An evaluation of incident learning using the taxonomy of the Canadian National System for Incident Reporting – Radiation Treatment

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Abstract

Radiotherapy is a crucial component of the treatment regime for almost two thirds of cancer patients, but is also associated with several risks. Incident learning is a relatively recent quality improvement initiative in radiotherapy that has been adopted as a result of its success in reducing the frequency of serious accidents in other industries including aviation and nuclear power. This thesis describes the development and clinical implementation of an in-house incident learning system entitled the Safety Incident Learning System (SaILS) that is compatible with the Canadian National System for Incident Reporting – Radiation Treatment (NSIR-RT). The codebase for SaILS was obtained from the Ottawa Hospital Cancer Centre where an earlier version that does not use the NSIR-RT taxonomy is in clinical use. As part of the present research project, many new features were incorporated into SaILS to establish an intuitive and optimized incident learning workflow; including incident templates, data retrieval and field population using the departmental electronic medical record, and automatic email reminders for incomplete investigations. SaILS was deployed in the Department of Radiation Oncology at the Cedars Cancer Centre of the McGill University Health Centre (MUHC) in January 2016.

One hundred and ten incidents were reported using SaILS from January to June 2016, 75 of which have been fully investigated, and analyzed in aggregate using incident distribution and trend plots. Many incident reports submitted to SaILS were difficult to classify with existing choices in the *Event Type* data element and *Incident Impact* domain of the NSIR-RT taxonomy. Resultantly, it is recommended in this thesis that a new event type for no-harm incidents be added, as well as new data elements to capture incident impact on patient experience and workflow. Also, an analysis of incidents reported to both SaILS and the NSIR-RT pilot system revealed that about 50% of incidents in both systems were assigned a value of *Other* for the *Primary Problem Type* data element. Several new choices for the *Primary Problem Type* element are suggested to allow better classification of certain patient-simulation, imaging, and documentation incidents.

SaILS will continue to be used clinically at the MUHC to learn from incidents, and as the system is open-source, it is available for deployment at other centres as interest arises.

Résumé

La radiothérapie est une composante essentielle du regime de traitement pour près de deux tiers des patients atteints de cancer, par contre plusieurs risques y sont associés. La connaissance des incidents est une nouvelle initiative d'amélioration de la qualité en radiothérapie adoptee à la suite de son succès dans la reduction de la fréquence des accidents graves dans d'autres industries, y compris l'aviation et l'énergie nucléaire. Cette these décrit le développement d'un système de connaissance des incidents interne intitulé *Safety Incident Learning System* (SaILS), compatible avec le système national de declaration des accidents et incidents – radiothérapie (SNDAI-RT). Plusieures fonctionnalités ont été incorporées dans SaILS permettant d'optimiser le flux de travaux par rapport aux connaissance d'incidents: des modèles d'incident, l'extraction des données du dossier médical électronique départementale, et des rappels par courier automatique concernant les enquêtes en cours. SaILS a été déployée dan le département de radio-oncologie au Centre du cancer des Cèdres du Centre universitaire de santé McGill (CUSM) en Janvier 2016.

Quatre-vingt onze incidents ont été signalés à l'aide du systéme SaILS de Janvier à Juin 2016, dont 75 on été examinées à fond et analysées à l'aide de graphiques de distribution et de tendance d'incidents. Plusieurs rapports d'incident étaient difficiles à classer utilisant l'élément *Type D'événements* et le domaine *Répercussions de l'accident ou incident* de la taxonomie SNDAI-RT. En consequence, il est suggéré d'ajouter un nouveau type d'événement pour des incidents sans préjudice ainsi que de nouveaux éléments de données pour saisir l'impact de l'incident sur l'expérience du patient et du flux des travaux. Une analyse des rapports d'incidents dans SaILS et SNDAI-RT a demontré qu'environ 50% des incidents avaient l'option *Autre* dans l'élément *Type de problème principal*. Cette analyse démontre que l'élément *Type de problème principal* est insufficient pour classer certains types d'incidents relié l'imagerie, la simulation et la documentation. Plusieurs nouveaux choix pour l'élément sont recommandés en consequence.

Sails continuera à être utilisé en clinique au CUSM d'apprendre des incidents, et parce que le système est open-source, il est disponible pour un déploiement dans d'autres centres que l'intérêt se pose.

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List of Abbreviations

AAPM	American Association of Physicists in Medicine
CAST	Commercial Aviation Safety Team
CCS	Canadian Cancer Society
CFIT	Controlled flight into terrain
CIHI	Canadian Institute for Health Information
CPQR	Canadian Partnership for Quality Radiotherapy
CPSI	Canadian Patient Safety Institute
CT	Computed tomography
CTV	Clinical target volume
EBRT	External beam radiotherapy
EMR	Electronic medical record
FMEA	Failure mode effects analysis
FTE	Full-time equivalent
GTV	Gross tumour volume
HRO	High reliability organization
IAEA	International Atomic Energy Agency
ILS	Incident learning system
MDS	Minimum Data Set
MLC	Multileaf collimator
MR	Magnetic resonance
MUHC	McGill University Health Centre
NSIR-RT	Canadian National System for Incident Reporting – Radiation Treatment
OAR	Organ at risk
PSO	Patient Safety Organization
PTV	Planning target volume
QA	Quality assurance
QC	Quality control
QM	Quality management
RISE	Resilience in Stressful Events
RMC	Risk Management Committee
ROSIS	Radiation Oncology Safety Information System
RO-HAC	Radiation Oncology Healthcare Advisory Council
RO-ILS	Radiation Oncology Incident Learning System
RTT	Radiation therapist
SAFRON	Safety in Radiation Oncology
SaILS	Safety Incident Learning System
TOHCC	The Ottawa Hospital Cancer Centre
UI	User interface
WHO	World Health Organization
WHO-ICPS	World Health Organization Conceptual Framework for the International Classification for Patient Safety

Chapter 1 – Introduction

1.1 – The Burden of Cancer and Treatment Thereof

Cancer refers to a number of related diseases that share common features. Two distinct features of cancer cells are their tendency to undergo rapid proliferation, and to avoid programmatic cell death, or apoptosis [1]. Accumulation of cancer cells due to the aforementioned features results in solid masses called tumours. Cancerous tumours are malignant, which means cells comprising the tumour can spread to other regions of the body and form additional, metastatic, lesions. Cancers are dangerous to the human body because they consume and waste energy that should otherwise be expended in performing functions of healthy tissue.

Effectively all Canadians are affected by cancer, directly or indirectly, at some point in their lives. The most recent estimates of the Canadian Cancer Society (CCS) predict that approximately two in five Canadians will develop cancer in their lifetime and roughly one quarter of Canadians will die of cancer [2]. Both occurrence rates and mortality rates are skewed slightly higher for males than for females; 45% to 42% and 29% to 24% respectively. In 2015 approximately 196,900 Canadians were expected to develop cancer and 78,000 were expected to die of their disease. In fact, 29.9% of deaths in Canada are due to cancer, making it the leading cause of death and premature death among Canadians. It is also pertinent to note that accidents account for about 4.4% of Canadian deaths. In addition to the primary cost of cancer associated with lost loved ones, cancer is also estimated as the seventh most economically costly illness in Canada and the costliest in terms of lost productivity due to premature death [2].

Cancer detection rates have been continuously rising since 1986; due partially to broader screening initiatives, improved detection techniques, and an aging population [2]. However, mortality rates have consistently decreased since 1988, accompanied by an increase in the average five-year survival ratio of cancer patients from 55.5% to 62.8% [2].

There are several modalities used to treat cancer, the three most common of which are surgery, chemotherapy, and radiation therapy or radiotherapy [3]. Surgical techniques involve extracting all or as much as possible of a cancerous tumour whereas chemotherapy refers to the use of cytotoxic drugs designed to specifically target and kill cells exhibiting certain characteristics; rapid proliferation for example. Radiotherapy encompasses all techniques whereby ionizing radiation is used to deliver a well-defined radiation dose to the site of the disease. Approximately 60% of cancer patients receive radiotherapy at some point during the course of their treatment [4]. Any combination of these modalities may be used to treat a single disease site, executed concurrently or in sequence, with either curative or palliative intent. Other less frequently applied techniques include hormonal therapy, targeted therapy, immunotherapy, and stem cell transplant [3].

The remainder of this chapter will describe the fundamentals of radiotherapy, including an overview of the radiotherapy treatment process. A focus will be placed on the role of the clinical medical physicist, particularly with regards to ensuring safe and high quality treatments of cancer patients. This information will provide a glimpse into the complexity of radiotherapy and begin to rationalize how incidents may arise as a result of this complexity. The final section of this chapter will outline the scope of the thesis, which is focused on learning from radiotherapy incidents.

1.2 – Radiotherapy

1.2.1 – Fundamental Radiation Physics

Radiotherapy is the use of ionizing radiation to treat a disease, most often cancer. Ionizing radiation, as opposed to non-ionizing radiation, encompasses any particle with high enough energy to ionize or excite atoms within the material through which it passes [5]. This may be further categorized into directly and indirectly ionizing radiation depending on the way by which the radiation species deposits energy. Directly ionizing radiation includes charged particles that deposit energy in a one-step process via Coulomb interactions. Indirectly ionizing radiation on the other hand encompasses neutrally charged particles that liberate charged particles within a material, which then proceed to undergo Coulomb interactions and deposit energy. It is also important to note that ionizing radiation may undergo scattering, in addition to being absorbed by matter. The frequency of scattering events varies highly with radiation species and absorber material and thus energy deposition events may be spatially separated by a large distance.

The amount of energy deposited by radiation per unit mass of absorber material is referred to as absorbed dose, measured in gray (1 Gy = 1 J/kg) [5]. This is the fundamental quantity that acts as a cornerstone for the dosimetry of radiotherapy. Radiotherapy treatments are designed to deliver a specific dose to the targeted disease site, while minimizing dose delivered to healthy tissue surrounding the disease. However as alluded to previously, the unavoidable occurrence of radiation absorption and scattering renders it impossible to completely prevent delivery of dose to healthy tissue when treating disease. Additional uncertainties involved in the positioning of patient during treatment compound this issue further. Thus despite radiotherapy being considered one of the safest disciplines of modern medicine, there is inherent risk associated with it [6].

1.2.2 – Radiotherapy Modalities

A number of modalities have been devised to deliver radiotherapy to patients, involving the use of many types of radiation sources that emit various species of ionizing radiation. Most commonly, photon or electron radiation is delivered using a clinical linear accelerator (linac) as the source. Radiotherapy delivered using a linac is known as external beam radiotherapy (EBRT). EBRT also encompasses the use of proton or heavy ion beams as well as ^{60}Co teletherapy and orthovoltage therapy using a low-energy x-ray generator. Brachytherapy is an alternative to EBRT used to treat particular anatomical sites and types of cancer and involves insertion of a radioactive source into or near the tumour to deliver dose in a short range around the source itself.

1.2.3 – The Radiotherapy Treatment Process

The exact pathway traversed by patients undergoing radiotherapy is different in every case, although there are a number of commonalities in most cases. A general overview of the radiotherapy process, beginning after physician consultation and diagnosis, is presented in Fig 1.1. Additional details on each step are presented below.

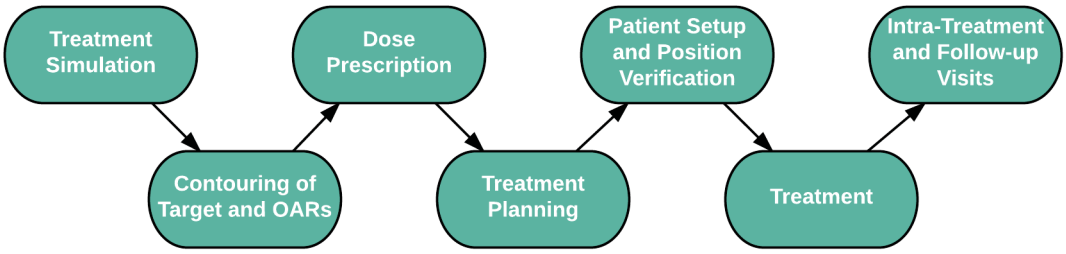


Figure 1.1: Flowchart depicting a generic overview of the radiotherapy treatment process.

1) Treatment simulation: A computed tomography (CT) or magnetic resonance (MR) simulator is typically used to image the patient in the same position with which they will be treated. Image data acquired from the simulation scan are used in the treatment planning process.
2) Contouring of target and OARS: Anatomical volumes of interest are outlined, or "contoured", using images acquired during simulation. The target volume is typically encapsulated in three distinct volumes defined by the International Commission on Radiation Units and Measurements [7]. Firstly, the gross tumour volume (GTV) contour is drawn around the visible disease on the simulation images. A clinical target volume (CTV) is then created around the GTV with margins to account for expected sub-clinical involvement of the disease. Finally, a planning target volume (PTV) is drawn around the CTV, with an additional margin accounting for setup uncertainty and organ motion. All organs at risk (OARs) that might receive significant doses of radiation are also contoured.
3) Dose prescription: The radiation oncologist treating the patient will specify the minimum dose to be delivered to the target volume, as well as dose constraints for the irradiation of the various OARs.
4) Treatment planning: During this stage, a treatment plan is developed to meet the dose prescription and constraints outlined in the previous step. For EBRT treatments, the plan will include the radiation beam orientations and beam types that should be used to provide the prescription. For brachytherapy, the plan will include the source type, the dwell positions, and dwell times of the radioactive source. This step is performed using

treatment planning software that includes plan optimization algorithms and dose visualization tools. Often the treatment plan is fractionated for radiobiological reasons (to spare the healthy tissue), meaning the patient will come in periodically to receive multiple treatments over a span of time.

5) Patient setup and position verification: Once the treatment plan has been completed, the patient is brought in for treatment and setup in the same position as during simulation. Additional imaging is typically performed to verify the position is sufficiently reproduced.
6) Treatment: The radiotherapy plan is delivered to the patient according to the prescription schedule.
7) Intra-treatment and follow-up visits: Once per week, during and following treatment completion, the oncologist will meet with the patient to assess disease control or progression.

A multidisciplinary and specialized team is required to safely and accurately carry out the aforementioned steps of the radiotherapy process.

1.2.4 – Health Care Professionals Involved in Radiotherapy

The broad spectrum of tasks involved in the radiotherapy process is conducive to the involvement of many specialized healthcare professions, each with a distinct role in provision of safe radiotherapy treatments [8]. Radiation oncologists are physicians trained for treating patients using radiotherapy and oversee the patient's status as the treatment progresses. As indicated previously, the radiation oncologist is responsible for defining the disease site and determining the dose to be delivered to it. Medical physicists are clinical professionals with a scientific perspective, who are responsible for ensuring the safe and accurate delivery of radiotherapy. The role of the medical physicist is presented in detail in Section 1.3. Radiation therapists (RTTs) are technologists who setup the patient for simulation and daily radiotherapy treatments, and deliver radiation while monitoring the patient. Dosimetrists are specialized RTTs trained for developing treatment plans.

A number of additional roles in radiation oncology are filled by management, nurses, engineers, nutritionists, social workers, and receptionists, among others. Professionals from each discipline

must collaborate and communicate clearly to provide the highest possible quality of treatments to patients.

1.3 – Role of the Clinical Medical Physicist

1.3.1 – Brief History of Medical Physics

Before outlining the role and responsibilities of a clinical medical physicist, it is important to first define what medical physics entails. In the prologue of his seminal textbook "Radiation Physics for Medical Physicists," Podgorsak describes medical physics as a branch of physics concerned with application of physics to medicine, which typically involves the use of ionizing radiation to detect and treat human disease [5].

Three discoveries are widely recognized as having formed the basis for modern medical physics [5]. These were:

1) The discovery of x-rays by Wilhelm Röntgen in 1895
2) The discovery of natural radioactivity by Henri Becquerel in 1896
3) The discovery of radium by Marie and Pierre Curie in 1898

Application of radiation to medical practice rapidly followed these discoveries. The need to consider quality when delivering radiation in a medical capacity became clear soon after. A detailed discussion of quality is presented in the following chapter, but two fundamental principles of quality are described here. Quality control (QC) may be generally defined as "the operational techniques that are used to fulfill requirements of quality" [9]. Definitions of quality assurance (QA) typically encompass "all those planned and systematic actions necessary to provide adequate confidence that a product or service meets the requirements for quality," including QC [9].

QA procedures in the early 20^{th} century, were much more primitive than they are today [10]. In the earliest stages, the amount of radiation deposited was measured via skin reddening, or erythema, but observation of other short and long term biological effects soon necessitated a quantitative means of measuring radiation exposure. The roentgen unit of exposure, representing 2.58×10^{-4} coulombs of charge per kilogram of air, was defined to address this.

Further sophistication of dose measurement, in the form of percent depth dose curves and isodose curves, was required with the advent of high energy ^{60}Co teletherapy. Clinical linear accelerators have since significantly broadened the need for robust QA, including the need for calibration between monitor dose and dose delivered to the patient [10]. Additional new technologies expanding on, and peripheral to, linear accelerator design also require new methods of QA. All of this clearly demonstrates the need for educated and specifically trained individuals to ensure safe and high quality radiotherapy for both patients and staff; a role which is largely filled by medical physicists.

1.3.2 – Responsibilities of the Clinical Medical Physicist

Report Number 38 by Task Group 1 of the American Association of Physicists in Medicine (AAPM) was published in 1993 and describes the fundamental responsibilities of a clinical medical physicist in radiation oncology [11]. Above all else, the report emphasizes that the first responsibility of the medical physicist is to the patient; to provide the best and safest treatment possible. The responsibilities of the clinical medical physicist that are necessary to achieve such treatments, as enumerated in AAPM Report 38, are briefly summarized below [11].

A large component of the clinical work done by medical physicists involves ensuring safe usage of radiotherapy technology and equipment. Commissioning and acceptance testing are performed on all new radiation sources, equipment, and technology and are followed by rigorous QC protocols to ensure continued compliance with commissioned baselines. The development and enforcement of an institution's radiation safety program is also the responsibility of the medical physicist. This includes shielding design for new facilities and equipment as well as monitoring of radiation exposure to personnel. Treatment planning, described in Section 1.2.3, is also a significant contribution of the medical physicist.

These core duties continue to form the essence of clinical medical physics work. However, the methodology by which safe and accurate treatment are achieved continues to evolve as radiation oncology evolves.

1.3.3 – Changing and Future Role of the Clinical Medical Physicist

Technology advancements over the last two or three decades have significantly improved the dose localization and delivery capabilities of modern radiotherapy treatments. Additionally, the advent of computers in virtually all aspects of radiotherapy has drastically altered the way that information is exchanged, largely through automation [10]. Medical physicists are responsible for ensuring radiotherapy treatments at their centre are at the forefront of technology whenever possible considering resource constraints.

Highly conformal EBRT treatments with steep dose gradients are possible because of the many degrees of freedom, and large number of available treatment accessories, for modern linear accelerators [10]. Capitalizing on these features requires sophisticated QA protocols to ensure each component functions as expected when coupled together. Physicists are responsible for designing and implementing such QA protocols and thus ensure that steep dose gradients are properly aligned with target volumes as planned.

