexity to safety and risk environments. When software and technological advancements are factored into this already complex environment, it is no wonder that it is hard to harness and gain control of safety risk and mitigation strategies. A failure to address known problems may occur from lacking time or focus, but they may also be reported due to a true failure of ability to address these issues with effective change.

A radiotherapy-specific error type that was associated with failures to address known problems was that of image guidance. As described earlier, image guidance procedures are used for patients to be aligned with accuracy and precision based on a comparison of real-time treatment images and baseline planning images. Image alignment software is complex, so consistent accurate use has a requirement for human intervention; radiation therapists, physicians, and physicists must be able to accurately assess patient alignment from both sets of images and confirm that any automated alignment functions are being performed accurately. There are several barriers in place that challenge that proficiency. One such reported issue concerned the correct identification of vertebral bodies. Inadequate image lengths, a lacking inclusion of anatomical landmarks, and poor image quality are three potential problems that challenge this image guidance process. This image guidance errors and a multitude of other image guidance errors are vulnerable to perception issues, and the human-computer interface involved with these systems has yet to be optimized. Software could be improved to offer enhanced protections in some key areas. Many of these advancements are already underway. The value of this finding is in highlighting the need for software companies to stay on top of the more systematic issues occurring in this space. Once effective software improvements are in place it is still incumbent on oncology centers to purchase and implement the new technology.

With an overwhelming amount of new and improved radiotherapy technology available, it takes time and resources to weed through the most impacting technology. For that reason, an annual task group working to link systematic issues like those mentioned here with validated and effective solutions may help to advance safety in this area. Not every center has the bandwidth to make these kinds of assessments, so publications or tools for making those determinations may go far to marry safety needs with the most cost effective purchases and the greatest safety improvement potential.

One last finding from the dissertation study that has implications for radiation oncology was the significant association between treatment planning and skill-based errors. The nature of errors involved with treatment planning was not based on lacking knowledge or skills but rather based on failure to execute routine procedures accurately. It is interesting in that the safety barrier could be mitigated with either automated solutions or solutions that improve the routine use of critical thought and mindfulness. Both are important and a balance is truly needed. Treatment-planning errors had the highest volume of reports among the 14 different error types. They most frequently involve dosimetrists, physicists, and physicians. Many of the errors reported in these categories could be addressed through advances in treatment planning software, through independent verification software, or through other communication tools that enhance mindfulness. Improving rushed workflows and staffing levels may also help advance safety in this area although those problems were not significantly associated with the problem as reported in this data set.

Implications for Further Research

This investigator uncovered several associations between human contributing factors to error and reported safety issues in radiation oncology. Further research in this area could

strengthen the backing for these findings and could also add to their specificity. A larger study of more reported events could aid in that effort as could an in depth qualitative or mixed methods study that may better allow for information in key areas to be obtained from participants.

The first area warranting further research is that of treatment-planning and skill-based errors. There was an association here highlighting the fact that errors made during the treatment planning process are not due to purposeful erroneous decisions but rather to careless errors made without thought while performing routine duties. There are multiple treatment planning systems available in the field of radiation therapy and some are more prominently used than others. Further research into which specific kinds of skill-based errors occur with treatment planning based on the experience of end users with different systems would be impactful. The results of such a study could be shared with software vendors so that the best and most validated safety mechanisms could be implemented more broadly, and the most detrimental aspects of these systems could be omitted.

A second area warranting further research is that of the human-computer interface. Through the dissertation study, associations were found between supervisory failures to address known errors and both image guidance errors and environmental preconditions for unsafe acts. Image guidance errors were also found to be associated with the environmental preconditions for unsafe acts. There is an opportunity here, especially in the area of image guidance, for software interfaces to be improved. In the radiation oncology field, certain issues, such as vertebral bodies being misidentified, are reported repeatedly and have not successfully been addressed with automated safety improvements. This opportunity is one of several for the human-computer interface to be improved to reduce safety risks. Other opportunities exist with electronic medical records. Reported events are not always the most useful data to use for this kind of work

because of the small minority of errors and near misses that are routinely reported. A survey or series of interviews (for example those that could be carried out at a national meeting) might serve to uncover more information that could allow for targeted improvements. Vendor-specific efforts are helpful, but findings should be shared among the radiation oncology community so that safety benefits can be optimized by all regardless of equipment portfolio.