There is also heightened public awareness of the medical physics profession. This new level of accountability of medical physicists to the public has stemmed from press coverage of recent high profile incidents as well as increasing expectations of healthcare institutions to demonstrate commitment to patient safety [10]. Thus, a crucial tenet of medical physics practice in the modern era is to ensure errors are minimal in frequency and severity. Further discussion on quality in radiotherapy, incidents, and incident learning will be presented in detail in Chapter 2 of this thesis.

1.4 – Thesis Motivation and Objectives

Health care professionals aim to provide the safest and highest quality of care to cancer patients who receive radiotherapy. However, the inherent risks associated with radiation and the complexity of the radiotherapy treatment process are conducive to the occurrence of incidents. Incident learning is a relatively new quality improvement initiative in radiotherapy that has been widely adopted as a result of its successes in other industries including aviation safety and nuclear power. The incident learning process is defined by an organization's ability to identify, report, and investigate incidents and subsequently take corrective actions to reduce the risk of incident recurrence and propagation [12].

This thesis will describe an evaluation of incident learning using the recently promulgated radiotherapy incident learning taxonomy of the Canadian National System for Incident Reporting – Radiation Treatment (NSIR-RT) [13]. There are many factors to consider when integrating an incident learning system into a radiotherapy department, as will be discussed in the following chapter. For this work, it was necessary that the incident learning system used would allow unambiguous sharing of incident data with other Canadian centres through use of the NSIR-RT taxonomy. However, it was also crucial that the system was well tailored to the radiotherapy workflow in the Department of Radiation Oncology at the Cedars Cancer Centre of the McGill University Health Centre. Thus, an internally developed incident learning system was chosen to ensure flexibility and customizability of the design, but utilize a backend database completely compatible with the NSIR-RT taxonomy.

As a result of this decision, the primary objectives of this work were to:

1. Develop and deploy an internal web-based incident learning system compatible with NSIR-RT. The system will involve engagement from all staffing disciplines to aid in fostering a positive and participative incident learning culture. Efforts will also be taken to make the system very intuitive and optimize workflow to reduce the burden of processing incident data.
2. Gauge staff awareness, participation, and appreciation of the incident learning system over time and use these findings to continuously improve the system.
3. Analyze incidents reported to the system within the framework of NSIR-RT via the results of incident investigations and plots of incident distributions and trends.
4. Provide recommendations for further improvement of the NSIR-RT taxonomy based on analysis of clinical incident data.

The following chapter will introduce the concept of quality in radiotherapy and use systems theory to rationalize how incidents can arise. The nuances of incident learning to reduce incident occurrence will also be discussed before presenting four national/international incident learning systems. Chapter 3 will describe the methodology used to address the four objectives outlined above. Subsequently, Chapters 4 and 5 will present the results of the project and discuss the

implications thereof. Finally, Chapter 6 will summarize the thesis and provide a blueprint for the remaining challenges to be addressed within the scope of the project.

Chapter 2 – Theory

2.1 – Quality in Radiotherapy

2.1.1 – Overview of Quality

Health care professionals strive to deliver safe and high quality care to their patients, and have done so since the time of Hippocrates, who urged medical providers to "Do no harm" [6]. Quality is an integral component of modern radiotherapy, and has been brought into recent focus due to public demand for increased transparency in healthcare delivery.

However, quality is a difficult concept to define as it may be perceived quite differently by individuals with different backgrounds and areas of expertise [14]. Consider the differences in perceived treatment quality in radiotherapy between patients, healthcare providers, and managers [14]. To a patient, quality may simply be a treatment that has a successful outcome. A healthcare provider may perceive a high quality treatment as one that is technology proficient, delivered safely, and yields a positive outcome, but with little regard for patient comfort and convenience. From a manager's perspective, high quality is defined by treatments that yield the best results with lowest cost and liability.

Nowadays, it is widely recognized that quality should encapsulate more than treatment outcomes. A prominent example of a non-medical indicator of quality is patient waiting time [15]. If patients are not provided with realistic waiting times, or are met with last-minute treatment delays, their level of satisfaction and perception of the quality of their care will be diminished. Additional factors that impact patient satisfaction include confidentiality, clear communication, and consideration of patient dignity or privacy [16]. Thus a robust definition of quality in radiotherapy could be *the provision of services that meet, or better yet, exceed patient expectations, and are provided with best professional practices to achieve optimal treatment outcomes and patient satisfaction, all while aligned with high level regulations and with minimal wasted resources* [17].

Beyond this, quality in radiotherapy is typically decomposed into three domains; quality management (QM), quality assurance (QA), and quality control (QC) [9]. The hierarchy of these three domains is presented in Fig. 2.1, and is described in detail below.

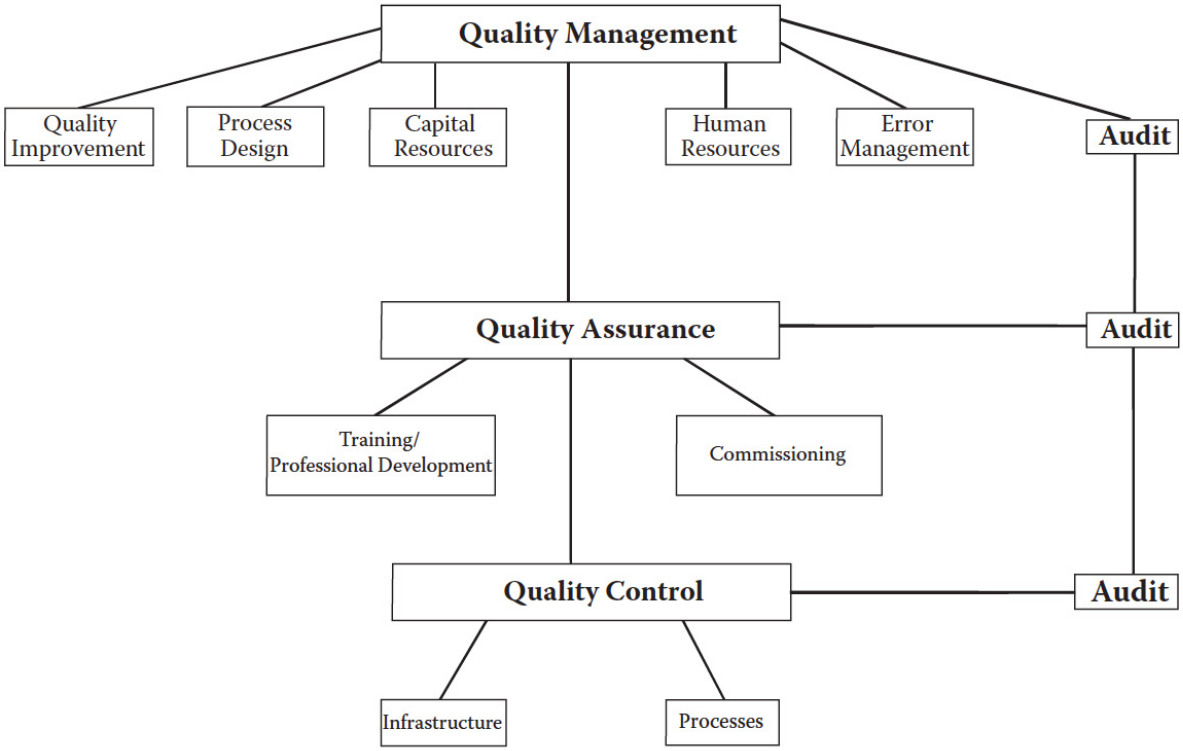


Figure 2.1: Domains of quality in radiotherapy [9].

Quality control is the lowest level domain and involves the design and implementation of techniques to ensure quality [9]. At a surface level this can include, for example, measurements of linac output to be compared with a target value. However, effective QC should give credence to issues involving the transfer of information, knowledge, and data between infrastructure elements, not just the elements themselves. An additional defining characteristic of QC is implementation of actions to address any deficiencies which have been identified [9].

Quality assurance is a broader domain that includes QC, but also encompasses acceptance testing and commissioning of new equipment to define the tolerance levels that are periodically referenced in QC. The remaining element of QA, training and professional development, is required to ensure

that the potential for high quality established by commissioning and regular QC, is achieved with appropriate human input [9].

Finally, quality management is the highest domain of quality and encompasses QA. Notably, QM also includes error management, which will be discussed in greater detail in the remainder of this thesis. Resource allocation also comprises a significant component of QM and thus inherently requires a level of judgement that is typically avoided in the lower level domains of quality. In other words, given certain resource constraints, the perceived need of one piece of equipment, staff member, or process may require another to be omitted [9].

2.1.2 – Quality Improvement

Quality and safety in healthcare, including radiotherapy, has been brought into greater focus in the last two decades. This is partially due to widespread media coverage of certain adverse medical events, which have raised public concern and necessitated greater transparency in healthcare practice. The report, *To Err is Human: Building a Safer Health System*, published by the Institute of Medicine in the year 2000, was an inflection point for quality improvement initiatives in North American healthcare [18]. This report was published to establish recommendations that should be followed to achieve a threshold change in quality over the following decade. Of particular note for this thesis is Recommendation 5.2, which encourages development of non-punitive voluntary incident reporting systems as a quality improvement project [18].

In the years following *To Err is Human*, many publications were released detailing various quality improvement initiatives, a number of which focused on radiotherapy. Three core components of continuous quality improvement are [19]:

1. Determining which data and quality indicators to collect and track. Due to resource constraints in virtually all healthcare environments, not all data can be gathered and used meaningfully to improve quality.
2. Testing system changes to determine if quality was indeed improved as a result of implementing a quality improvement initiative. If so, additional systems or processes must be developed to ensure that recent changes are consistently implemented whenever appropriate.

3. Motivating, empowering, and providing support for staff to take responsibility for ensuring and improving quality.

The pre-eminent constraints on quality improvement in healthcare in general, and radiotherapy in particular, are finite resources. Healthcare professionals are under pressure to treat a rising number of patients with either equivalent or fewer resources [19]. This problem is confounded further by the consistent annual increase in treatment cost per patient, which was found in Canada to be 5.5% per year on average even prior to widespread adoption of such techniques as image-guided radiotherapy, intensity-modulated radiotherapy, and stereotactic radiotherapy [20]. As a result, staff are often overworked or undertrained, which greatly increases risk of incidents in healthcare [21].

Thus every effort should be made to minimize costs associated with quality improvement initiatives while still achieving the desired outcomes. An introduction to incident learning as a quality improvement initiative will be presented in Section 2.3. Prior to this, the occurrence and types of incidents in healthcare, and radiotherapy specifically, are discussed below in Section 2.2.

2.2 – Incidents

2.2.1 – Incidents in Healthcare

In Chapter 1, it was mentioned that 4.4% of Canadian deaths were due to accidents [2]. While automobile accidents are often associated with this statistic, fatal accidents occur in many other areas, including in healthcare. An alarming estimate that 44,000 – 98,000 Americans die per year due to avoidable medical accidents was published in *To Err is Human* in 2000 [18]. At the time, this figure was larger than that for automobile accidents, breast cancer, or AIDS. This estimate was based on two independent studies, the results of which revealed that between 2.9% and 3.7% of hospital patients are impacted by an adverse event [18]. A Canadian report on the prevalence of adverse events in Canadian healthcare, published in 2004, estimated that 7.5% of acute medical care patients experience an adverse event [22]. Expert analysis also indicated that 36.9% of these patients experienced adverse events that were highly preventable, or in other words 2.8% of hospital patients experienced preventable adverse events [22]. The fraction of patients affected by

adverse events could indeed be much larger if consideration is given to events which have no medical impact, but affect the patient in other ways.

The financial costs associated with preventable adverse events are estimated to be between $17 and $29 billion per year in the United States, and approximately $397 million per year in Canada [18] [23]. These financial burdens reduce available funds for quality improvement initiatives that could otherwise reduce the frequency of errors, and thus compound the issue further. In addition to financial costs, there are countless unquantifiable costs including loss of patient trust, diminished patient satisfaction regarding their treatments, diminished morale of healthcare staff, physical or psychological harm, and death [18]. The reported frequency and cost of incidents convey the need for quality and safety improvement in healthcare, but they do not reveal the specific areas most in need of change. The actual narratives surrounding specific incidents do reveal some of the problematic processes requiring improvement. Two examples are provided here.

Betsy Lehmen was a distinguished health columnist for the Boston Globe who died as a result of a chemotherapy overdose in 1994 [24]. She received four times the safe dosage of cyclophosphamide as a result of miscommunication and lack of proper and formalized protocol for the experimental procedure with which she was being treated [25]. The incident received a frenzy of media coverage, and led to development of a strict electronic order-entry system as well as a refined error detection and reporting policy for chemotherapy [25].

Another tragic case involved Kevin Murphy, who died in 1999 due to an undiagnosed solitary parathyroid adenoma [26]. Many factors contributed to the system failure which ultimately led to his death. Prevalent among these was an expectation bias held by the treating physician, who previously had success in diagnosing patients exhibiting similar symptoms with a different, rare, disease [26]. This expectation bias blinded the physician to other factors in Kevin's blood tests including an abnormally high level of calcium. The test results, including calcium levels, were recorded on a post-it note that was not seen by other specialists during document transfer. Since the incident, many health professionals have agreed that the true diagnosis should have been clear and Kevin could have undergone a surgery with 96% success rate and subsequent normal life

expectancy [26]. Frustrating this case further was the lack of transparency by some healthcare professionals when conveying information, including causes, to Kevin's family.

These two events enumerate many potential areas of system failure that contribute to catastrophic errors. Miscommunication, automaticity, lack of transparency and accountability, poor process design, undocumented process changes, and fatigue are among them [27]. In some cases, negligence or misconduct are primary causes of error, but in medicine, system failure is often the true culprit. The following section will discuss a systems approach to identifying and classifying incidents.

2.2.2 – Systems Theory and Incident Occurrence

A system may be defined as a set of interdependent elements (human or non-human) interacting to achieve a common aim [18]. Emergence refers to the phenomenon whereby a complex system exhibits unexpected behaviour, implying that the system is more than the sum of its parts [28]. An interesting example of a biological system exhibiting emergence is the human brain, which is composed of cells that specialized into neurons. The emergent property of these neurons in the context of a human brain is consciousness [28]. All of this is to say that complex systems containing many elements and elaborate relationships often do not behave in anticipated ways. This includes the ability of such systems to fail in unforeseen ways.

The "Swiss Cheese Model" succinctly describes system failure and is shown in Fig. 2.2 [29]. This model uses layers of Swiss cheese as a metaphor for subsequent layers of defense, or safety barriers, in complex system. Each barrier can fail in one or more ways as represented by the holes in the corresponding layer of cheese. The failures may be active failures due to negligence or loss of attention, or may be latent conditions that are not easily discerned outside of the context of a particular incident. A well-defined and successful system will have few holes, and these holes are misaligned from one another. In this case, an error may progress through a single safety barrier, but will be caught by another as demonstrated in the left side of Fig 2.2. A poor system has many holes that may align, allowing an incident to propagate through the entire system unfettered and result in a catastrophic error, as shown in the right side of Fig 2.2.

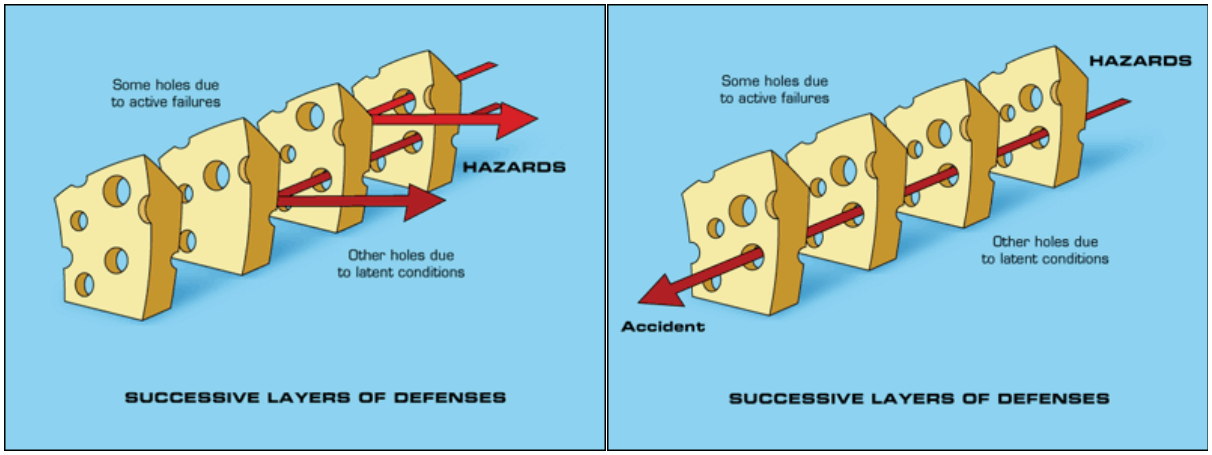


Figure 2.2: The "Swiss Cheese Model" of system failure. System safety barriers are represented as slices of Swiss cheese and potential modes of failure within each barrier are represented as holes. **(left)** A successful system that prevented the error from propagating through the entire system. **(right)** A faulty system where failure modes have aligned, allowing an error to pass through the system. Adapted from [29].

Involuntary automaticity is the behaviour that causes an individual to perceive what they are expecting to see rather than what is actually occurring, and allow incidents to propagate through a system [27]. A simple yet poignant example of how easily this can occur is depicted in Fig. 2.3 [30]. System processes that rely on human input should thus be active rather than passive to counteract this. For example, if relying on verbal identification of a patient at the time of treatment in radiotherapy, one should ask the patient for their entire name rather than RTTs providing the expected patient's name and receiving a yes or no answer [27].

Figure 2.3: Example demonstrating how involuntary automaticity can bias perceived results and lead to errors [30].

There is an unfortunate public perception that incidents often result from individual failure rather than system level failures. A survey conducted by Louis Harris & Associates for the National

Patient Safety Foundation in the US revealed how the public thought incidents in healthcare could be reduced [18]. The most frequently identified solution was to prevent healthcare professionals associated with high rates of incident occurrence from practicing altogether. The second most commonly proposed solution was to better train healthcare professionals. Public perception of medical error, and these proposed solutions, are likely due largely to the tendency of media to focus blame on singular organizations or individuals. While the second identified solution has some merit in terms of system improvement, the first solution would rarely address the root causes underlying most healthcare incidents. Increased transparency in the qualifications of healthcare individuals, treatment processes, occurrence of errors and near-misses, and remedying actions to address such errors will help to shift the public perception to a systems-based one.

2.2.3 – Incidents in Radiotherapy

Radiotherapy offers unique ways to treat cancer patients, and is thus prone to incidents that are not encountered in other aspects of medicine. While proven very useful at eliminating or controlling specific types of cancer, ionizing radiation also poses significant risk of catastrophic error if delivered incorrectly [31]. Two additional factors which contribute heavily to the uniqueness of the field are the broad spectrum of healthcare disciplines involved, and the highly advanced technology involved in modern treatment techniques. Such state-of-the-art treatments and algorithms, which are highly automated, have virtually infinite ways to fail; particularly when coupled together [32]. While it is impossible to account for all possible modes of failure, extensive efforts should then be taken to minimize risk and establish new safety barriers in response to detection of incidents and near-misses.

Before discussing incident learning, it is first important to clarify some of the nomenclature relevant to incidents in radiotherapy. The definition of an incident that will be used in this thesis is an unwanted or unexpected change from normal system behaviour that causes, or has a potential to cause, an adverse effect to people or equipment [12]. A survey of existing literature on incidents in radiotherapy reveals a number of additional terms used to express the same or similar sentiment; including “accident”, “error”, “condition”, or “event” [18] [31] [33]. For consistency with the Canadian NSIR-RT taxonomy, which will be discussed in Section 2.4.4, the terms incident and event will be used in this thesis interchangeably.

Thus, an incident may refer to an event that did affect one or more patients, or an event that did not affect a patient but could have if not caught by an existing safety barrier. Such events may be referred to as "near-misses", "near-incidents", "unsafe conditions", "reportable circumstances", etc. Because the scope of this thesis includes analysis of radiotherapy incident data using the NSIR-RT taxonomy, the terms and definitions that will be used are those from the taxonomy itself, and are provided in Table 2.1 [34]. Another classification scheme for any patient safety incident in healthcare, published by the Canadian Patient Safety Institute (CPSI) in 2012, will be referenced at various points throughout this thesis, and is provided in Table 2.2 [35]. It is prudent to note that NSIR-RT includes reportable circumstances, which are not explicitly defined by the CPSI. Conversely, the CPSI defines "no harm incidents", which are not explicitly accounted for in the NSIR-RT taxonomy.

Table 2.1. NSIR-RT Incident/Event type definitions [34].

Event Type	Definition
Reportable Circumstance	A hazard that did not involve a patient but that has the potential to impact patients if not corrected
Near-miss	An incident that was detected before reaching the patient
Actual Incident	Any incident that reaches the patient

Table 2.2. CPSI patient safety incident definitions [35].

Event Type	Definition
Near miss	A patient safety incident that did not reach the patient
No Harm Incident	A patient safety incident that reached a patient, but no discernible harm resulted
Harmful Incident	A patient safety incident that resulted in harm to the patient

Ultimately the precise classification of an event as a near-miss, reportable circumstance, actual incident, or however else it may be defined, does not matter as much as capturing the event in the first place. The narrative and details around the event are most important for learning [31]. However, clearly articulated definitions of the event types aid in ensuring incident reporting

compliance. If the event types are poorly defined, then potentially informative events may not be recorded if deemed incompatible with the provided definitions [31].

There are various levels of harm and impact that can result from incidents categorized as any of the event types defined in Table 2.1. While many aspects of harm apply generally to any healthcare incident, there is additional nuance associated with harm in radiotherapy. In addition to acute medical harm, patients may also experience worsened normal tissue toxicity and reduced tumor control [27]. Both of these may induce latent medical harm that does not manifest until later in life due to the linear no-threshold nature of stochastic effects, and potential late deterministic effects, that arise from radiation damage. Incidents may also lead to treatment delays, patient anxiety or anger, as well as other non-medical effects on patients [27].

Adverse outcomes may also be experienced by individuals who are not the primary victims (patients and loved ones, or staff in some cases). Second victims are health care providers who are involved with a patient-related adverse event, and resultantly experience emotional, psychological, or physical distress [36]. There are many possible symptoms of becoming a second victim including feelings of guilt and doubt in personal knowledge and competence to continue performing one's job [37]. Unsupported and stressed staff feed into a negative feedback cycle that is conducive to causing further incidents, as shown in Fig. 2.4. A voluntary and confidential peer support system for second victims has been developed and implemented at Johns Hopkins Hospital in Maryland [37]. This Resilience in Stressful Events (RISE) system shows initiative in developing necessary support services for staff and has aided in improving morale and reducing staff turnover [37].

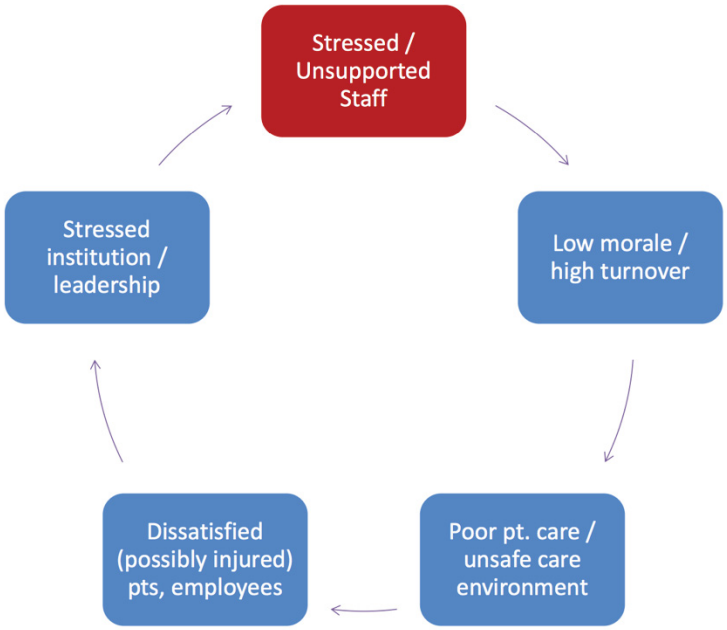


Figure 2.4: Feedback loop depicting how second victims (stressed and unsupported staff) as a result of previous incidents can lead to further incidents [37].

There have been several high profile incidents in radiotherapy over the last two decades that have brought into focus the need for well-defined systems to learn from incidents and prevent their recurrence [38]. One of these tragedies involved the death of Scott Jerome-Parks in 2007 due to a fatal overdose of radiation given during his intensity-modulated radiotherapy treatments [38]. Due to an unnoticed software error, the multileaf collimator (MLC) was left open and not shaped conformally around the target as intended, causing fatal irradiation to the brainstem. Software crashes prevented the intended MLC pattern from being saved to the treatment plan, which then passed unnoticed through plan inspection and treatment delivery. Thus, this incident arose due to an unforeseen combination of software issues, resource constraints, time pressure, and loss of attention. Such contributing factors are easily translatable to other treatment types and other institutions. Above all else, Scott reportedly wished that others would learn from the accident and hoped others would not suffer the same fate [38].

This event, the event involving the radiation overdose of Rene Jn-Charles due to a missing physical wedge in 2007, and several others have all served as a wake-up call for redefining incident management in radiotherapy [38]. Ultimately the risk of incidents in radiotherapy can never be

eliminated, but significant effort should be taken to minimize this risk [32]. Incident learning is one area of quality improvement to achieve this.

2.3 – Incident Learning

2.3.1 – Introduction to Incident Learning

Incident learning is defined as an organization's ability to identify, report, and investigate incidents, and to take corrective actions that improve the patient care system and reduce the risk of recurrence [12]. Crucial to incident learning is an understanding that reporting is not the end goal [31]. Instead, incident reports should be used to evaluate processes and facilitate follow-up actions to improve the reliability of radiotherapy systems. In doing so, a positive safety culture into which all staff are engaged, should be fostered.

Learning from incidents is typically represented as a circular feedback loop that includes several key steps, as shown in Fig. 2.5. Following an incident, in order for learning to occur, the incident must first be detected and reported. An investigation should then be performed to elucidate further details on the causes and severity of the incident, and result in corrective actions or other outcomes to address the incident and its underlying causes. Learning from each of these steps, as well as from aggregation of the findings from multiple incidents (i.e. trending), must then be implemented back into the healthcare system to prevent further incidents.

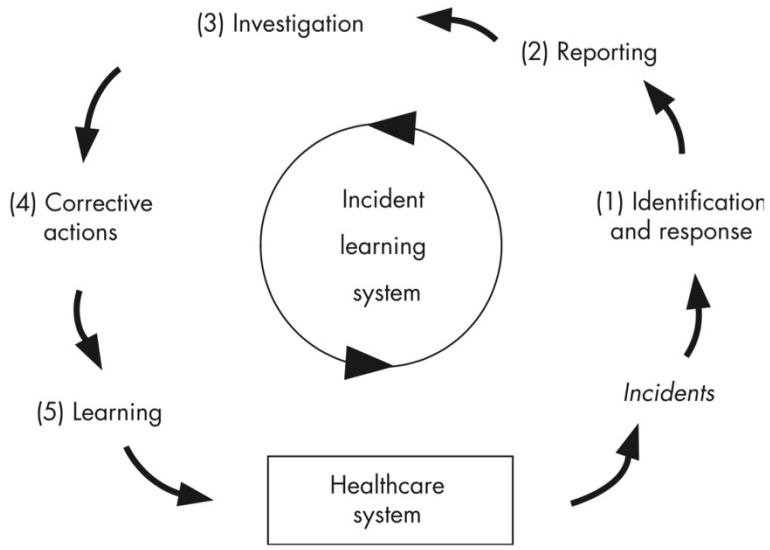


Figure 2.5: Feedback loop depicting the fundamental elements of incident learning [12].

Incident learning was not founded in radiotherapy, rather it has been adopted as a result of its success, and the success of similar methods in other disciplines, over the last several decades. Essentially, incident learning is a form of root cause analysis; the origins of which date back to the 1950s [39]. Sakichi Toyoda is often credited with inventing the first form of root cause analysis, known as "The Five Whys Method", for use in the Toyota manufacturing processes [39]. The goal of this method is to unveil the root cause of problems or anomalies by asking a series of "why" questions, and systematically eliminating other potential causes with each iteration.

Incident learning, a modern analog of root cause analysis, is a methodology that has had demonstrable success in many other industries and organizations; which are often labeled as high reliability organizations (HRO)s.

2.3.2 – High Reliability Organizations

A high reliability organization (HRO) is defined as an organization or industry that has potentially catastrophic consequences of failure, but boasts low failure rates despite relatively demanding working conditions [40]. Identification as an HRO is not awarded via certification or a badge; rather it is a characteristic that is achieved through proof of practice. Notable examples of HROs

include air traffic control systems and aircraft operations systems (i.e. military and commercial aviation industries), as well as nuclear power plants [41].

The acknowledged characteristics that define HROs have varied over time, but a commonly accepted formalism was published by Weick et al. in 1999 [42]. They proposed that organizations or industries exhibiting high reliability are those that demonstrate five characteristics that ultimately yield a collective "mindfulness" in the organization [42]. These characteristics and brief descriptions of each are listed below [42] [41]:

1) Preoccupation with Failure: HROs treat any incident or near-miss as a symptom of a larger systematic problem that could produce more severe consequences in the future. They thus encourage staff to report incidents, articulate and disseminate what was learned from near-misses, and are consistency wary of the dangers of complacency.
2) Reluctance to Simplify: HROs acknowledge that simplification is potentially dangerous because it may limit the degree of precaution staff take. Doing so is conducive to surprising undesired consequences, and organizations that tend to simplify issues are defined by what they ignore.
3) Sensitivity to Operations: HROs are attentive to frontline staff who engage with fundamental tasks for the organization. Employees of HROs have high situational awareness and are empowered to make necessary adjustments to prevent accumulation of errors. Resource constraints are insensitive to operations, and can negatively impact an organization striving to become highly reliable.
4) Commitment to Resilience: HROs accept the inevitability of error, but have well-developed policies and culture regarding anticipation and resilience. An HRO's anticipatory capabilities include its ability to predict and prevent potential incidents before they occur, whereas its resilience refers to its capability to recover from unanticipated circumstances.
5) Deference to Expertise: HROs make it easier to determine root causes underlying incidents by detecting errors at the frontline, rather than at higher occupational levels typical to a traditional corporate hierarchy. Errors detected at higher levels are often aggregates of multiple low-level errors, and are thus more difficult to accurately diagnose. Therefore,

HROs promote decision making in accordance with expertise and knowledge, rather than seniority and pay scale.

The characteristics outlined above demonstrate that, among many things, HROs are dedicated to learning from all incidents and pre-emptively prevent occurrence of high severity incidents by utilizing the wisdom and expertise of all staff. Incident learning, as defined in the previous section, embodies much of the nuance associated with HROs and is thus employed in many HROs [43].

An example of the efficacy of a robust incident learning process in an HRO may be gleaned from the operations of the Commercial Aviation Safety Team (CAST), which was formed in 1998 in the United States and has since been translated across the globe [44]. CAST is a partnership between government and industry that was assembled as a result of the preventable crash of American Airlines Flight 965 in 1995. This crash, classified as a controlled flight into terrain (CFIT), was due largely to miscommunication and inadequate technology [44].

Following this incident, experts from government and industry were brought together to form CAST. They were tasked to analyze past fatal plane crashes, including that of Flight 965, and to develop strategies to dramatically reduce risk of recurrence [44]. Also crucial to the mission of CAST is formulating plans to sustainably implement the proposed strategies. In response to CFIT accidents, upon review of data from Flight 965, CAST identified loss of situational and locational awareness as a prominent contributing factor. Inclusion of industry representatives within CAST led to the rapid development and widespread adoption of new ameliorating technologies, including a terrain awareness and warning system. This system is now installed on all registered aircraft in the United States. Across the globe, there have been zero CFIT accidents involving aircrafts that utilize this technology [44]. This example demonstrates the potential benefits of dedicated and systematic incident learning.

2.3.3 – Healthcare and Radiotherapy as HROs

Healthcare, including radiotherapy, has many features in common with HROs; including the demanding and complex nature of the field as well as the potential gravity of errors. However, it is typically not considered an HRO because of the comparatively high rate of actual incidents [40].

Additionally, healthcare faces many unique challenges towards becoming recognized as an HRO [44]. In 2009, Pronovost outlined four considerations that remain to be addressed in healthcare in order to emulate the successes of CAST in the aviation industry [44]:

1) Differing Context (between healthcare disciplines, etc.)
2) Participation of Stakeholders
3) Finances
4) Incentives for participation

Essentially these considerations emphasize the need to tailor quality improvement and organizational mindfulness to each discipline in healthcare, involve government and industry for sustainable efforts of national and international scope, devise new and creative means of securing resources for these initiatives, and clearly demonstrate benefits at a staffing and institutional level [44].

Unengaged and unempowered staff at any position can also be highly detrimental to the success of quality improvement and thus are a barrier to achieving HRO status. For example, a study by Singer et al. in 2003, demonstrated clear divides in perceived safety climate between frontline staff and management in Californian hospitals, with frontline staff providing significantly more responses reflective of a negative safety culture than management [45]. These results are in direct conflict with two of the fundamental constituents of HROs: sensitivity to operations and empowered staff. This will be discussed further in Section 2.3.5.

An additional hurdle towards reaching HRO status in healthcare is the shortage of high quality data, and lack of transparency in that data. In both commercial and military aviation, it is considerably more straightforward to deconstruct incident root causes partially due to availability of voice recordings [40]. These data, including the follow-up investigations, are made public so that everyone can learn from previous accidents. Historically, in healthcare, incidents have largely been kept private and there were only limited tools available for meaningful and efficient collection, analysis, and aggregation of data. Recently however, some medical disciplines have begun to adopt lessons from HROs and sought to improve safety culture, including intensive care and more recently, radiotherapy [40].

A number of lessons may be inferred from the operations and success of HROs as described in this section and Section 2.3.2, and are applicable to all healthcare disciplines. With regards to implementing a formalized incident learning system in radiotherapy, the following five lessons were distilled from the discussion above, and are each discussed in the following sections:

1. Implement an incident learning system tailored to radiotherapy
2. Foster a positive and participative incident learning culture
3. Optimize incident learning workflow where possible, in consideration of limited resources
4. Standardize approach to gathering and learning from incident data
5. Disseminate learnings among colleagues for joint learning

2.3.4 – Implementing an Incident Learning System in Radiotherapy

Successful evidence of its usefulness in reducing incidents in other industries has motivated integration of incident learning into radiotherapy. The need for radiotherapy incident learning was also articulated in the 2008 report *Towards Safer Radiotherapy* authored by the Royal College of Radiology [27]. Three of the fourteen recommendations proposed in this report pertain to incident learning, including specifically recommending that each department have a system for reporting and analyzing errors whereby lessons are fed back to staff [27]. Such a system is known as an incident learning system (ILS).

Also believed crucial to the success of implementing an ILS, is the capability of such a system to capture near-miss events. In other words, an ILS should aid in proactively identifying dangerous latent conditions in addition to facilitating retrospective analysis on actual incidents that have already occurred. López suggested that lessons learned from previous actual incidents are insufficient on their own because those events were not foreseen [46]. Analysis of near-miss events can lead to elimination of potential problems before they occur. Other means of modeling and predicting risk using techniques such as failure mode effects analysis (FMEA) offer additional advantages as they are not subject to reporting bias. Such models exist within the spirit of incident learning and root cause analysis, but are beyond the scope of this thesis.

There are a number of options that should be considered when developing or implementing an ILS. Firstly, distinction should be made between mandatory and voluntary incident reporting

systems. A diagram summarizing the types of events to be captured in each system is shown in Fig. 2.6. Mandatory systems are usually affiliated with legal requirements, and thus mandate reporting all incidents of "high" severity. Such systems are not typically affiliated with incident learning, but instead serve to provide organizations with incentive to improve safety in order to avoid penalties and provide the public with a minimum level of protection and transparency [18]. Voluntary reporting systems on the other hand offer significant potential for incident learning, because these systems should capture low severity events and near-misses in addition to high impact incidents captured in a mandatory system. The goal in capturing all these events is to reveal system weaknesses and potential areas of failure, and to proactively fix them. There are no financial or legal repercussions associated with such systems and thus they require staff to be motivated and convinced of the efficacy of reporting events by demonstration of learning. Collecting reports in these systems and not doing anything with the information serves no purpose [18].

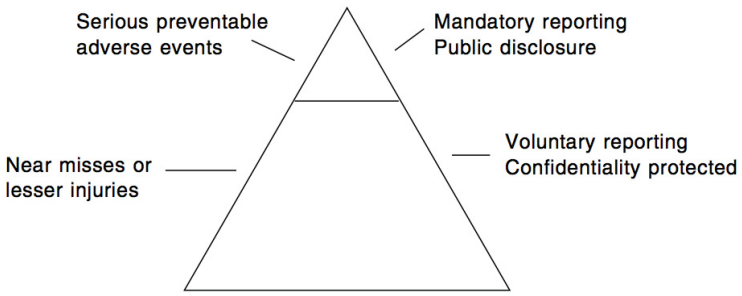


Figure 2.6: Types of incidents that should be reported into mandatory and voluntary reporting systems [18].

Consideration should be given towards implementing a paper or electronic system. Paper systems are largely outdated due to the slowness with which paper is circulated between individuals, the effort and physical space required to maintain reports, and the inability to trend and share incident data when recorded only on paper [31]. Paper forms do offer some advantages in the form of personalization and facilitating discussion which will be addressed further in Chapter 3. Electronic systems are much more in vogue nowadays because they allow integration of features to enhance system intuitiveness and reduce workload, as well as offer a centralized database to store incident data, which facilitates queries and aggregation.

An additional consideration is whether or not to use an internal, usually internally-developed, ILS or an external ILS. An external system allows aggregation of data among multiple institutions, but may not be designed to accommodate local workflow and is not easily customized. Internal systems can be tailored to institution-specific needs, but are typically unstandardized and thus inhibit sharing of data and learnings with other centres. Regardless of the choices made for each consideration described above, if an ILS is to be meaningfully maintained, it requires motivated staff.

2.3.5 – Incident Learning Culture

An organization's culture is characterized by the shared values and beliefs that interact with the organization's infrastructure and processes to establish behavioural norms [31]. Incident learning is one approach that provides a platform for all staff to engage in improving safety culture through participation and follow-up. In order to empower staff to take responsibility for safety, existing hierarchies and perceived power distance must be broken down [24]. Constructive questions and concerns should be encouraged and vocalized within staffing groups and between them.