A third distinct area that warrants further research is that of deficient knowledge and skills leading to decision-based errors in radiation oncology. Associations were found between decision-based errors and both supervisory failures to address known problems and inadequate supervision. More specifically, errors made with quality assurance processes were associated with both decision-type errors and with failures to address known problems. Increased automation and a decreased need for critical thinking may have contributed to these decision-type errors. Ineffective continuing education could also have played a role. The newly overhauled maintenance of certification program (from the American Board of Radiology) that are required of board certified radiation oncologists and physicists may reduce the risk of these kinds of errors. A survey done now and several years into the new program may be helpful in assessing the value of this educational change. Quality assurance errors were focused mostly on physics work during calibrations and with complex calculations. Future work to more explicitly identify the nature of these issues may help with efforts to prevent them. Automated calculation and verification programs along with collaborative information sharing may help to reduce the risk of these kinds of errors. As it will be difficult to statistically demonstrate improvement based on voluntarily reported errors, qualitative or mixed methods research may help point to directionally accurate improvements.

One last area recommended for further exploration is that regarding the effects of organizational factors on radiotherapy error. There were significant associations found between the organizational climate and physical or technological environmental factors. The number of involved cases was too low to be reported as a significant finding but with an odds ratio of 8.6 that area seems worthy of additional research. Similarly, an association between organizational climate and inadequate supervision was found and could be researched further.

Limitations and Delimitations

There were several limitations in the dissertation study that must be accounted for. The anonymous nature of report data limited this study with regard to understanding the diversity of contributing institutions. In other words, it was impossible to know if certain radiation therapy departments contributed a disproportionate share of the data. The dissertation study was also limited in its ability to understand the geographic spread of where these data came from. If a certain kind of error was strongly associated with a particular part of the world, for example, information about culture and communication could have biased the analysis. That depth of understanding was not able to be ascertained with these data.

The nature of incident learning data is also such that the information provided was finite. Some reports left the investigator with important questions, yet there was no resource available to provide any additional information. For these reasons, each report was rated in terms of its quality and that quality distribution was addressed in the analysis.

One delimitation of this study was the exclusion of incidents with minor or no specified clinical severity. The majority of incidents in the full SAFRON database were of minor clinical severity, yet it would have been beyond the scope of this study to carefully read through and analyze well over 1,000 cases. If the time and manpower were available to include those events,

the study may have uncovered additional or stronger findings. The study may also have been able to differentiate between contributing factor patterns leading to minor and more serious clinical harm.

A second study delimitation was that included incident reports were only those containing discrete information about potential causes. In order to associate each event with the radiotherapy and human contributing factor schema, some information about perceived causal factors was needed. Most reports did contain at least one selection from the available drop-down list, and for that reason, this data element was part of the inclusion criteria. Additional free text information about contributing factors was included on approximately half of the reports. It would be rare but possible for a report to contain a free text description of contributing factors without a selection from the drop-down menu of options. Such events were not included in the study. This delimitation was utilized in order to promote both consistency and quality within the selected sample of reports.

<div align="center">**Recommendations**</div>

Based on the findings from this dissertation study, there are several recommendations that would likely improve the safety environment in radiation oncology. Education and additional research (with increased specificity) should be done around the association between treatment planning errors and skill-based errors. There are multiple kinds of professional staff involved with treatment planning, namely radiation oncologists, physicists, and dosimetrists. Each position has continuing education requirements, and that education should include an opportunity to learn about the nature and detail of reported error. Radiation oncology software vendors involved with treatment planning and related quality assurance should also be made aware of these issues. Validated mechanisms for maintaining mindfulness while performing

these computer-centered duties should be enhanced and utilized. More common mistakes, such as manual data entry errors should be caught with enhanced automated checking systems. Critical thinking skills should be developed and maintained through advancing and more dominating automation.