The essential element of a positive incident learning culture is that individuals do not fear reprisal for reporting incidents. Assignment of blame does not amend the multitude of factors that compounded into causing the majority of incidents [18]. Thus, staff should have indemnity against reprisal in order to establish a successful non-punitive and blame-free, ILS [31]. In lieu of affixing blame, a systems approach to incident response must be taken and demonstrated clearly to staff.

Voluntary incident learning systems can only be maintained if system successes are well communicated [47]. This allows staff to know their efforts have effected positive change in the department, and will aid in motivating continued participation [31]. Precisely how feedback is provided to staff typically varies with the size and physical layout of the institution, among other factors [31]. There are however certain features that should be common to all feedback mechanisms, including the timeliness of those mechanisms and participation of management and leaders [31] [47]. A common way to include all levels of staff in incident learning is to establish a multidisciplinary incident learning committee with representation from all staffing groups. This group will form the backbone of the incident learning program by facilitating teamwork and

collaborative learning between individuals with various professional backgrounds [47]. After each meeting, members of the committee can relay discussion points back to their colleagues.

Culture has a significant impact on two additional characteristics of incident learning; the risk of under-reporting and perceived willingness of an organization or individual to make changes as a result of incident reporting. A study by Cooke et al. in 2007 aimed to evaluate effectiveness of an internal ILS by surveying staff, and addresses both of these concerns [12].

Firstly, regarding concerns about under-reporting, Cooke et al. found that staff were very willing to participate in incident reporting and learning, and that staff positively indicated organizational commitment to identifying and reporting incidents [12]. However, one of the most frequently identified reasons for not reporting an incident was the belief that the event was not important enough to report. The three most negative responses from the survey reflected poorly on the organization's ability to make changes based on incident learning. Only 26% of respondents gave a positive response for sufficient allocation of departmental resources to incident investigations [12]. Additionally, only 43% of staff felt positive about the organization's ability to learn from incidents, with proportionally higher negative responses submitted by front line staff than management [12].

The above findings emphasize the need for clear definitions of what should be reported, and for provision of evidence to staff that reporting events that were perceived as unimportant actually lead to positive departmental change. In order to achieve this, sufficient resources must be provided to effectively learn from incidents. Complementary to this, tools should be provided to optimize report submission, investigations, and analysis.

2.3.6 – Resource Constraints and Optimization of Incident Learning

In order for an incident learning program to succeed, it must be sustainable in terms of resource requirements. Mutic and Brame postulated that the potential benefits of "discovering obscure error propagation mechanisms far outweighs the time and effort required to investigate insignificant events" [31]. While this may be true, clinical limitations on resources make this difficult to justify

particularly when integrating a new, unproven incident learning program. One way to counteract this is to design or incorporate an ILS that captures all salient data, but is also intuitive and efficient.

A study published by Bolderston et al. in 2015 provided the results of a survey of Canadian and American RTTs regarding incident reporting habits [48]. They found one of the most egregious barriers to reporting to be difficulty in using the reporting system due to poor design or the time-consuming nature of using it. This highlights the importance of incorporating tools into the ILS to reduce the burden of data entry. Examples of features to address this burden include context sensitive menus, dropdown data options, and interfacing with the electronic Record and Verify system [31]. Additionally, the ability to define "explicit events" that occur commonly in a particular institution can allow rapid processing of frequent events [31].

Yet even provided optimization tools such as those described above, a successful ILS still does require significant resource allocation. The CAST project in aviation requires input from approximately 40 experts who dedicate one week of work per month to incident learning [44]. Gabriel et al. report conservative estimates of approximately 2 full-time equivalent (FTE) staff members dedicated to incident learning, for a radiation oncology program encompassing 14 linacs and 5 proton gantries [33]. Zeng et al. estimated about one FTE dedicated to incident learning, with duties spread among several members of their incident learning committee [49]. This is in addition to weekly meetings on incident learning, to which approximately 20 staff attend. Thus management must buy into an incident learning program and dedicate resources accordingly in order to ensure its success.

The final main consideration in implementing an ILS pertains to use of a standardized nomenclature. This will be discussed in the following section.

2.3.7 – Standardized Incident Reporting

Use of a standardized nomenclature is essential for effective dissemination of data and learnings within an institution and across institutions. The need for dissemination of knowledge has been widely articulated including by Margaret Murphy, mother of Kevin Murphy, and now external

lead advisor of the World Health Organization (WHO) Patients for Patient Safety committee, who experienced firsthand the dangerous consequences of poor communication [26].

Standardization of nomenclature has already been proven effective in other aspects of modern radiotherapy. For example, widespread adoption of DICOM and DICOM-RT have hugely bolstered electronic communication between software and hardware components, as well as between centres [50]. Prior to this, unstandardized manual transfer of information between treatment planning software, record and verify systems, etc. was a common source of errors in radiotherapy [50].

Oftentimes, errors experienced in one centre have already occurred, or are likely to occur, in another centre [18]. Due to the diversity amongst radiation oncology programs in terms of personnel, available equipment and software, protocols, etc. it may be unfeasible or misguided to translate the findings of an incident at one centre to another. However, in some cases, the underlying problems and contributing factors may indeed be highly similar. In the remaining cases, at the very least, an incident and associated findings at one centre may inspire reflection of current policies at another centre and ultimately result in betterment of practice [51]. Inclusion of details about the personnel, equipment, protocol, etc. within the incident report will help other centres to decide how applicable the corresponding findings are.

The radiation oncology community has previously lacked a platform for disseminating this type of information. In 2009 however, the WHO published the Conceptual Framework for the International Classification for Patient Safety (WHO-ICPS), the goal of which was to detail how healthcare incidents should feed into a continuous and adaptive learning cycle to improve systems and patient safety [52]. This framework, shown in Fig. 2.7, forms the basis of several modern national and international radiotherapy incident reporting taxonomies that are focused on sharing incident learnings on equivalent scales.

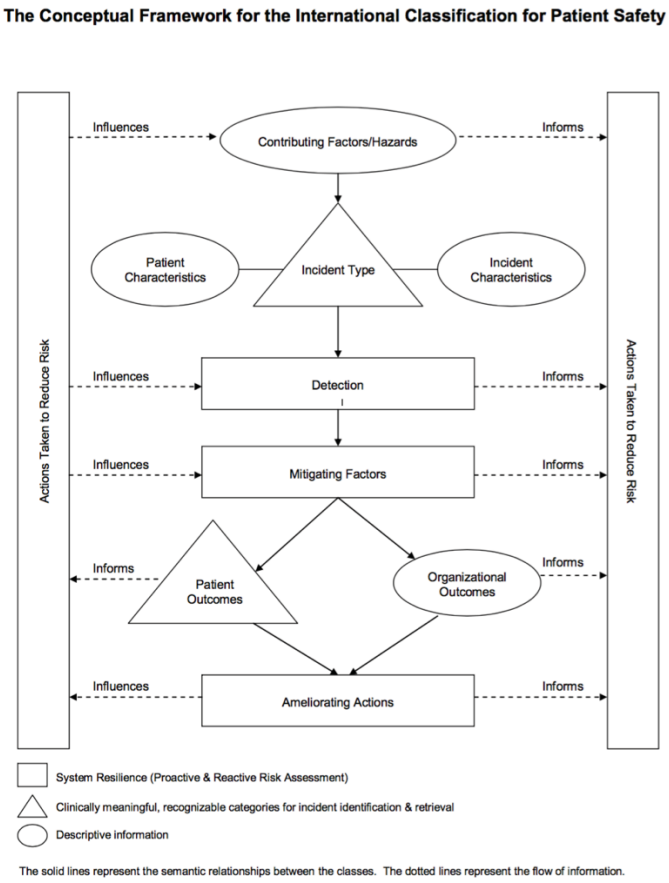


Figure 2.7: The Conceptual Framework for the International Classification for Patient Safety, which demonstrates the incident factors that should be captured for incident learning and how each factor should feed into a continuous improvement cycle [52].

The most prevalent national and international incident learning systems across the globe currently include the Radiation Oncology Safety Information System (ROSIS), the Safety in Radiation Oncology (SAFRON) system, the Radiation Oncology Incident Learning System (RO-ILS), and the Canadian National System for Incident Reporting – Radiation Treatment (NSIR-RT). The characteristics and objectives of each will be discussed in the following section.

2.4 – National and International Incident Learning Systems

2.4.1 – Radiation Oncology Safety Information System

ROSIS was the pioneer international system for incident learning in radiotherapy, having been established in 2001 [53]. The system was originally funded by ESTRO, but ongoing maintenance efforts were largely on a volunteer basis by a core group of individuals including Joanne

Cunningham and Mary Coffey at Trinity College Dublin. It was created as an online learning tool that European radiotherapy centres could voluntarily enroll in. The goal of the system was to reduce incident occurrence by [53]:

- enabling sharing of incident reports
- allowing collection and analysis of the occurrence, detection, severity, and correction of radiotherapy incidents
- disseminating results thereby promoting safety culture among all participants

There are two distinct categories of data collected using ROSIS; departmental profiles and incident data [53]. Collection of departmental infrastructure allows examination of whether the infrastructure itself has any effect on incident occurrence or detection based on common trends.

The ROSIS incident reporting taxonomy encompasses actual incidents as well as near-miss events that did not affect any patients. Details about the detection and occurrence of incidents, including location, process step, and associated individuals are captured for each incident. Newsletters were published approximately biannually to highlight particular incidents and discuss what actions were taken to address underlying issues [54]. The newsletters were themed, for example on data transfer errors or patient identification errors. Additionally, Cunningham et al. published a report on the first 1074 incidents submitted to the system by 101 participating institutions between January 2003 and August 2008 [53]. All anonymized incident data submitted to ROSIS are available online [54].

However, input into ROSIS has tapered significantly in the years following this report. There have been no reports submitted since February 2015 [54].

2.4.2 – Safety in Radiation Oncology System

SAFRON is another European/international incident learning system, that was initiated in December 2012 [55]. Although SAFRON was originally developed to be collaborative with ROSIS, the former has largely replaced the latter. The main proposed advantage of SAFRON over ROSIS was the funding and backing provided to it, as SAFRON is funded by a regular budget provided by the International Atomic Energy Agency (IAEA) [56]. Additionally, thanks to the global reach of IAEA, the system has significant potential to reach a broad audience.

The goals and data captured by SAFRON are similar to ROSIS, with a notable difference in the inclusion of safety barriers. These are represented by additional fields in the incident report to identify safety barriers that were successful in preventing an incident (in the case of near-misses) and those that failed to prevent an incident [56]. This feature relates back to the Swiss Cheese model discussed earlier in Section 2.2.2, and facilitates a systems approach to characterizing incidents. SAFRON also has incorporated a simple plotting toolkit to allow for incident trending by number of incidents and a few key fields within the taxonomy. Like ROSIS, newsletters are also released every three to six months to highlight key findings.

Currently there are over 50 registered facilities, and over 1300 incidents submitted to the SAFRON registry [55]. However, these 1300 incidents include all incidents from the ROSIS database. In fact, there have only been 14 incidents submitted to SAFRON in 2016 as of July 1st [55]. One potential problem with SAFRON is the prevalence of "Other" and "Unknown" options, which if overused make it more difficult to glean meaningful statistics from the data. Additionally, both the SAFRON and ROSIS taxonomies do not allow characterization of non-medical impact.

2.4.3 – Radiation Oncology Incident Learning System

The Radiation Oncology Incident Learning System debuted in the United States on June 19th, 2014 following a beta test that began in September 2013. This system was conceived following approval of the ASTRO board of directors to establish a national radiation oncology specific ILS [57]. The system is non-punitive and is protected as such through a Patient Safety Organization (PSO), called Clarity. PSOs were defined as part of the 2005 Patient Safety and Quality Improvement Act, which was formulated in response to *To Err is Human* [58]. RO-ILS is the first medical-specialty-sponsored PSO in radiation oncology as both AAPM and ASTRO are stakeholders in the system [58]. The Radiation Oncology Healthcare Advisory Council (RO-HAC) oversees the national database and is responsible for interpreting data.

RO-ILS is an online ILS that is provided free of charge, albeit only to institutions in the United States. Data elements included in the taxonomy were selected based on consensus recommendations published by Ford et al. in 2012 [57] [43]. A complete list of the data elements included in RO-ILS is provided in the RO-ILS Participation Guide which is publicly available to

all individuals with ASTRO login credentials [59]. The system is designed to capture incidents that reached patients, near-misses, and unsafe conditions. There are more data elements in the RO-ILS taxonomy than in ROSIS or SAFRON, although not all are mandatory. Incidents are submitted via a two-step process including an initial submission followed by a detailed investigation.

As of May 2016, 103 practices spanning 209 facilities were enrolled in RO-ILS and have reported over 1750 incidents [60]. It must be noted that incidents submitted to RO-ILS are not recorded in the national registry by default. Rather, participants can submit incidents to RO-ILS and process them internally to their institution, then upload to the national registry if desired [60].

Clarity and RO-HAC produce periodic reports on incident data submitted to the national registry. The suite of reports includes quarterly and annual general reports, biannual institution-specific reports, and monthly tips. A key development in RO-ILS is the current revision to expand the event classification (event type) field, as detailed in the RO-ILS 2016 annual report. Originally the options were unsafe conditions, near-misses, and incidents that reached the patient. The revised options that will be rolled out in an update to RO-ILS in the near future are [60]:

- Therapeutic Radiation Incident
- Other Safety Incident (e.g. collision / fall)
- Near-miss
- Unsafe Condition
- Operational / Process Improvement (non-safety event)

These modifications were agreed upon based on user experience, expert opinions, and two inter-rater reliability studies [60]. It is expected that these changes, that encompass non-medical impact, will support more rigorous analysis and trending.

2.4.4 – Canadian National System for Incident Reporting – Radiation Treatment

Finally, the most recent national/international incident learning system to enter the fray is the Canadian NSIR-RT. The initiative to develop and implement NSIR-RT was put into motion by the Canadian Partnership for Quality Radiotherapy (CPQR) in 2011. The CPQR itself was founded in 2010 as an alliance of the Canadian professional radiotherapy organizations CARO, COMP, and CAMRT [61]. Its mandate was, and continues to be, to establish national guidelines for quality

assurance programs, technical quality control, and patient engagement in Canadian radiotherapy programs [61].

Integration of NSIR-RT into the Canadian radiotherapy community aims to establish a secure, anonymous, and voluntary online ILS that facilitates sharing of incident data and analysis to improve patient safety [13]. It is not designed to dictate the way by which incidents are investigated, but rather provide a platform for disseminating investigative results [34]. Participation is free and data is anonymized as well as protected from discovery according to provincial health quality-of-care legislation [13].

NSIR-RT is overseen by a CPQR working group with representation from radiation oncologists, medical physicists, and radiation therapists. The working group collaborates with the Canadian Partnership Against Cancer and the Canadian Institute for Health Information (CIHI) [13]. CIHI has previous experience in developing a national incident reporting system for chemotherapy drugs, and is in charge of designing the online portal for NSIR-RT and overseeing the radiotherapy incident database. Currently, NSIR-RT is deployed in a pilot phase which began in September 2015 and is expected to conclude at the end of 2016. As of July 1st 2016 there are 26 institutions participating in the pilot, out of 44 total in Canada.

The taxonomy was constructed using a Delphi study, which is a qualitative exercise based on sequential rounds of consensus building [13]. Twenty-seven participants representing 17 radiotherapy programs participated in the study to achieve a final taxonomy that was complete in terms of data elements but would not be unreasonably resource intensive to utilize in practice. The resulting taxonomy consists of 33 data elements across 6 distinct information domains. Subsequently an inter-user agreement study was performed to refine the options within each field. The final taxonomy including all options for each data element is presented in detail in the NSIR-RT Minimum Data Set (MDS) [34].

An important consideration in developing the taxonomy was to align the final product with other national/international taxonomies. A complete list of elements within the NSIR-RT taxonomy, and

the alignment of those elements with RO-ILS, ROSIS, SAFRON, and WHO-ICPS is displayed in Fig. 2.8.

Table 1 Summary of the 33 NSIR-RT data categories and general alignment with other relevant reporting systems and taxonomies

NSIR-RT taxonomy data category [a]		Alignment with other relevant taxonomies			
		RO-ILS	ROSIS	SAFRON	WHO
1. Impact					
1.1	Description of incident	Y	Y	Y	N
1.2	Incident type	Y	Y	Y	Y
1.3	Acute medical harm	Y	Y	N	Y
1.4	Dosimetric severity	Y	Y	Y	N
1.5	Latent medical harm	N	Y	N	N
2. Discovery					
2.1	Functional work area	N	Y	N	N
2.2	Date–detected	N	Y	Y	Y
2.3	Date–occurred	N	Y	N	Y
2.4	Time–detection	N	Y	N	Y
2.5	Time–occurred	N	Y	N	Y
2.6	Health care provider(s)–detected	Y	Y	Y	Y
2.7	Health care provider(s)–involved	N	N	N	Y
3. Patient					
3.1	Year of birth	N	Y	N	N
3.2	Month of birth	N	Y	N	N
3.3	Patient gender	Y	Y	N	Y
3.4	Diagnosis relevant to treatment	Y	Y	N	N
4. Discovery					
4.1	Process step–occurred	Y	Y	Y	Y
4.2	Process step–detected	Y	Y	Y	Y
4.3	Problem type	Y	N	Y	Y
4.4	Contributing factors	Y	Y	Y	Y
4.5	Number of patients affected	Y	Y	Y	N
5. Treatment delivery					
5.1	Radiation treatment technique	Y	Y	N	N
5.2	Total dose prescribed	Y	Y	Y	N
5.3	Number of fractions prescribed	Y	Y	Y	N
5.4	Fractions delivered incorrectly	Y	Y	Y	N
5.5	Hardware involved	Y	Y	Y	N
5.6	Software involved	Y	Y	Y	N
5.7	Body region(s) treated	Y	Y	N	N
5.8	Treatment intent	Y	Y	N	Y
6. Investigation					
6.1	Ameliorating actions	N	Y	N	Y
6.2	Safety barriers–failed	N	N	Y	Y
6.3	Safety barriers–effective	N	Y	Y	Y
6.4	Actions to reduce risk	Y	Y	Y	Y

Figure 2.8: Table summarizing each of the 33 data elements within NSIR-RT, spread across six information domains. The alignment of each field with the other major national/international incident learning systems and the WHO-ICPS is also shown. An entry of "Y" implies the data element, or equivalent, is also found in that system. An entry of "N" implies the data element is not represented in that system [13].

The taxonomy encompasses actual incidents, near-misses, and reportable circumstances; each of which was defined previously in Table 2.1. All data elements are defined as mandatory or optional conditionally dependent on the incident type, as described in the NSIR-RT MDS [34]. Additionally, the impact or severity of each incident is classified using three data elements; *Acute Medical Harm*, *Dosimetric Severity*, and *Latent Medical Harm*. These three fields allow distinction

between acute medical effects and the unquantifiable risk for late effects associated with dosimetric variation. The Algorithm for Categorizing the Impact of Radiation Treatment Incidents is included in the NSIR-RT MDS, to aid users in determining impact in accordance with each of these three data elements, and is presented in Fig. 2.9.