Common issues with the human-computer interface should be recognized and addressed by radiation oncology software vendors and by end users as well. Image-guidance errors are associated with these kinds of errors, and as radiotherapy staff become more and more dependent with automation, they may be less likely to catch these errors. While enhanced automation can be used to eliminate common issues, such as the misidentification of vertebral bodies, radiation therapy staff should be kept aware of these issues so that they can work towards being more mindful in their image analysis. Repeated issues should be reported to vendors. The safety culture in radiation therapy departments is key to advancement in these and any other safety areas. A "shame and blame" culture works against the transparent communication that can advance these topics and lead to safety enhancements.

Quality assurance issues in radiation oncology are related to purposeful erroneous decision making and are often ignored. As physicists who perform many of these tests often work alone, it is imperative that oversight and communication networks are incorported into safe operations. As technology continues to advance at a rapid pace, the knowledge and skills needed for safety change quickly as well. Continuing education programs are one path for growth but fall short of ensuring safe knowledge and skill development in all areas. Networks with regular communication should be strongly recommended or mandated. Certain key publications could also be highlighted for mandatory reading and assessment. Self-assessment has become part of the maintenance of accreditation process for board certified physicists radiation oncologists

although there is variable quality and relevance in the offerings for these credits. Lastly, participation in incident learning could be a mandatory part of maintenance of certification, and it is currently not. Even if not submitting reports, learning about some of the more prominent safety risks reported by others can be critical to similar error avoidance. The attention brought to radiation therapy errors by the *New York Times* in 2010 launched a historic safety initiative in this field, and the victims of those unfortunate stories had asked that safety improvements and continued learning about reported errors be inspired by their fate.

<div align="center">**Summary**</div>

Radiation therapy is an inherently complex medical field that specializes in the treatment of cancer patients. While radiotherapy presents life-saving and life-extending care to so many, it also brings the risk of errors that can lead to intense suffering and even death. For those reasons, a continuous effort to optimize safety is warranted and has taken shape in many ways throughout the decades. Lessons learned from errors and accidents inform safety improvement strategy in many industries, health care being just one. Historically, analysis work done with radiotherapy errors have neglected to take on a human factors perspective; while extensive work studying human factor contributions to error has been done in other high reliability industries, there has been little work done in this area for radiation therapy errors. The HFACS was utilized in this study to classify 141 reported events. The classified data were then analyzed to uncover associations between human contributing factors to error and between those factors and specific radiotherapy error types.

Report data utilized in this study sample contained enough information about the event itself and about the contributing factors involved to meet a baseline quality level. Eighty-two percent of reports surpassed that baseline and had either medium- or high-quality information.

The quality of information submitted was sufficient to provide the level of detail needed to carry out this study. Each included report, 141 in total, was reviewed and was labeled with a single radiotherapy-error type.

Each report was assigned as many human contributing factors as were mentioned in the report. The factors assigned were subcategories from the HFACS, all falling under one of the four tiers in that classification system. Ninety-six percent of 564 assignments fell within the first three tiers of the HFACS: tier one unsafe acts, tier two preconditions for unsafe acts, or tier three supervision. Tier four organizational influences were rarely reported by submitters, which may be explained by a lack of consideration as opposed to a true lack of association. Organizational influences are the most remote to unsafe acts within the four-tiered HFACS and are, therefore, more likely to lack obvious relationships with the reported errors.

The HFACS subcategory that was reported most frequently was the tier three supervision subcategory called inadequate supervision. That subcategory was clinical in nature (as opposed to being operational in nature) and did not have any requirement for the issue to be known and ignored. The more general nature of this subcategory may have contributed to its more frequent reporting. Another tier three subcategory, failure to address known problems, was reported 34 times and was often reported alongside a real or perceived pressure to continue treating patients. Clinical needs and other external pressures to keep treating sometimes prevents the interruption needed to investigate problems. Within tier two preconditions for unsafe acts, the most frequently reported subcategory was personnel factors. Communication was central to this subcategory. New and evolving electronic medical records and an increase in multidisciplinary care challenge safety in this area. Tier one unsafe acts had a strong prevalence of skill error,

decision error, and perception error subcategories. Each is unique in nature and had unique associations with higher tier HFACS subcategories and with radiotherapy event types.