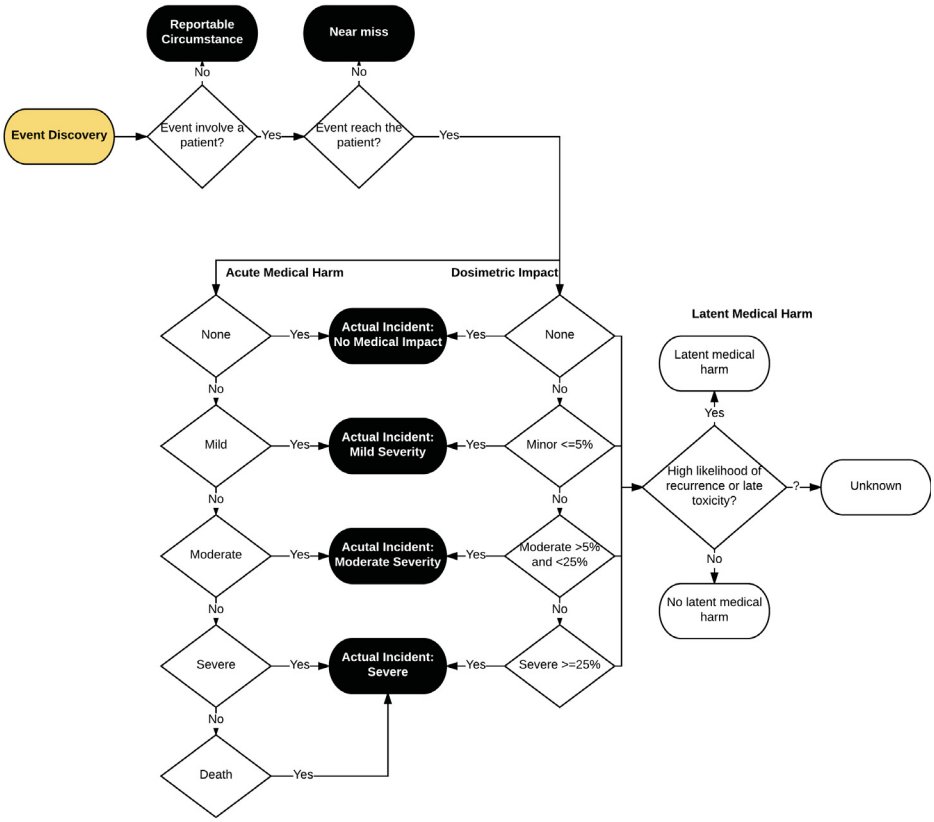


Figure 2.9: The NSIR-RT Algorithm for Categorizing the Impact of Radiation Treatment Incidents. This algorithm may be used to classify the type and impact of a radiotherapy incident. Adapted from [34].

Additional features of NSIR-RT include an anonymous communication tool and an online analytical tool for trending local, provincial, and national incident data. An important note regarding the NSIR-RT taxonomy is the lack of data elements and options to classify non-medical impact, which contrasts the aforementioned revision of RO-ILS to include *Operational/process-improvement incidents*.

Chapter 3 – Methodology

3.1 – Overview of Project Deliverables and Methods Used

The project presented in this thesis was designed to rejuvenate the incident reporting and learning process in the Department of Radiation Oncology at the Cedars Cancer Centre of the McGill University Health Centre (MUHC). Development of a novel, web-based, radiotherapy incident learning system represents the backbone of the work. The process of developing the ILS as well as the methods used to analyze results of its clinical implementation will be detailed in this chapter. Due to the resource-intensive nature of a successful ILS, as discussed in the previous chapter, a significant emphasis was placed on designing features within the ILS to reduce the workload associated with reporting and analyzing incidents. These features will be discussed in Section 3.5.

A fundamental objective of this work was to design the ILS to be fully compatible with the Canadian National System for Incident Reporting – Radiation Treatment (NSIR-RT). As mentioned in the previous chapter, NSIR-RT was not designed to govern how incident investigations are carried out. As such, NSIR-RT does not delineate responsibilities among staff nor does it include feedback channels to frontline staff. However, the potential benefits of radiotherapy incident learning at a national level via the NSIR-RT registry are important to the scope of this project. Thus it was crucial that the ILS developed in this work utilized the NSIR-RT taxonomy so that locally-reported incident data can be shared with the national database. Additionally, incorporation of the NSIR-RT taxonomy allowed participation in the ongoing validation and revision of the taxonomy itself.

As mentioned throughout the previous chapter, the types of incidents that are most likely to occur at a particular institution depend on many factors, including the equipment and software available. Knowledge of these factors will make more clear the applicability of the findings presented in the following chapter to other centres, depending on how similar or dissimilar the quantities, types, and manufacturers of equipment are. The Department of Radiation Oncology contains six *Varian Truebeam*^{TM} linear accelerators (two of which are *STx* units), an *Accuray Cyberknife®*, as well as an *Elekta microSelectron®* high-dose-rate brachytherapy remote afterloader. There are three

simulation suites in the department consisting of two *Philips Brilliance Big Bore* CT simulators and a 3.0 Tesla *Philips Ingenia* MR system. Treatment planning is performed on several systems including *Varian's Eclipse* ^{TM} *Treatment Planning System*, *Accuray's Multiplan® System*, *Brainlab's iPlan® RT*, and *Elekta's Oncentra® Brachy*. The departmental electronic medical record is *Varian's ARIA® Oncology Information System.*

3.2 – Development of an Internal Incident Learning System

3.2.1 – Overview of Development

Prior to this work, a simple online incident reporting system with an unstandardized taxonomy was implemented in the department. A screenshot of the report component of the system is shown in Fig. 3.1, which was used in conjunction with paper forms. Following occurrence of an incident, a paper incident report form was filled out by the individual who detected the event. Subsequently, the report would be submitted to the assistant chief radiation therapist, who would then transcribe it into the online system. In theory, the departmental multi-professional Risk Management Committee (RMC) would then use the online system to provide additional details on the incident. In practice however, the unstandardized data elements within the online system made it cumbersome to categorize incidents and only a few incidents could be processed during each meeting of the RMC. This led to incident investigations often remaining incomplete.

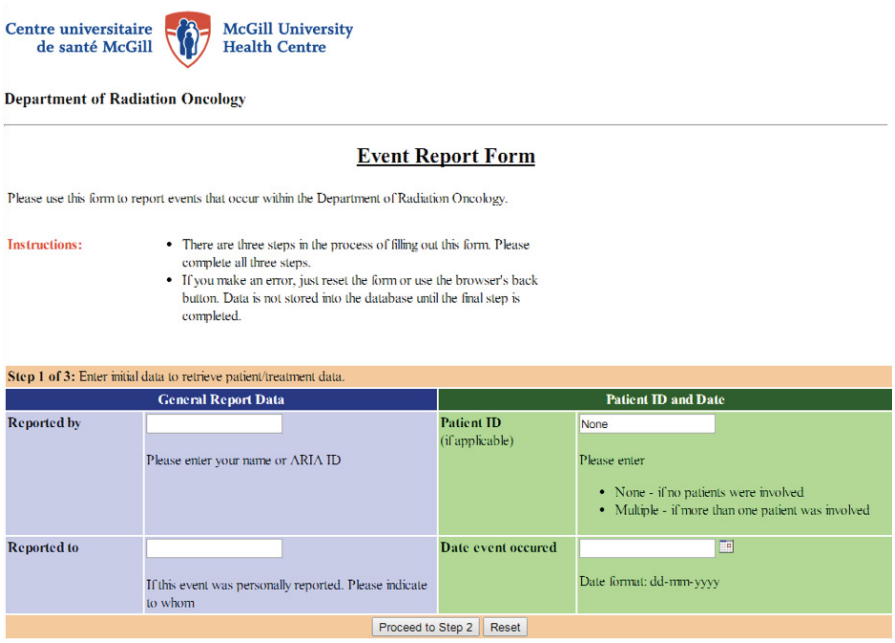


Figure 3.1: Screenshot of the report page of the previous online incident reporting system implemented at the MUHC Department of Radiation Oncology at the Cedars Cancer Centre.

A primary deliverable of this work was to develop a new ILS to address these concerns of encumbrance and limited feedback. When this project began in July 2015, an ILS designed and developed at The Ottawa Hospital Cancer Centre (TOHCC) was recommended. This system, entitled the Safety Incident Learning System (SaILS), offered a very intuitive and aesthetically pleasing user interface (UI). Because SaILS is open-source, the code and backend database could be retooled to meet the objectives of this work, and it thus was chosen as a starting point.

The data elements used within the initial version of SaILS were constructed somewhat in accordance with the consensus recommendations published by Ford et al [43]. Thus, the initial task required to adapt SaILS to the needs of this project and the department, was to redesign the database and aspects of the UI for compatibility with the NSIR-RT taxonomy described in the NSIR-RT MDS [34]. This initial overhaul of SaILS took place over the first few months of the project. In January 2016 the new NSIR-RT-compatible version of SaILS was deployed into clinical use.

3.2.2 – SaILS Technical Specifications

SaILS is a web application that was developed using Django, an open-source Python web framework [62]. Table 3.1 summarizes the core programming languages and frameworks used to develop SaILS. A brief description of the philosophy behind Django and how it was applied to the development of SaILS is presented below. A diagram that summarizes the design is shown in Fig. 3.2, including the core features of SaILS that will be discussed in Section 3.4.

Table 3.1. Frameworks and programming languages used in SaILS.

Framework	Purpose
Django (v. 1.6.11)	Python web framework used for the entire site design (frontend + backend).
HTML (v. 5)	HyperText Mark-Up Language. Standard markup language used to create webpages.
CSS	Cascading Style Sheets. Formats how HTML elements are displayed.
JavaScript + jQuery (v. 1.11.0)	Programming language used to generate scripts that are executed on the client side of the site (user's web browser) to facilitate dynamic webpage interaction.
MySQL (v. 14.14)	Relational database management system that is connected to the website and stores all incident data, user profiles, etc.

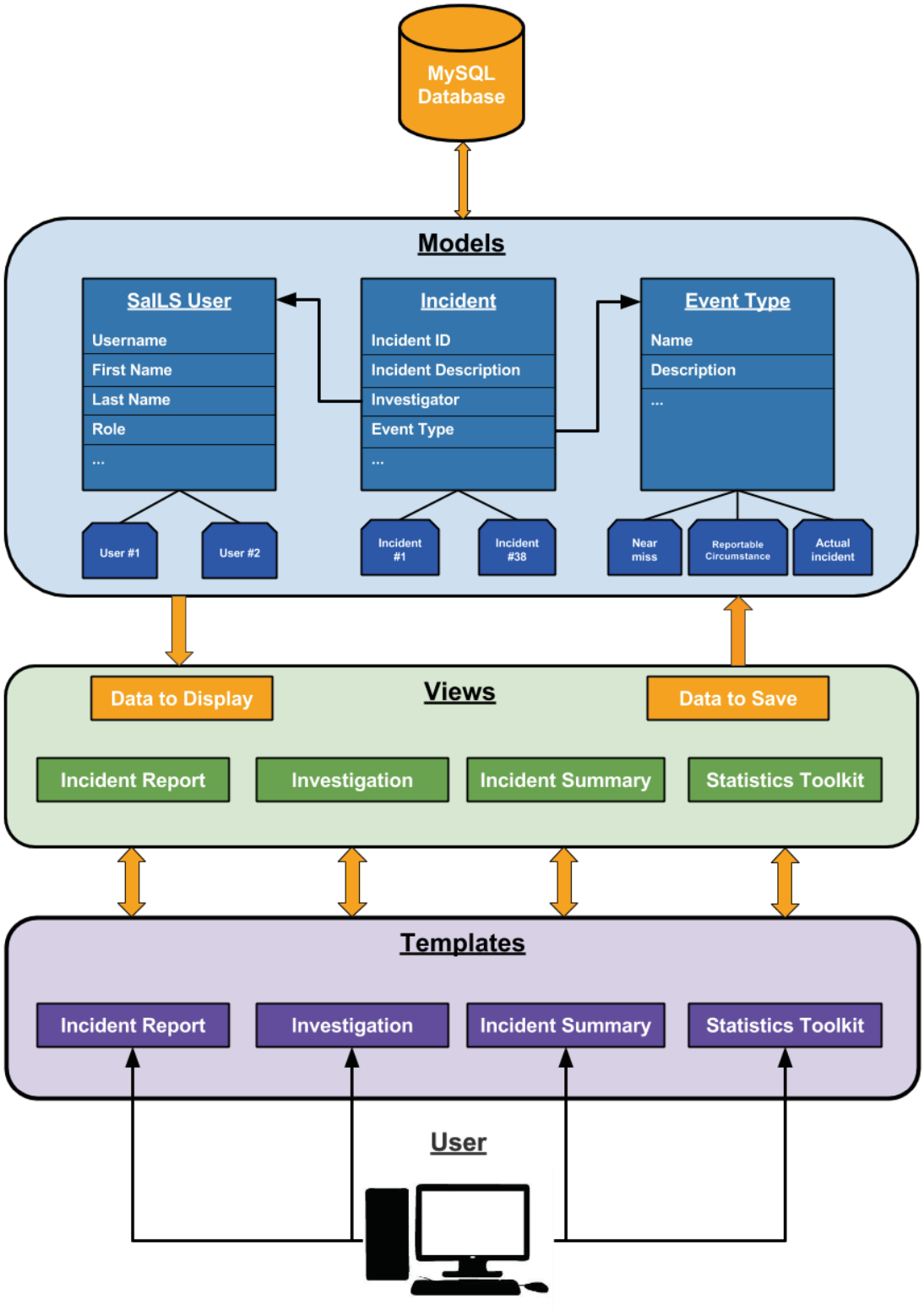


Figure 3.2: Schematic diagram that depicts the Django model-view-template design philosophy as applied to the core features of SaILS.

Django is known as a model-view-template (MVT) web framework [62]. Models, views, and templates are described below in the context of SaILS:

1. Model – The power of the Django framework is realized when the website is tied to a relational database such as MySQL. Models are defined as objects in Python code and correspond to tables in the relational database. Each field within a model is represented as a column in the corresponding database table. For example, an *Incident* model was defined with a field for each data element in the NSIR-RT taxonomy. Each instance of the *Incident* model represents a reported incident, and is stored in the database.

   All select-type data elements in the NSIR-RT taxonomy were also defined with unique models that are linked to the corresponding field in the *Incident* model. Instances of these NSIR-RT models are the available choices for that data element as defined in the NSIR-RT MDS, and are stored in the database. For example, the *Event Type* field in the *Incident* model is linked to the *Event Type* model as shown in Fig. 3.2. The instances of the *Event Type* model are *Reportable Circumstance, Near-miss*, and *Actual Incident.* Defining the data elements, and instances thereof, in this this way will allow for future changes to the taxonomy to be easily incorporated, instead of hardcoding definitions within the Python code itself.

2. View – Views are Python classes that define the data that are to be presented to the user and to be collected from the user, respectively, on a particular webpage.

3. Template – Templates allow for generation of HTML pages conditionally dependent on data passed into the template by a view. For SaILS, the frontend UI is bolstered by JavaScript, which allows user interactions to dynamically alter the webpage appearance (for example, conditional display of form fields according to inputs in other fields). Use of Asynchronous JavaScript and XML (AJAX) also allows user inputs and requests to interact with the server backend without having to reload pages. These tools are common in modern web development and provide a user-friendly experience that ultimately reduces time to process data.

Many additional software packages and libraries were used in the development of SaILS. Table 3.2 lists some notable packages, and the features generated using them. These features will be detailed throughout this chapter.

Table 3.2. Notable software packages and libraries used in the development of SaILS.

Package/library	Version	Feature
Django-celery	3.1.18	Automatic email reminders for investigations
Highcharts	4.2.5	Incident plotting toolkit
JSChosen	1.5.1	Improved UI for dropdown form fields
JSPlumb	1.4.1	Dynamically generated flowchart on feedback pages
Redis	2.10.3	Automatic email reminders for investigations
Supervisor	3.2.3	Automatic email reminders for investigations

3.3 – Incident Learning Workflow

The clinical version of SaILS that was deployed in January 2016 was designed to facilitate a slightly revised in-house incident reporting and learning workflow, which is shown in Fig. 3.3. Rationale for particular components of the workflow is provided below, but a goal of establishing a new workflow that was largely similar to the previous workflow was to more seamlessly integrate the new software component, SaILS, without a decline in reporting compliance.

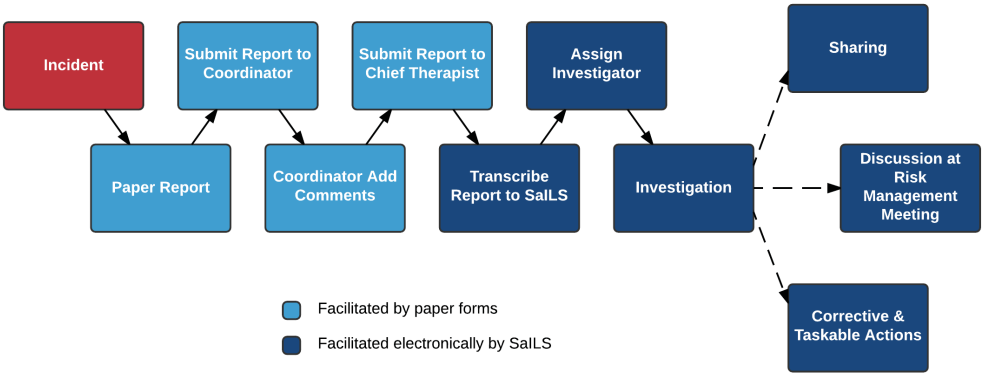


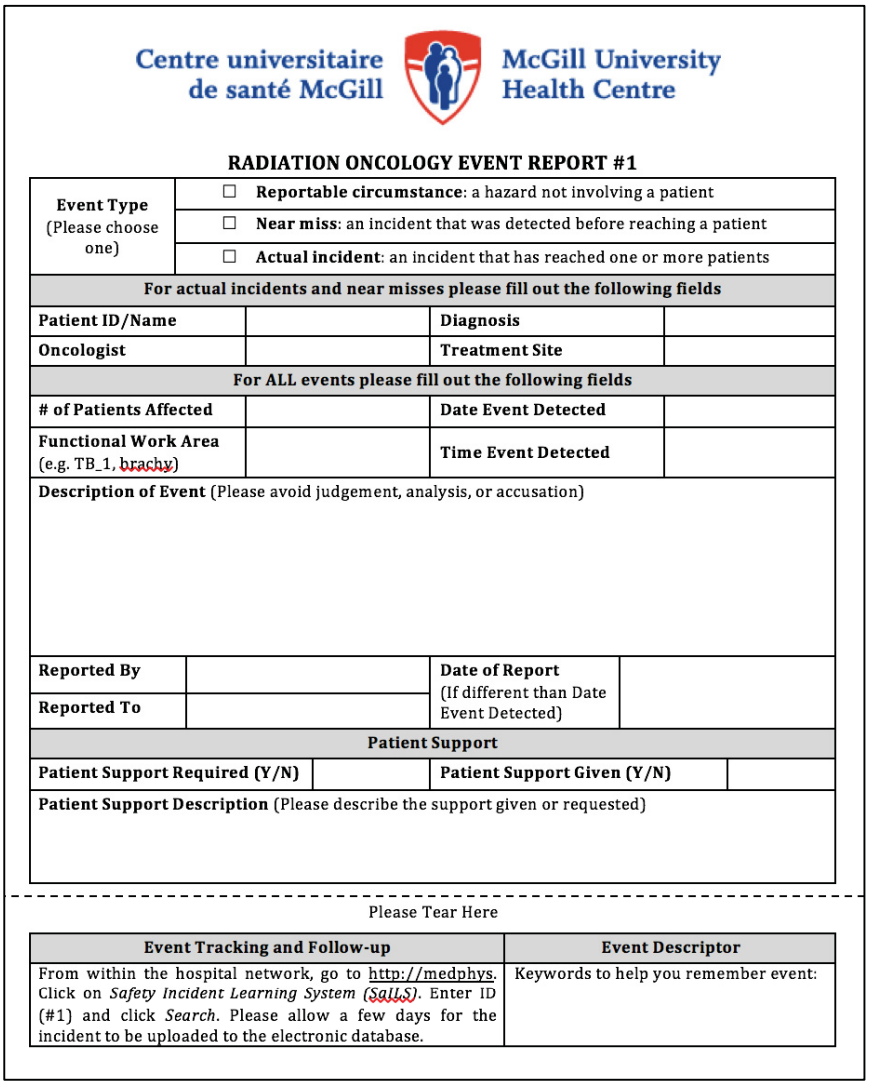
Figure 3.3: Flowchart of the updated radiotherapy incident reporting and learning workflow at the MUHC. Components in light blue are facilitated by paper forms, whereas those in navy are facilitated electronically by SaILS.

Following detection of an incident, a report should be filed. For an incident detected by an RTT a paper report form is filled out and submitted to a technical coordinator[1] with whom a discussion will be held about the incident. Subsequently, the report is submitted to the assistant chief therapist who transcribes paper reports into SaILS. Note that physicists, dosimetrists, oncologists, or whomever else with login rights to SaILS may also submit reports directly to SaILS without filling a paper form. In either case, an investigator must be assigned to successfully submit a report online. This approach was taken instead of triaging incidents in effort to prevent incidents from remaining uninvestigated, at least at a cursory initial level, for long periods of time.

The investigator is responsible for elucidating further details on the incident within the NSIR-RT framework. This includes establishing the underlying problem and contributing factors, identifying safety barriers that failed to prevent the incident as well as those that were successful, and categorizing the overall impact to the patient for actual incidents. The investigator may also choose to flag the incident for discussion at the next RMC meeting. Some incidents additionally require ameliorating actions, actions to reduce further risk, or follow-up actions to be tasked to an individual in the department.

The rationale for maintaining a paper component in the incident learning process was motivated by the technical coordinators and assistant chief RTT who identified the handoff process between the reporter and coordinator receiving the report as a point of useful discussion. A new paper incident report form was developed that matches the SaILS incident report page, and includes a unique ID and receipt to allow RTTs to track the status of the corresponding investigation online. An example paper form is shown in Fig. 3.4.

[1] Technical coordinators are senior radiation therapists who oversee workflow in the radiotherapy clinic and liaise between RTTs and the other staffing groups.



Centre universitaire de santé McGill — McGill University Health Centre

RADIATION ONCOLOGY EVENT REPORT #1

Event Type (Please choose one)	☐ **Reportable circumstance**: a hazard not involving a patient
	☐ **Near miss**: an incident that was detected before reaching a patient
	☐ **Actual incident**: an incident that has reached one or more patients

For actual incidents and near misses please fill out the following fields

Patient ID/Name		**Diagnosis**	
Oncologist		**Treatment Site**	

For ALL events please fill out the following fields

# of Patients Affected		**Date Event Detected**	
Functional Work Area (e.g. TB_1, brachy)		**Time Event Detected**	

Description of Event (Please avoid judgement, analysis, or accusation)

Reported By		**Date of Report** (If different than Date Event Detected)	
Reported To			

Patient Support

Patient Support Required (Y/N)		**Patient Support Given (Y/N)**	

Patient Support Description (Please describe the support given or requested)

Please Tear Here

Event Tracking and Follow-up	**Event Descriptor**
From within the hospital network, go to http://medphys. Click on *Safety Incident Learning System (SaILS)*. Enter ID (#1) and click *Search*. Please allow a few days for the incident to be uploaded to the electronic database.	Keywords to help you remember event:

Figure 3.4: Example paper incident report form deployed alongside the NSIR-RT version of SaILS in January 2016. Each form has a unique ID number and receipt to allow individuals who submit a paper report to later follow-up on the status of the corresponding investigation online. Each form is watermarked with "Do Not Photocopy".

Additionally, fields that allow reporters to indicate need for patient support are included in the form (staff support is also included on the reverse side of the form, which is filled out by a technical coordinator when necessary). Inclusion of fields that reflect the need for staff support services was motivated by the success of the RISE program at Johns Hopkins Hospital in supporting second victims in radiotherapy [37].

3.4 – The Safety Incident Learning System Software Product

3.4.1 – Overview of Core Features

SaILS is a multipage website, the pages of which are dedicated to particular electronic components of the incident learning workflow. A page for reporting incidents, uniquely-generated investigation and feedback pages for each incident, and an incident plotting and trending toolkit are the core components of the software. Each of these will be discussed in turn in the following sections.

An email notification framework is used to convey responsibility and feedback to staff who use SaILS. Each SaILS user has a unique username and password associated with their McGill or MUHC email address. All physicists, radiation oncologists, and dosimetrists were provided with unique login credentials. The chief and assistant chief RTT, all radiotherapy technical coordinators, and the head nurse of the Cedars Cancer Centre were also given login credentials. Any user who is logged-in can view a personalized dashboard that lists all ongoing investigations or actions for which he/she is responsible.

The RTTs in the department do not have institutional email addresses. To prevent confidential incident information from being circulated on external email clients, RTTs were not provided with login credentials for SaILS. As a result, the summary pages, report page, and plotting toolkit of SaILS are all accessible anonymously whereas investigations and dashboards are only accessible if users are logged-in.

User tutorials that describe how to report and investigate incidents were written and published on the internal departmental document management system, DepDocs. Links to the appropriate tutorial are provided on the report and investigation page.

3.4.2 – Incident Report Page

The incident report page of SaILS was designed to be fully compatible with the paper report forms mentioned in Section 3.3. A screenshot of the report page is shown in Fig. 3.5. The first form field, *Type of Report*, allows users to indicate whether the report was transcribed from a paper report or was submitted online directly. If transcribed from a paper report, an additional field is provided

for the user to input the unique paper form ID. Otherwise, an ID is assigned automatically and presented to the user upon successful submission of the report.

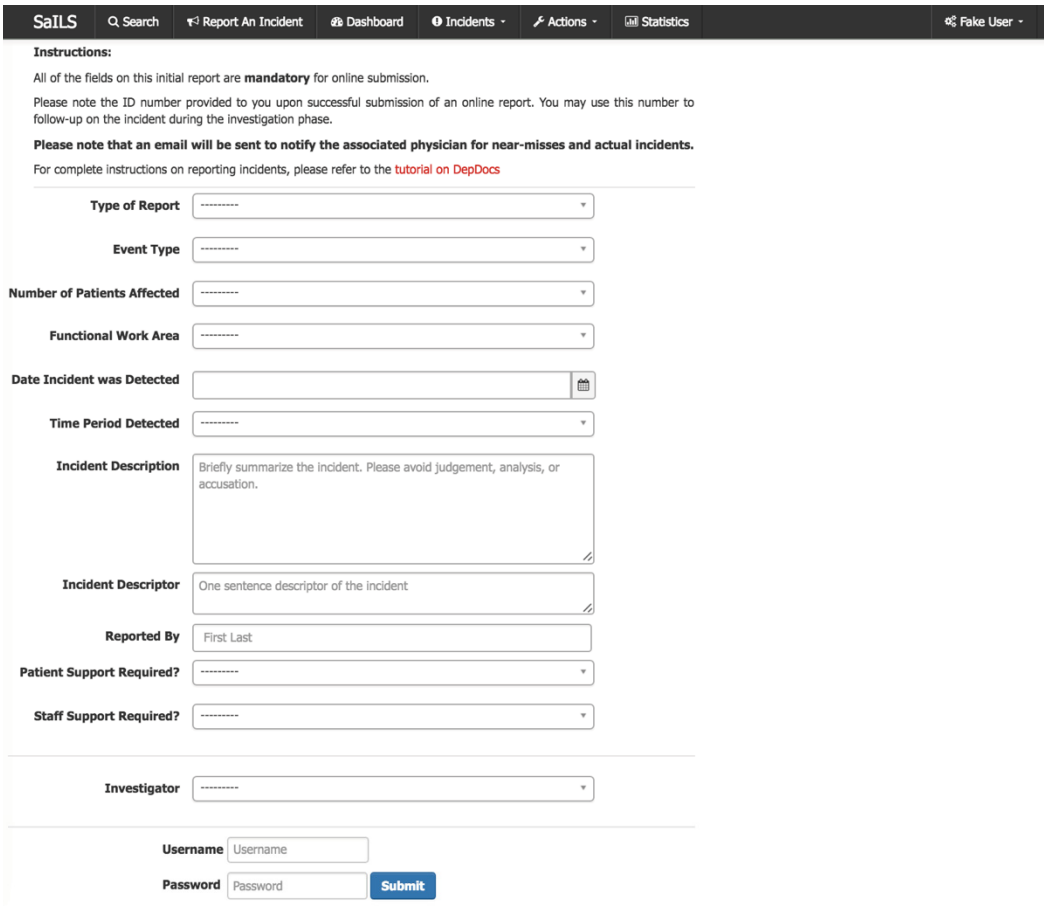


Figure 3.5: Online incident report page of SaILS. Fields are analogous to those on the paper forms, an example of which was shown in Fig. 3.4.

Additional form fields are displayed conditionally dependent on the *Event Type* field. For actual incidents and near-misses, these fields include the patient ID number, diagnosis, treatment site, and treating radiation oncologist. The oncologist is notified via email whenever an incident report involving one of his/her patients is submitted.

An investigator must be designated in order to complete an electronic report submission. A default investigator is suggested based on the role of the currently logged-in user (i.e. dosimetrist vs. radiation oncologist, etc.). All physicists, as well as the chief and assistant chief RTT, technical coordinators, head nurse, and chief radiation oncologist may serve as investigators. The user may

choose to assign any of these individuals as the investigator, who will be notified via email once the report has been submitted.

3.4.3 – Incident Investigation Page

A screenshot depicting a sample investigation page for a fake incident is shown in Fig. 3.6, and the main features of these pages are described below. Many supplementary investigative features, often conceived at RMC meetings, were added in the months following clinical deployment and will be discussed in Section 3.5.

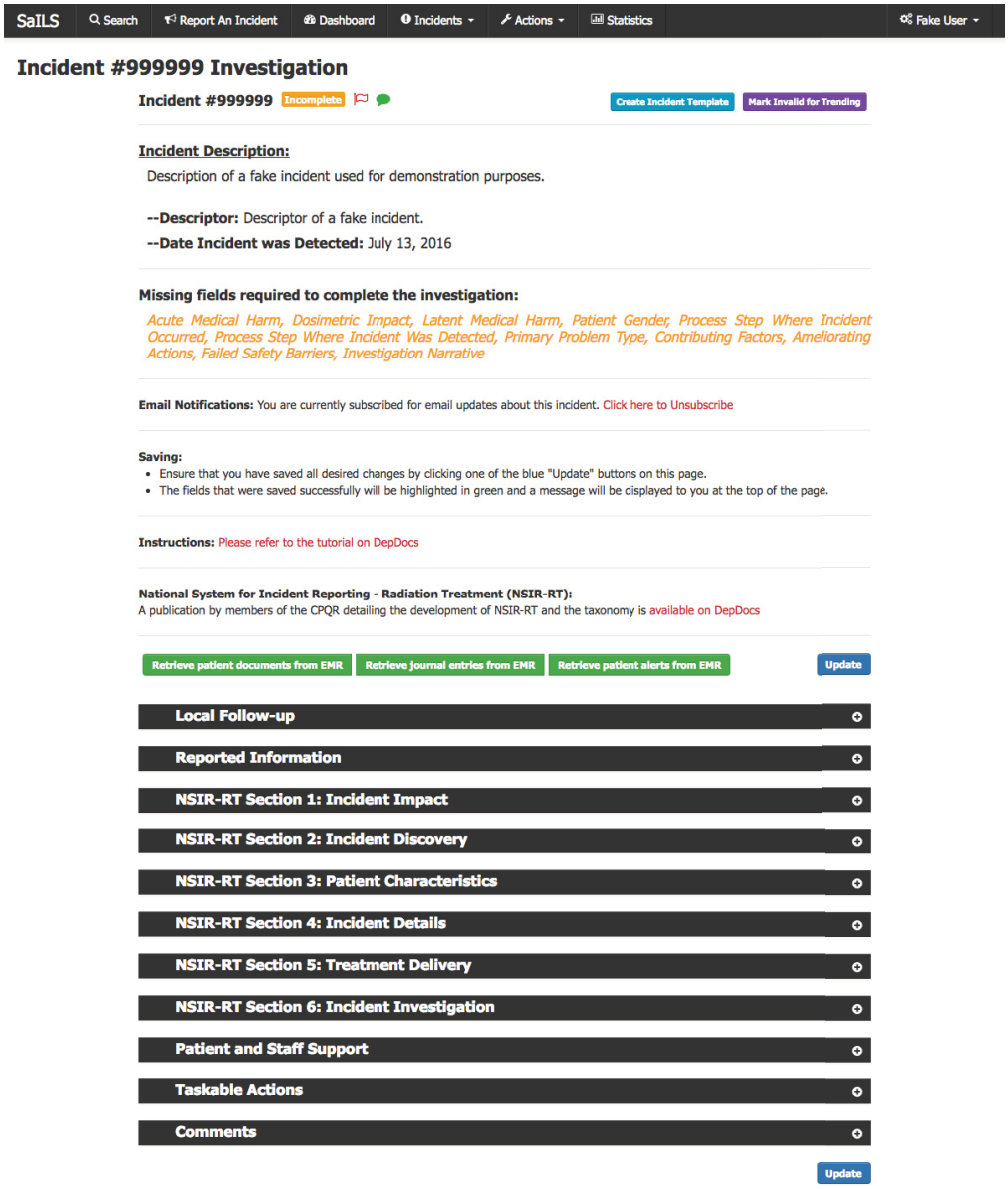


Figure 3.6: Example investigation page of SaILS. Clicking on any of the section headers (shown in black) will reveal form fields to be filled out in the investigation. By default, most fields are displayed upon opening the page.

The fields to be filled during the investigation are distributed under various section headers as shown in Fig. 3.6. NSIR-RT fields are grouped by the six domains promulgated in the NSIR-RT MDS. By way of example, a screenshot of the expanded *NSIR-RT Section 1: Incident Impact* is shown in Fig. 3.7. Most fields that were filled in the initial incident report are included under the *Reported Information* header and are immutable, but the event type may be changed using the link shown in Fig. 3.7 to allow for misconceptions in the initial report.

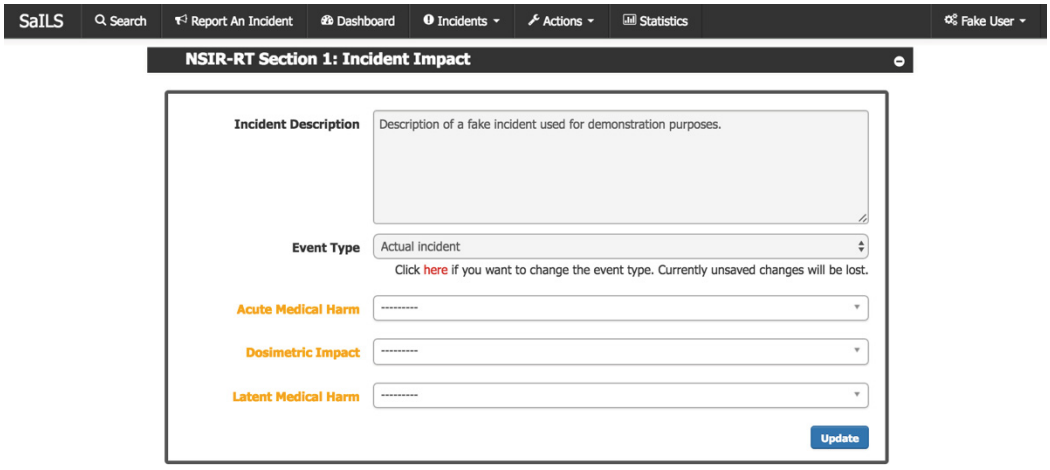


Figure 3.7: Example expanded section of the SaILS investigation form containing fields from the *Incident Impact* domain defined in the NSIR-RT MDS. The investigator may change the event type by clicking on the link provided. They will be required to supply additional information to justify the change.

Mandatory fields that have yet to be filled are listed near the top of the investigation page as shown in Fig. 3.6 and are highlighted in orange throughout the investigation form as shown in Fig. 3.7. The list and field highlights are updated dynamically as field values are saved. Which fields are mandatory is dependent on the event type, as defined in the NSIR-RT MDS [34]. The investigation is registered as complete once all mandatory fields have been filled, or the investigator may close an investigation if it is deemed as invalid. The invalid-incident feature is accessible via the purple button shown in Fig. 3.6 and requires the investigator to provide justification for closing the investigation as such. An example investigation that was closed using this feature was for an incident that described a delivered treatment fraction in which the couch was rotated less than 1.0 degree from the intended angle. The treatment was delivered correctly as planned and the incident report was due to a misunderstanding. Events closed as invalid are not included in any graphical or trending analysis.

The investigation can only be modified by the currently-assigned investigator. However, other logged-in users can flag an incident for discussion at the next RMC meeting, post comments, or create a “taskable action” (these are described in Section 3.5.4). The investigator may also reassign the investigation to another user, if appropriate.

3.4.4 – Incident Summaries

An example summary page for a fake incident is shown as it would appear immediately after being submitted to SaILS in Fig. 3.8. Summary pages allow frontline staff to follow-up on incident reports and review outcomes or actions that took place as a result, but do not include the name of the individual who reported the incident to provide confidentiality.