Goodman and Kruskal's lambda testing was performed to see if there were associations between subcategories at different tiers of the HFACS. There were four associations uncovered and presented in Chapter 4. Associations with organizational climate were too few in number to be reported although the tests showed significant associations, indicating that further research in this area would be warranted.

Tier three inadequate supervision was associated with decision errors from tier one. If the supervision of structured learning is lacking, staff will eventually fall short of the knowledge and skill required to make correct decisions. Failures to address known problems were also associated with decision errors. These data showed that with these reported supervisory failures, it is 14% to 25% more likely to expect decision-type errors, which underscores the need to ensure that staff members have the resources needed to maintain an appropriate knowledge base so that correct decisions can be made. The supervisory failure to address known problems was also associated with tier two precondition for unsafe act's subcategory of environmental factors. These factors relate to either the physical or technological environment. Automation and the human-computer interface were central to these reports and require further attention in the way of safety mitigation. The same supervisory failure to address known problems was also related to the tier two subcategory of personnel factors. It was noted that this category is often reported to describe communication breakdowns between staff members. The odds ratio for this relationship was less than one, showing that communication failures are not seen as being contributing factors to issues that are known and ignored; supervisory failures to address known problems obfuscate the concept that communication breakdowns are to blame for related errors.

Radiotherapy-error types were assigned to each event to describe in a very general sense the information that was being reported. Associations were uncovered between several human contributing factor subcategories and these error types. Skill-based errors were associated with treatment planning errors. These are errors that occur due to lack of thought or attentiveness during routinely performed procedures. In order to address these issues, further work was recommended to hone in on which specific errors are most common. The issues in this study included erroneously documented doses and fractionation patterns, erroneous manual calculations and data entry, issues with independent check systems, and misconceptions at the human-computer interface. Improved automation may help with some of these error types although it is contrasted by the fact that increasing automation contributes to mindlessness. In order to prevent skill-based errors, it is necessary to enhance alertness and critical thinking. Software developers in the treatment planning space can improve safety by balancing these issues and making improvements that serve both needs.

Decision-type errors were found to be associated with quality assurance. The physics work that is often involved is both complex and rapidly advancing, which leaves physicists susceptible to lagging knowledge and skills. Physics work is also often done in environments with one or very few people, which makes these errors harder to identify. Supervisory failures to address known problems were also associated with quality assurance errors. For the same reason of having one or a few people with the involved skill set, supervisors may feel unable to affect change in this area, which could be one explanation of why issues are known and are not addressed.

Perceptual errors were found to be associated with image guidance. When radiotherapy staff members are tasked with reading images to assess the positioning of patient anatomy, they

are subject to perception challenges. Reported errors show a lacking understanding of that which the images actually show. Software enhancements are needed to reduce the risk of common issues, such as the misidentification of vertebral bodies, which is one example of when there is opportunity to improve safety at the human-computer interface.

Environmental contributing factors were found to be associated with equipment errors. In some instances when radiation-producing machines malfunctioned, patients were severely hurt or even killed. While the safety of linear accelerator operation has grown tremendously over the decades, the human response to equipment failure is similar. Equipment failures leave people in less familiar environments and often result in increased stress or time pressures. In these environments challenges at the human-computer interface are exacerbated and the risk for a safety event is increased. Findings in this area have highlighted the need for improved clarity and situation management. Effective safety improvements should be made through a human factors engineering perspective.

Environmental contributing factors were also associated with image-guidance errors, which again revolved around perception issues and the human-computer interface. Larger image detector areas that encompass relevant anatomical landmarks would improve the risk from these errors, and some equipment on the market today has that advancement. It will take some time before that improvement becomes widely available to patients. Improved automation, such as the identification of specific vertebral bodies, could cut back on some of these reported issues.