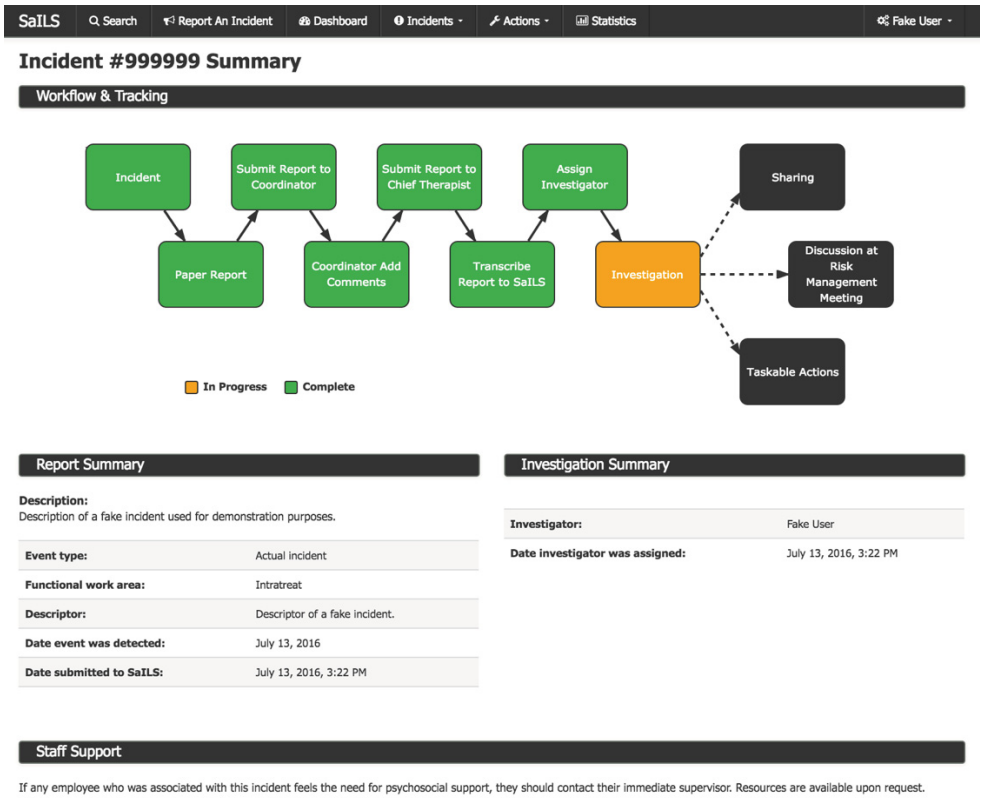


Figure 3.8: An example summary page of SaILS for a fake incident. This page is updated automatically as the investigation is completed.

The flowchart included on the summary page depicts the incident learning workflow presented in Fig. 3.3. Steps that have been completed are green, steps that are ongoing are orange, and steps that have not yet been addressed are black. This diagram will update automatically as the investigation progresses. For example, if the incident is flagged for discussion at the next RMC meeting, the corresponding block will be shown in orange. Additionally, key fields from the investigation will be added to the table under the *Investigation Summary* header as they are filled out. All specific actions that have been tasked to staff members as a result of the corresponding incident are also listed under *Taskable Actions*. An example of a summary page for an incident

with a complete investigation is shown in Fig. 3.9. Note that the *Sharing* component depicted in the flowchart of Fig. 3.8 and Fig. 3.9 is currently a placeholder that will be updated once SaILS allows batch upload of incidents to the national registry.

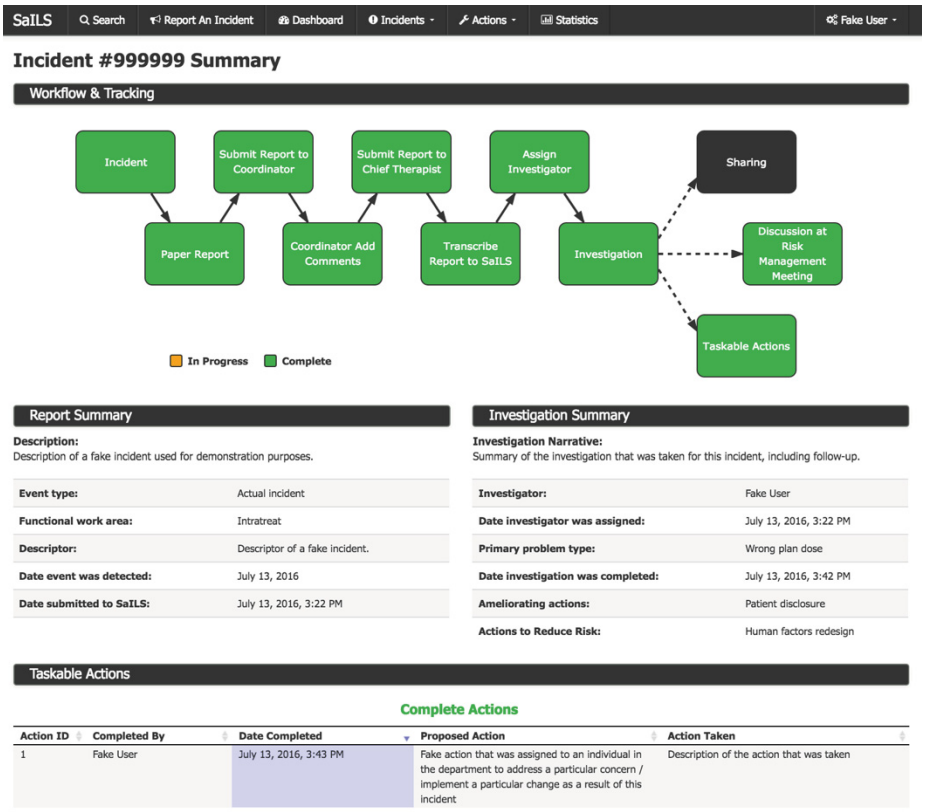


Figure 3.9: An example summary page of SaILS for a fake incident, for which the investigation is complete. Key fields from the investigation are included under the *Investigation Summary* header. The flowchart is updated to reflect the outcomes of the investigation. All actions that arose as a result of the investigation are listed and described.

3.4.5 – Incident Plotting Toolkit

The final core component of the NSIR-RT compatible version of SaILS is the incident plotting toolkit, which was designed to allow users to plot incident data sorted by any select-type data element in the NSIR-RT taxonomy. Three types of plots may be produced; column charts, pie charts, and stacked column charts (for incident trending). Users may select a monthly or yearly range from which all valid incidents will be plotted and may additionally choose to filter incidents by completion status. A simple online form was created to allow users to quickly specify plotting parameters, and is shown in Fig. 3.10.

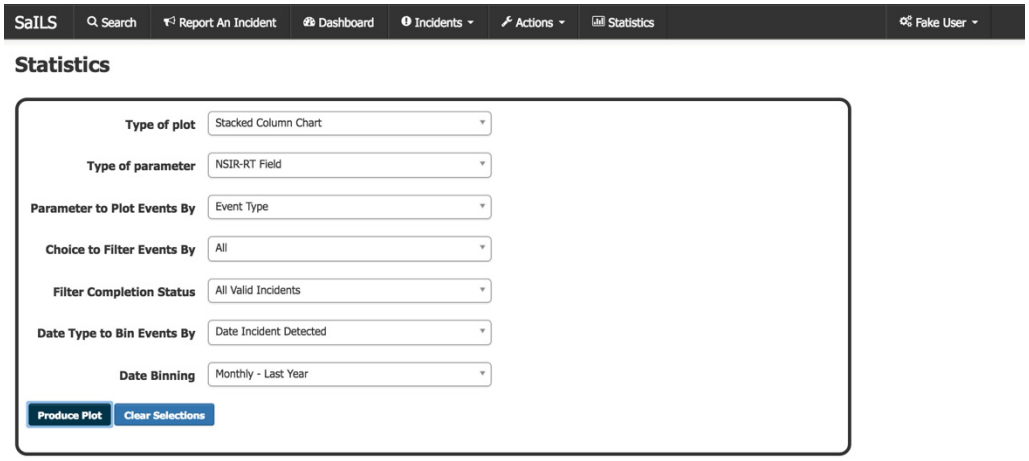


Figure 3.10: Example of a form on the *Statistics* page of SaILS. This form is used to generate plots of incident data.

The *Highcharts* JavaScript library was used to generate interactive plots. An example plot depicting trends in event type for fake incident data is shown in Fig. 3.11. Clicking on any chart element will produce a table that lists all incidents comprising that element, and is also depicted in Fig. 3.11. Multiple plots may be produced within the same page, and are displayed sequentially below the form.

This toolkit is conducive to performing aggregate analysis of incidents with common features, including severity, contributing factors, failed safety barriers, etc. An overview of multi-incident analysis methodology is included in the Canadian Incident Analysis Framework published by CPSI in 2012 [23]. The goal of multi-incident analysis is to identify patterns or trends in similar incidents that may not be evident for a single incident, and to subsequently take action to prevent similar incidents from occurring in the future. Plots produced using this toolkit, and trends among incidents composing each piece of a plot, were evaluated to identify issues in the radiotherapy workflow in the department. These findings will be presented in the next chapter.

Figure 3.11: Example plot generated using the statistics toolkit of SaILS, depicting fake incident data. The plot corresponds to form field inputs specified in Fig. 3.10. The column for reportable circumstances reported in March was clicked to produce the table of incidents shown beneath the plot. Links to each corresponding investigation are provided.

3.5 – SaILS Workflow Optimization Features

3.5.1 – Motivation for Feature Implementation

Following the clinical deployment of SaILS, it was found that fully categorizing incidents within the extensive NSIR-RT framework demanded significant time investment. Much of the literature on radiotherapy incident learning emphasizes the need for sufficient resources and positive culture for an ILS to be successful, as discussed in the previous chapter. Incident investigators burdened with substantial amounts of incident data were found to be less likely to complete investigations in a timely manner. Thus, workflow optimization features were developed, often based on recommendations by members of the RMC, to improve the user experience and quicken

turnaround time on completion of investigations. The most notable features that were implemented are each briefly discussed in the following sections.

3.5.2 – Link to Electronic Medical Record

Interfacing an ILS with the patient electronic medical record (EMR) allows retrieval of existing data and eliminates the need for such data to be re-entered into the ILS. Mutic and Brame, and Gabriel et al. have described success in implementing such a link to their EMR [31] [33]. In both cases, they used the patient ID number submitted with an incident report to retrieve additional patient specific information such as age and gender.

A series of PHP scripts were prepared to query the departmental EMR; *Varian's ARIA® oncology information system* (v. 11) using the patient ID already provided. Five green buttons on the investigation page (three of which are shown in Fig. 3.6) each call a PHP script to perform one of the following functions:

1. Auto-populate all fields within the Patient Characteristics domain of the NSIR-RT taxonomy.
2. List all treatment courses and plans within those courses. Several parameters relevant to the NSIR-RT taxonomy are listed for each plan including plan name, number of factions, and total prescribed dose.
3. List all treatment documents and provide links to open each, in-browser.
4. List all journal entries.
5. List all treatment alerts.

The latter three buttons were incorporated to allow quick access to potentially relevant treatment information and reduce the need to use additional software while investigating.

3.5.3 – Incident Templates

Mutic and Brame discussed the benefits of defining explicit events in an institutional ILS [31]. These are events that an institution is aware of, are often specific to a given institution, and should be tracked but may occur frequently and thus should be processed quickly. Such frequently occurring events were identified locally in the department within the first four months after SaILS was deployed. In particular, a few types of explicit events were reported in Dosimetry including

unclear/improper documentation and significant time pressure to produce plans due to late reception of prescriptions. To allow these types of events to continue to be investigated, so they may be aggregated and trended, without requiring significant processing time, the ability for investigators to create and use incident templates was added to SaILS.

To use the feature, SaILS users must first click on the teal *Create Incident Template* button near the top of the investigation page, shown in Fig. 3.6, to activate the template creation process. This will allow the user to enter a name and description of the template. All fields within the investigation form that will be saved in the template are highlighted in teal while the template creation tool is active, allowing investigators to review all such fields and enter values accordingly. Currently, all dropdown type fields may be saved in a template. Any field that should not have a template value assigned must be left blank, but may be filled and saved to the investigation once the template is created. Once the template has been saved, it may be applied to any future incident using a dropdown menu.

3.5.4 – Taskable Actions

As previously indicated, investigators often wished to task another staff member with a specific action as a result of an incident investigation. This led to the development of "taskable actions", which are included at the bottom of the investigation page for each incident. A user can describe the action they wish to be taken, and assign an individual who is responsible for carrying it out. Once the action has been taken, the user who completed the action should return to SaILS to mark the action as complete and explain how they carried out the task. Any number of actions may be created for a single investigation.

3.5.5 – Automatic Investigation Reminders

Several investigators noted their tendency to forget about pending investigations they were responsible for due to numerous other obligations. The SaILS dashboard does list user-specific investigations but cannot communicate this information unless the webpage is visited. The idea for periodic and automatic reminders for incomplete investigations came about to address this deficiency.

An automated Python task for sending emails asynchronously (without requiring user input) was developed using three of the software libraries listed in Table 3.2. The task runs once per day to query all incomplete incidents in the database and check the date that the most recent investigation reminder was sent for each. If the date exceeds a defined threshold, a reminder is sent to the investigator. Currently an initial reminder is sent one week following assignment of an investigation and biweekly after that, but the frequency can be adjusted by SaILS admin users.

3.6 – Feedback on SaILS and Incident Learning

A survey consisting of nine questions was created to evaluate RTT perceptions of SaILS and incident learning in general at the MUHC Department of Radiation Oncology, and is provided in the Appendix of this thesis. To summarize, six questions were framed around participants' awareness, engagement, and appreciation of the system. One question asked respondents to rank on a scale of 1 to 10 how well they believed the department could learn from incidents and make positive system changes. Another question asked if respondents would like to receive periodic newsletters that detail specific incidents and actions that have been taken to address issues raised by incidents. The final question allowed respondents to provide recommendations for changes to the ILS.

Feedback from members of the RMC and incident investigators was gathered informally throughout the entire SaILS development process and incorporated into design changes and feature additions. Quantitative metrics used to evaluate use of some of the workflow optimization features that were presented in Section 3.5, will be discussed in the Results and Discussion chapters

3.7 – Validation of the NSIR-RT Taxonomy

Analysis of radiotherapy incident data submitted to SaILS over the first six months of clinical use revealed a number of interesting findings. Among these was frequent use of the choice *Other* for certain data elements among the thirteen elements allowing *Other* to be selected, which hindered the ability to glean meaningful information from incident trends. Frequent use of *Other* choices was not limited to the initial months following deployment of SaILS and thus cannot be explained by lack of familiarity with the taxonomy. A similar observation was made by CIHI regarding

incident data submitted to the NSIR-RT pilot program, and was communicated to the author during a conversation about NSIR-RT data. This trend, common to both datasets, implied that there may be deficiencies in the NSIR-RT taxonomy. An analysis of incident trends in both SaILS and the NSIR-RT pilot system, and qualitative evaluation of specific incidents reported to SaILS was thus undertaken. The goal of this analysis was to provide recommendations on the NSIR-RT taxonomy to reduce the number of incidents with *Other* selected.

Regarding the use of CIHI's NSIR-RT pilot data, MUHC signed a service agreement with CIHI on April 4th, 2016 to allow participation in the NSIR-RT pilot. This agreement permitted the author to perform aggregate analysis on anonymized and de-identified incident data submitted to the NSIR-RT pilot system, and will allow the MUHC to contribute incident data to the pilot system. Explicit confirmation that it was acceptable to publish aggregate analysis of incidents submitted to the pilot system, for the purposes of evaluating the NSIR-RT taxonomy was also obtained for this thesis through direct communication with CIHI.

An *Other-event* was defined as any incident that was reported with at least one field filled using the *Other* option. A Python script was developed to query the SaILS database for all investigation-complete *Other-events* and to process the results. The input of the *Incident Description* field, which is a free-text field, for all *Other-events* was parsed into an array of words. The array was filtered to remove any repeated words in a single incident description (ignoring letter casing), in order prevent biasing frequencies towards words that were repeated many times in a single description. All arrays were then merged into a single array of words representing all the *Other-events*.

A similar approach was taken for incident data reported to the NSIR-RT pilot system, although the national database is not available for direct queries by external users. Thus, the analysis tool built into the pilot system was used to export spreadsheet files containing all *Other-events* for each data element separately. The files were combined, and duplicate incidents were removed (i.e. to account for incidents with multiple data elements completed using *Other*). The combined file was then also processed with a similar Python script to that described previously, resulting in a second array of words representing the NSIR-RT pilot data.

Both arrays were merged and a word frequency analysis was performed on the combined array using the Python Natural Language Toolkit (v. 3.0). Common "stopwords" such as "the", "and", and "it" were ignored. Words that occurred in more than 10% of *Other-events* were identified and their frequency plotted on a histogram.

The remaining incidents in both the SaILS and NSIR-RT pilot database (i.e. those without *Other* selected for any data element) were similarly aggregated and used to establish a control group. Words that occurred in at least 10% of *Other-events* were compared with the frequency of occurrence of the same word in the control group. The difference in occurrence frequency was also plotted on a histogram to determine which words were relatively more common in *Other-events* compared to the control group.

This entire analysis was repeated for just the incidents with *Other* selected for the *Primary Problem Type* data element. *Primary Problem Type* was selected for this additional analysis because it was the data element with the most *Other* selections in both the SaILS and NSIR-RT pilot databases.

Chapter 4 – Results

The NSIR-RT compatible version of SaILS was deployed in the Department of Radiation Oncology at the Cedars Cancer Centre of the MUHC in January 2016. During the first six months of clinical use, from January 2016 until the end of June 2016, 110 incidents were detected and reported using the system. Table 4.1 provides the numbers of valid incidents, investigation-complete incidents, and invalid incidents.

Table 4.1. Summary of incident reports submitted to SaILS between January and the end of June, 2016.

Category	Number of Incident Reports
Number of valid incident reports	91
Number of investigations completed	75
Number of invalid incident reports	19

This chapter reports on the experience that was gained by using SaILS to handle these 110 incident reports. It begins with a detailed study of the data themselves in an attempt to elucidate any underlying trends or causes that might be used to learn how to reduce the occurrence of future incidents. It then examines the utility of the workflow optimization changes that were introduced to SaILS before evaluating the user experiences, as captured by the RTT survey discussed in the previous chapter. The chapter concludes with an analysis of the *Other* incident data that were obtained locally using SaILS and nationally by the NSIR-RT pilot program.

Throughout this chapter various graphical distributions and trend plots are used to describe the incident data that were collected. The number of incidents included in each distribution or trend is provided in the corresponding caption. The number of incidents varies with data element because some elements are not filled-in until the investigation phase (and thus have not yet been provided for incomplete incidents), some elements are not applicable for certain event types, and some elements are not mandatory in the NSIR-RT taxonomy.

4.1 – High Level Results

As of June 30th 2016, there were 44 user profiles in SaILS; 23 of which had recorded activity. The distribution of users by role within the department is shown in Table 4.2. All clinical medical physicists, dosimetrists, and radiation oncologists were provided with login credentials and are thus included in Table 4.2. The RTTs included in Table 4.2 consist of the chief RTT, assistant chief RTT, and the three technical coordinators.

Table 4.2. Distribution of SaILS users by departmental role.

Role	Number of Users
Dosimetrist	9
Medical Physicist	13
Oncology Nurse	1
Radiation Oncologist	14
Radiation Therapist	5
SaILS Administrator	2
Total	**44**

The distribution of incidents by event type (as defined in Table 2.1), reported between January and the end of June 2016, is shown in Table 4.3. These data are broken down by month the incident was detected in Fig. 4.1. It was found that approximately two thirds of reported incidents were deemed to be actual incidents. However, as is clear from Fig. 4.1, the proportions of near-misses and reportable circumstances were notably increased in the last two months, May and June. Possible explanations for this are discussed in the next chapter.

Table 4.3. Distribution of valid incidents by event type (n=91).