These same image-guidance issues were also associated with supervisory failures to address known problems. When resolutions to problems are presumed to require new equipment and advanced technologies, they may be more likely to be ignored by supervisors. Additional

training may help, but widespread inexpensive safety upgrades would help to reduce risk in this area.

Through this study, the HFACS was confirmed to be an appropriate and useful tool for analyzing human contributing factors to error in the radiotherapy space. As in other published studies, there were relationships found between multi-tiered subcategories on the HFACS. When information about higher-tier subcategories, such as supervisory failures to address known error are known, there is a significantly higher chance of correctly predicting the involvement of lower tier factors subcategories, such as tier one decision errors. James Reason's finding is supported by the understanding that latent errors accumulate to increase risk and when aligned the right way, they can lead to harm. The importance of the human-computer interface was also noted in the literature prior to this study. The previously published finding that equipment and image guidance errors are associated with tier two preconditions for unsafe acts was confirmed in this study as well. Continued improvements at the human-computer interface are critical to safety improvements in radiation oncology.

Sidney Dekker's publications about the complexity of human contributing factors were relevant to this study. He recognized the need for safety improvement work to be done through a human-factor lens. The study findings presented have detailed information about how human contributing factors relate to one another and to specific radiotherapy-error types. These findings have highlighted appropriate paths to think through effective safety improvement strategies.

Implications for practice and for further research have been described with the uncovered associations. There were limitations to this research, including an inability to source the reported data or to follow up and illicit additional information. Delimitations for this work existed as well. Events with minor or no specified clinical severity were excluded as were events without

sufficient information about contributing factors. Despite these issues, the study was successful in showing significant associations between human factors contributing to error and between those factors and radiotherapy-event types.

Recommendations for future work include further research with larger data samples. There were significant organizational influence associations found with very small numbers of cases that were considered inconclusive for this study. Treatment planning software enhancements are needed to specifically address skill-type errors that are made without thought while performing routine duties. Human-computer interface issues must be addressed to reduce perception and other issues with image guidance and to improve safety in situations of equipment failure. Quality assurance duties have been shown to be particularly risky in that they are often performed by highly specialized professionals who tend to work alone or in small groups. Improved education and training may aid with decision-type errors in this area. Improved automation may also help with some of the reported issues. Lastly, networking and oversight are needed to prevent quality assurance errors, which are sometimes overlooked and sometimes known by supervisors but purposefully left unaddressed.

Concluding Remarks

Human contributing factors to error transcend time and geographic location. It is necessary, therefore, to optimize safety and to reduce risk by learning why errors were made and approaching safety mitigations strategically. The most frequently reported safety events in radiation therapy are those involved with treatment planning. The predictable association between treatment planning and skill-based errors underscores the need to consider the issue of mindfulness. As the most effective safety improvements are also those involving increased automation, these advances must be carefully balanced against the preservation of critical

thought. The practice of quality assurance is also critical to the field of radiation therapy and often involves physics work done after hours, either solo or in very small groups. Its association with both decision-type errors and supervisory failures point to where future safety improvements should be focused.   Rapid technological and safety advancements challenge the maintenance of best-practice knowledge and skills. Further, when mistakes are made, the real or perceived ability to catch and correct those errors is atypically limited. Access to high-quality continuing education is critical to safety improvement as is the need for transparent communication with professional networks. Image-guidance failures are also prevalent with predictive associations. Perception errors are frequently reported as being associated with a suboptimal human-computer interface. Software improvements with a strong focus on human factors engineering would be an effective here. Specific examples, including that of vertebral body recognition, were given earlier in this chapter.

There is a lot of good work that can be addressed through software development and automation enhancement, but some of the work must be done within clinical practices. Without regard to time or geographic location, human factors persist and complicate safety environments. These factors manifest in a multitude of interactions and safety challenges. They must ultimately be incorporated into safety improvements. This investigator uncovered some predictive associations that can help direct future work in that area.   Radiation therapy staff members must have appropriate work environments, resources, supervision, and safety cultures. Pressures, anxieties, and staff priorities must be balanced against an awareness of safety risk; safety culture priorities must be familiar and prominent in all clinical departments. Most importantly, there must be commitment to continuous improvement, knowing that human nature and the complexity that it brings will always leave opportunity for better safety.

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Appendix A

SAFRON Incident Report

IAEA Nucleus. https://rpop.iaea.org/SAFRON/IncidentReport/IncidentReportList.aspx

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Please choose your preferred dataset in the top right corner of this screen. Based on this selection, you can browse your own or all incident reports.

All process step for: [External beam radiotherapy ▼] (or brachytherapy)

What phase in the process is the incident   [   ] SELECT

associated with?

Who discovered the incident?   [▼]

How was the incident discovered?   [▼]

Any word in the free text fields: [   ]

Clinical incident severity: [dropdown] HELP TEXT

Did the incident reach the patient?

☐ Yes ☐ No

Was any part of the prescribed treatment [dropdown]

delivered incorrectly?

Was anyone affected by the incident? [dropdown]

Describe the causes of the incident (Select one

or several reasons): SELECT INCIDENT CAUSES

Start Date of discovery (YYYY-MM-DD): [text field]

End Date of discovery (YYYY-MM-DD): [text field]

What safety barrier failed to identify the [text field]

incident?

What safety barrier identified the incident?

What safety barrier might have identified the incident?

Is risk assessment complete?

☐ Yes ☐ No

Equipment used:

Treatment method:

First day of treatment:

☐ Yes ☐ No

Appendix B

Data Entry Options for Data Fields on SAFRON Incident Report

Phase in the process that the incident is associated with

⊟ 1. Non-clinical phase

⊟ 1.1. Equipment and software specific activities

⊟ 1.1.1. New equipment

1.1.1.1. Installation

1.1.1.2. Acceptance tests

1.1.1.3. Customization and configuration of equipment

1.1.1.4. New equipment - Commissioning

1.1.1.5. Data recording

1.1.1.6. Preparation of data files for planning computers

1.1.1.7. Other

⊟ 1.1.2. Routine machine QA

1.1.2.1. Daily consistency checks

1.1.2.2. Planned QA programme checks

1.1.2.3. Regular preventive maintenance and repair programme

1.1.2.4. Handover of radiotherapy equipment

1.1.2.5. Routine radiation safety checks

1.1.2.6. Other

⊟ 1.2. Other

⊟ 1.2.1. Room design

1.2.1.1. Patient safety

1.2.1.2. Staff and public safety

1.2.1.3. Environmental controls

1.2.1.4. Access control

1.2.1.5. Other

⊟ 1.2.2. Scientific infrastructure

1.2.2.1. Implementation of codes of practice for radiation dosimetry

1.2.2.2. Development of dosimetry algorithms for local application

1.2.2.3. Development of treatment planning algorithms for local application

1.2.2.4. Other

⊟ 1.2.3. Booking process (pre-treatment and treatment)

1.2.3.1. Booking of appointment

1.2.3.2. Recording of booked appointment

1.2.3.3. Communication of appointment to patient

1.2.3.4. Other

⊟ 1.2.4. Processes prior to first appointment

1.2.4.1. New patient registration process

1.2.4.2. Old patient location of details

1.2.4.3. Availability of reports/imaging required by protocol for treatment

1.2.4.4. Availability of consent documentation

1.2.4.5. Other

2. Pre-treatment phase

2.1. Assessment of patient

2.1.1. Identification of patient

2.1.2. Verification of diagnosis/extent/stage

2.1.3. Other

2.2. Decision to treat

2.2.1. Completion of required information

2.2.2. Recording of patient ID

2.2.3. Recording of previous treatment details

2.2.4. Recording of patient's specific requirements

2.2.5. Recording of non-standard information/protocol variations

2.2.6. Other

2.3. Prescribing treatment protocol

2.3.1. Choice of dose

2.3.2. Choice of modality

2.3.3. Choice of energy

2.3.4. Choice of fractionation

2.3.5. Choice of start date

2.3.6. Consideration of patient condition/co-morbidities

2.3.7. Choice of other interventions and their sequencing

2.3.8. Consent process

2.3.9. Other

2.4. Positioning and immobilization (mould room/workshop activities)

2.4.1. Confirmation of ID

2.4.2. Production of immobilization devices

2.4.3. Production of other accessories/personalized beam shaping device

2.4.4. Recording of information in patient record

2.4.5. Instructions to patient

2.4.6. Other

2.5. Simulation, imaging and volume determination

2.5.1. Confirmation of ID

2.5.2. Positioning of patient

2.5.3. Localization of intended volume

2.5.4. Production of images

2.5.5. Labelling of images

2.8.3. Confirmation of fertility/pregnancy status

2.8.4. Advice on procedure

   2.8.5. Other

  2.9. Other

☐ 3. Treatment phase

☐ 3.1. Treatment setup

☐ 3.1.1. Patient setup

3.1.1.1. Patient ID process

3.1.1.2. Patient data ID process

3.1.1.3. Explanation/instructions to patient

3.1.1.4. Patient positioning

3.1.1.5. Use of reference marks

   3.1.1.6. Other

☐ 3.1.2. Treatment unit setup

3.1.2.1. Setting of treatment machine parameters

3.1.2.2. Setting of collimator angle

3.1.2.3. Setting of jaw position

3.1.2.4. Setting of asymmetry

3.1.2.5. Setting of couch position/angle

3.1.2.6. Setting of energy

3.1.2.7. Setting of monitor units

3.1.2.8. Other

3.1.3. Use of treatment accessories

3.1.3.1. Use of immobilization devices

3.1.3.2. Use of beam shaping devices

3.1.3.3. Use of beam direction aids/applicators

3.1.3.4. Use of compensators

3.1.3.5. Use of wedges

3.1.3.6. Availability of treatment accessories

3.1.3.7. Other

3.2. Treatment delivery

3.2.1. Treatment

3.2.2. Other

3.2.3. Correct treatment site

3.3. Treatment verification

3.3.1. On-set imaging process

3.3.2. Recording of data

3.3.3. Other

3.4. Treatment monitoring

3.5. Other

4. Unknown

Who discovered the incident?

- Radiation oncologist (physician)

- Medical physicist

- Radiation therapist/staff at treatment unit treating patients

- Radiation therapist/staff at simulator and/or in-house CT

- Staff doing technical maintenance on the radiotherapy equipment

- No information provided

- Other, please specify

How was the incident discovered?

- Chart check

- In vivo dosimetry

- Portal imaging

- Clinical review of patient

- Quality control of equipment

- Found at the time of first patient treatment during regular checks

- Found at a later stage during patient treatment

- External audit

- No information provided

- Other, please specify

Clinical incident severity

- Minor incident

- Potential serious incident

- Serious incident

- Potential major incident

- Major incident

- Critical incident

- No information provided

Definitions of clinical incident severity categories

- Minor Incident

  - o Dose variation from prescribed total dose of <5%

  - o Near miss or unsafe condition which could potentially cause a treatment error

  - o Patient complaint

- Potential Serious Incident

  - o A near miss that could have been a serious incident

- Serious Incident

- o Dose variation from prescribed total dose of 5 - 10%

- o Radiation dose or medication error causing side effects requiring minor treatment or ongoing monitoring and assessment

- o Set up variation > 1cm - no critical structures included

- Potential Major Incident

  - o A near miss that could have been a major incident

- Major Incident

  - o Dose variation from prescribed total dose of 10 - 20%

  - o Radiation dose or medication error causing side effects requiring major treatment and intervention or hospitalization

  - o Set up variation that will/could impact on normal tissue (e.g. heart, lung, eyes, kidney etc.)

- Critical Incident

  - o Radiation dose or medication error causing death or disability

  - o Dose variation from prescribed total dose of >20%

  - o Completely incorrect volume

Was any part of the prescribed tx delivered incorrectly?

- No

- Yes

- No, but there were unsafe conditions

- No, but patient could have been affected

- No information provided

Was anyone affected by the incident?

- Yes, more than one patient

- Yes, one patient

- Other, e.g. staff

- No, but someone could have been, potential incident

- No information provided

Describe the causes of the incident

Job Factors

⊟ Standards/Procedures/Practices

- ☐ 1.1 Not developed

- ☐ 1.2 Inadequate standard/procedure/practice

- ☐ 1.3 Standard/Procedure/Practice not followed

- ☐ 1.4 Inadequate communication of procedure

- ☐ 1.5 Inadequate assessment of risk

- ☐ 1.6 Not implemented

⊟ Materials/Tools/Equipment

- ☐ 2.1 Availability

☐ 2.2 Defective

☐ 2.3 Inadequate maintenance

☐ 2.4 Inspection

☐ 2.5 Used incorrectly

☐ 2.6 Inadequate assessment of materials/tools/equipment for task

⊟ 3. Design

☐ 3.1 Inadequate hazard assessment

☐ 3.2 Inadequate design specification

☐ 3.3 Design process not followed

☐ 3.4 Inadequate assessment of ergonomic impact

☐ 3.5 Inadequate assessment of operational capabilities

☐ 3.6 Inadequate programming

⊟ Systemic/Management Factors

⊟ 4. Planning

☐ 4.1 Inadequate work planning

☐ 4.2 Inadequate management of change

☐ 4.3 Conflicting priorities/planning/programming

☐ 4.4 Inadequate assessment of needs & risks

☐ 4.5 Inadequate documentation

☐ 4.6 Personnel availability

☐ 5. Communication

☐ 5.1 Unclear roles, responsibilities, and accountabilities

☐ 5.2 Lack of communications

☐ 5.3 Inadequate direction/information

☐ 5.4 Misunderstood communications

☐ 6.Knowledge/Skills

☐ 6.1 Inadequate training/orientation

☐ 6.2 Training needs not identified

☐ 6.3 Lack of coaching

☐ 6.4 Failure to recognize hazard

☐ 6.5 Inadequate assessment of needs and risks

☐ Personal Factors

☐ 7. Capabilities

☐ 7.1 Physical capabilities (height, strength, weight, etc.)

☐ 7.2 Sensory deficiencies (sight, sound, sense of smell, balance, etc.)

☐   7.3 Substance sensitivities/allergies

☐ 8. Judgment

   ☐   8.1 Failure to address recognized hazard

   ☐   8.2 Conflicting demands/priorities

   ☐   8.3 Emotional stress

   ☐   8.4 Fatigue

   ☐   8.5 Criminal intent

   ☐   8.6 Extreme judgment demands

   ☐   8.7 Substance abuse

☐ Natural Factors

☐ 9 Natural Factors

   ☐   9.1 Fires

   ☐   9.2 Flood

   ☐   9.3 Earthquake

   ☐   9.4 Extreme weather

   ☐   9.5 Other

What safety barrier failed to identify the incident?

- Image based position verification

- In vivo dosimetry

- Independent confirmation of dose

- Independent confirmation of dose calculation

- Independent review of commissioning

- Independent verification of source strength

- Intra-treatment monitoring

- Physician peer review

- Post treatment evaluations (evaluation of clinical and process)

- Post-irradiation survey to confirm removal of sources

- Post-treatment dosimetry and review

- Regular clinical patient assessment

- Regular equipment performance verification

- Regular external audit

- Review of treatment plan

- Time out

- Use of record and verifying system

- Verification of correct applicator size

- Verification of correct transfer tube length

- Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)

- Verification of patient ID

- Verification of treatment accessories

- Verification of reference points

- Verification that pretreatment condition have been taken into account

- Other, please specify

Equipment used

- Linear Accelerator

- Cobolt 60

- Superficial X-Ray

Treatment method

- Simple (two dimensional or electrons)

- 3D (three dimensional) conformal

- IMRT (intensity modulated radiation therapy)

- Modulated arc therapy

- Stereotactic radiosurgery (cranial or body)

- Protons or other particles