Event type	Number of incidents	Percentage of incidents (%)
Reportable circumstance	23	65.9
Near miss	8	25.3
Actual incident	60	8.8

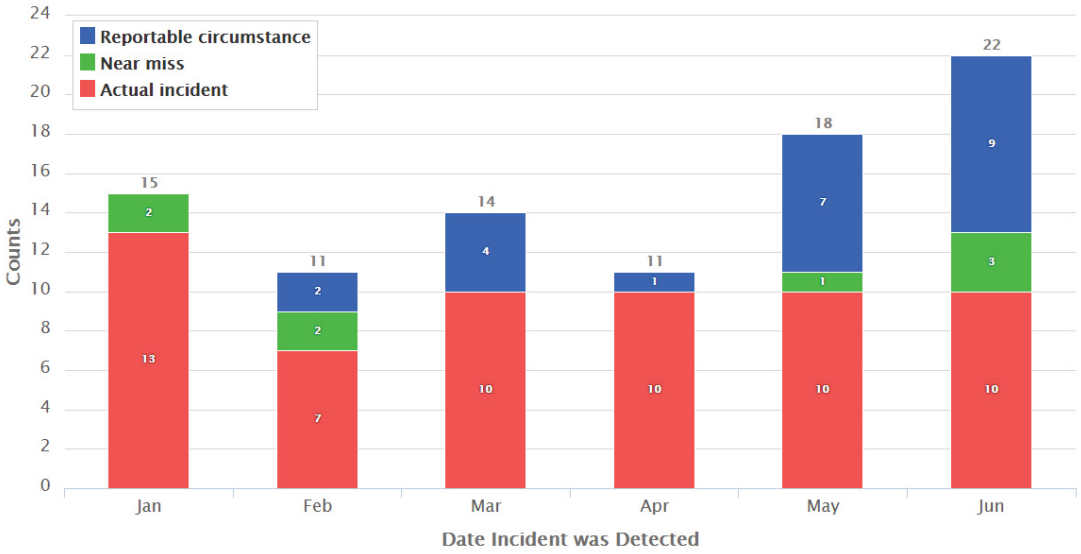


Figure 4.1: Number of valid incidents reported per month sorted by event type (n=91).

The severities of investigation-complete actual incidents, as characterized by three pertinent NSIR-RT data elements, *Acute Medical Harm, Dosimetric Impact,* and *Latent Medical Harm*, are shown in Table 4.4. The full definition for each level of severity may be found in the NSIR-RT MDS [34].

Table 4.4. Severity of actual incidents investigated using SaILS (n=49).

Acute Medical Harm		*Dosimetric Impact*		*Latent Medical Harm*	
Grade	Count	Grade	Count	Grade	Count
None	47	None	44	No	35
Minor	2	Minor	4	Unknown	13
Moderate	0	Moderate	1	Yes	1
Severe	0	Severe	0		
Death	0				

It was found that 54.7% of actual incidents and near-misses involved female patients compared to 45.3% for male patients. These results are consistent with the slightly higher proportion of female patients (52.2%) compared to male patients (47.8%) treated in the department. An SQL query to the departmental electronic medical record database also revealed that approximately 16% of radiotherapy patients are treated for breast cancer, which is similar to the reported 20.3% of

incidents pertaining to patients with a breast cancer diagnosis. Further investigation of the correlation between the proportion of patients treated for a particular disease and proportion of incident reports affiliated with the same disease is envisaged in a future study.

Also with regards to diagnosis, it was found that three incidents that involved patients being treated for metastases of either a malignant neoplasm of the breast or lung were assigned *Other* for the *Patient Diagnosis* data element. A modification to the NSIR-RT taxonomy to better allow classification of treatment of metastatic disease without the need for a *Patient Diagnosis: Other* option is presented in the following chapter.

4.2 – Incident Distributions and Trends

The incident plotting and trending toolkit discussed in Section 3.4.5 facilitated generation of plots for all select-type data elements in the NSIR-RT taxonomy. Each data element was plotted to examine incident distribution among the available choices, as well as the number of incidents reported per month for each choice. Plots that demonstrated the most interesting findings are provided in this section. These results are distributed among three domains of the NSIR-RT taxonomy; *Incident Discovery, Incident Details,* and *Incident Investigation*.

4.2.1 – Incident Discovery

A plot showing the distribution of incident reports by functional working area is provided in Fig. 4.2. Reports were relatively evenly distributed across the six *Varian Truebeam*^{TM} linear accelerators (including two *STx* units). Combined, the *Truebeam* treatment units accounted for approximately 56% of incident reports. A significant portion of incidents were also reported in treatment planning and simulation (two CT simulators and an MRI simulator), accounting for 19% and 18% of reports respectively.

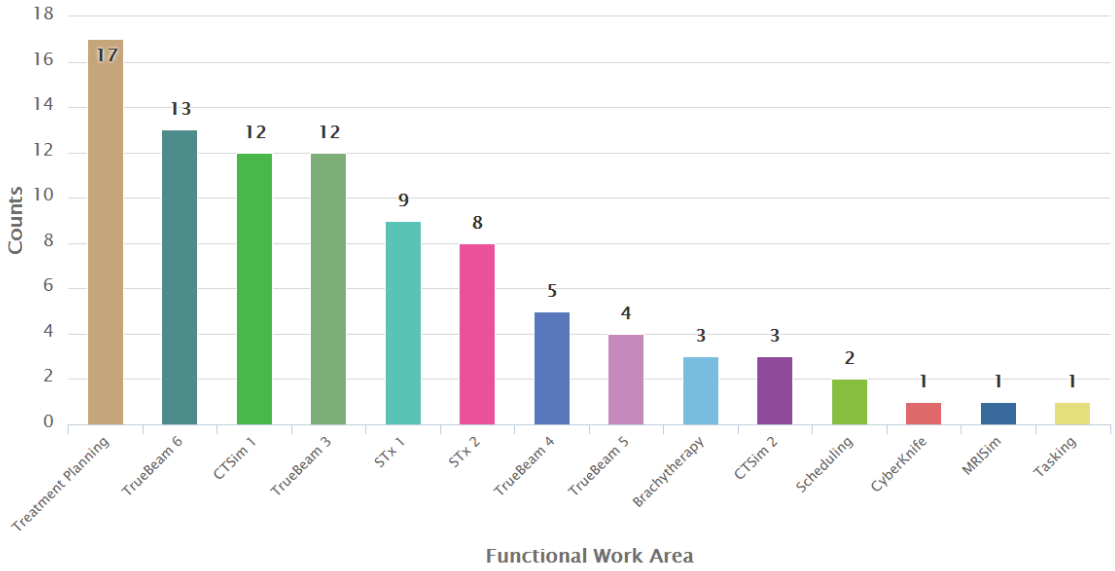


Figure 4.2: Number of incidents reported per functional work area (n=91).

The distribution of incidents for the *Time Period Incident was Detected* data element revealed that incident detection was evenly distributed across the working day (from 7:00AM to 6:00PM). The main finding from the distribution of *Time Period Incident Occurred* was that a value for this data element was only provided for 21 incidents (28% of investigation-complete incidents). For both data elements, the "Unknown" option was used frequently (23% and 14% respectively).

The distribution of number of incident reports by the type of individual who detected the incident is shown in Table 4.5. Approximately two thirds of incidents were detected by RTTs, and one third by dosimetrists. Two incidents were also reported by radiation oncologists. These findings are reflected in the distribution of the *Process Step where Incident was Detected* data element (not shown), where it was found that the majority of incidents (83%) were detected during treatment planning, pre-treatment review, treatment delivery, or imaging for RT planning.

Table 4.5. Distribution of individuals who detected incidents (n=56/75).

Individual classification	Number of incident reports	Percentage of incident reports (%)
Radiation therapist	39	69.6
Treatment planner or dosimetrist	15	26.8
Radiation oncologist	2	3.6

4.2.2 – Incident Details

Distributions for the *Process Step where Incident Occurred* data element and *Primary Problem Type* data element are shown in Fig. 4.3 and Fig. 4.4 respectively.

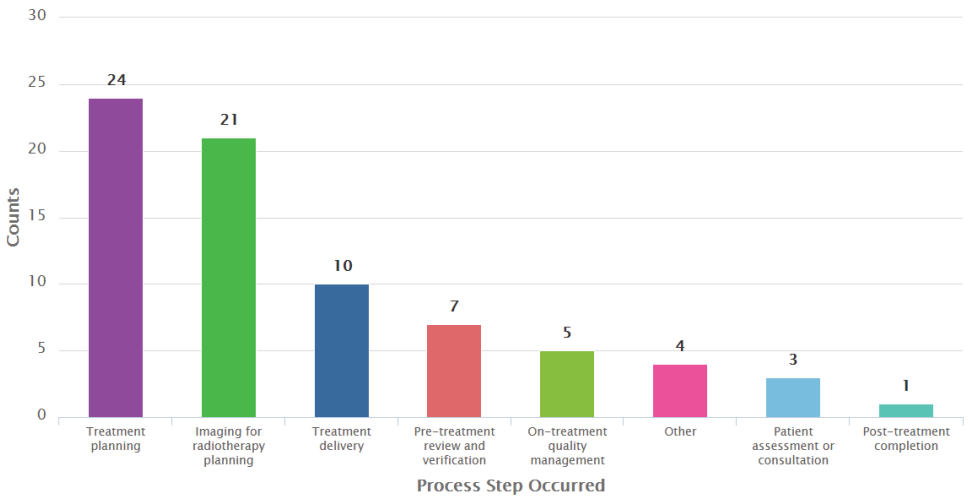


Figure 4.3: Distribution of incidents by the process step in which they occurred (n=75).

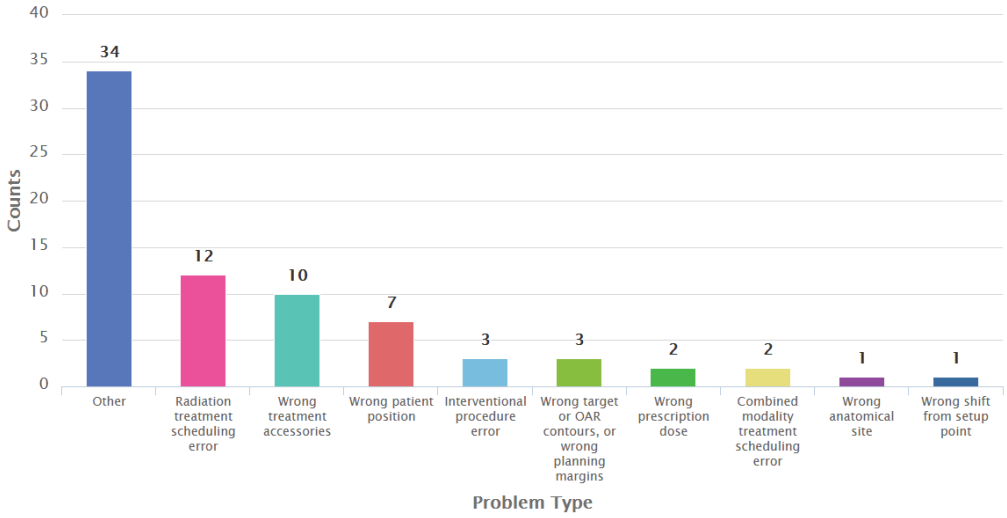


Figure 4.4: Distribution of incidents by the identified primary problem type (n=75).

Figure 4.3 shows that the two process steps that most frequently gave rise to incidents were treatment planning and imaging for radiotherapy planning. As shown in Fig. 4.4, the most frequent problem identified as having been responsible for an incident was *Other*, which accounts for

almost half of investigation-complete incidents. A trend plot of incidents that arose in imaging for radiotherapy planning or treatment planning was generated, shown in Fig. 4.5, to aid in determining if incidents that arose in these process steps were often assigned a problem type of *Other*. Complimentarily, a trend plot of incidents that were assigned a problem type of *Other* was also generated and is shown in Fig. 4.6.

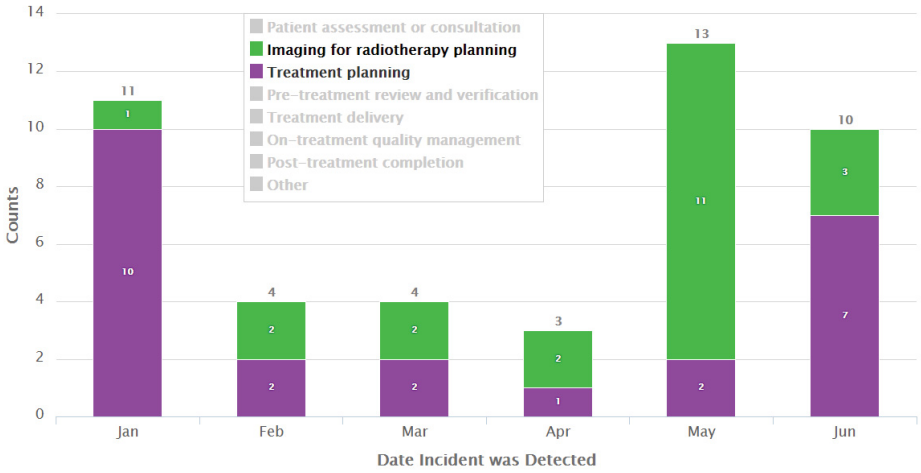


Figure 4.5: Number of incidents detected per month, that occurred during imaging for radiotherapy planning or treatment planning (n=45/75).

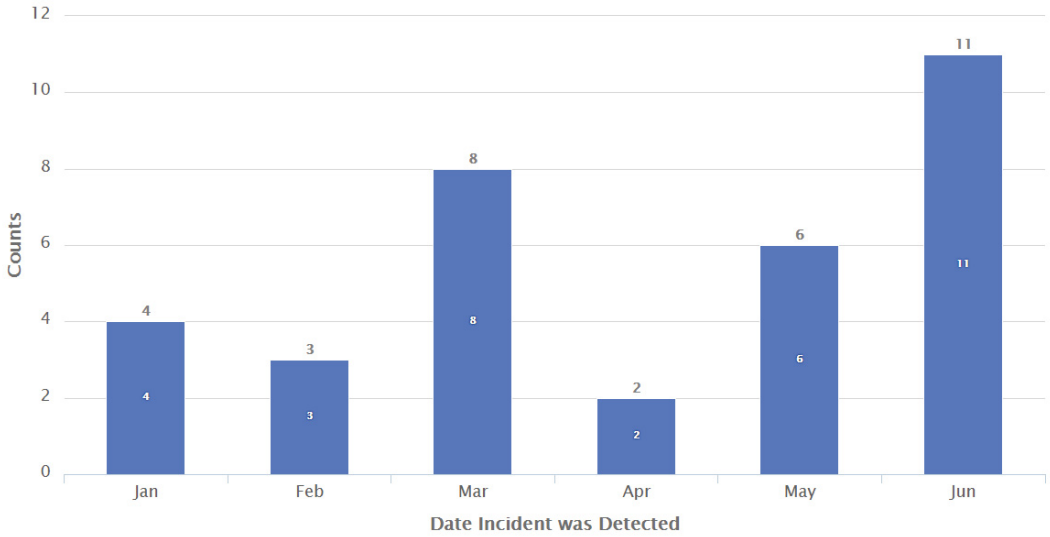


Figure 4.6: Number of incidents with *Primary Problem Type* identified as *Other*, sorted by the month the incident was detected (n=34/75).

All 14 incidents that arose during imaging in May and June were assigned a problem type of either *Other* or one of the scheduling error options. Also, all nine incidents that occurred in treatment planning during the same time period were assigned a problem type of either *Other* or *Wrong treatment accessories*. Combined, these account for 12 of 17 incidents that were reported with *Problem Type: Other* in May and June. Suggestions to reduce the number of incidents categorized with *Problem Type: Other* that occur during imaging and treatment planning are presented in the next chapter.

Finally, the factors identified as having contributed towards at least 5% of incidents are listed in Table 4.6. *Documentation poor, incomplete, unclear, or missing* was identified most frequently and attributed to 25% of incidents. Other frequently identified factors were related to human factors such as loss of attention, miscommunication, or failure to follow policy.

Table 4.6. Most frequently identified contributing factors and the percentage of incidents to which they were assigned (n=75). Multiple factors were permitted per incident.

Contributing factor	Percentage of incidents (%)
Documentation poor, incomplete, unclear or missing	25.0
Policy not followed	20.7
Loss of attention	15.2
Communication inappropriate or misdirected	8.7
Human resources inadequate	6.5
Human behaviour involving staff	6.5

4.2.3 – Incident Investigation

The breakdown of safety barriers that were identified as having failed for at least 5% of incidents with complete investigations are shown in Table 4.7. It is prudent to note that the NSIR-RT MDS categorizes safety barriers as either *Hardware/Software* related or *Process* related, and only *Process* related safety barriers were indicated as having failed for at least 5% of incidents. Several incidents were reported whereby bolus was forgotten to be placed for one or more treatment fractions, and partially constitute the relatively high proportion of incidents (14.7%) that were caused by failure to verify treatment accessories. Two additional treatment accessory-related incidents involved poorly-labeled vacuum cushions that are used to position patients during

simulation and treatment; one was found unlabeled before treatments began and the other could not be identified at the time of treatment. Actions are currently underway to address both of the accessory-related issues mentioned above, and will be discussed in the next chapter. Verification of relevant clinical information was the safety barrier that most frequently failed, and was typically associated with documentation errors (incorrect plan documentation, CT setup sheets, etc.).

Table 4.7. Safety barriers that were most frequently identified as having failed and the percentage of incidents for which they failed (n=75). Multiple failed safety barriers could be identified per incident.

Safety barrier	Percentage of incidents (%)
Verification of relevant clinical information	29.3
Verification of treatment accessories	14.7
Radiation therapist review of treatment plan	10.7
Verification of imaging data for planning	6.7
Review of portal or CBCT images	6.7
Physicist review of treatment plan	5.3

Finally, the ameliorating actions and actions to reduce further risk that were taken as a result of investigations were examined. Table 4.8, shown below, lists all actions of either type that were performed for at least 5% of incidents. Ameliorating actions are defined in the NSIR-RT taxonomy as actions taken to compensate or make better any harm after an incident, whereas actions to reduce risk are those that are implemented as a reaction to a certain incident to minimize future harm [34]. Notably, all of the actions taken for at least 5% of incidents are considered "soft" compared to "hard" actions such as new forcing functions, interlocks, etc. A discussion on the tendency and appropriateness for soft actions to be taken instead of hard actions is presented in the next chapter.

Table 4.8. Ameliorating actions and actions to reduce further risk that were most frequently assigned and the percentage of incidents they were assigned for (n=75). Multiple actions of either type could be assigned per incident.

Action type	Action	Percentage of incidents (%)
Ameliorating action	Education or training	49.3
	Staff debriefing or counselling	36.0
	Other	9.3
Action to reduce risk	Process standardization	25.3
	Improved compliance with existing policies or procedures	25.3
	Staff reminder(s)	21.3
	Reduce distraction(s)	18.7
	Reminder(s) or checklist(s)	14.7
	Additional education or training	10.7

4.3 – Utility of Workflow Optimization Features

4.3.1 – Template Usage

An education session that explained the use of the incident template feature was held with the two investigators who have completed the majority of investigations within SaILS (accounting for 74% of investigations completed). The templates created following this session and the number of times each was applied to a subsequent incident are shown in Fig. 4.7. Thus far, the majority of templates were created for actual incidents with no medical harm or near-misses that were reported in Dosimetry. The most frequently applied template, *Dosimetry – planning instructions unclear*, was used to categorize incidents detected in Dosimetry pertaining to improperly specified target volumes requiring replans and thus treatment delays. These events have not had direct medical impact on patients, but the treatment delays and potential negative effects on patient experience were noted.

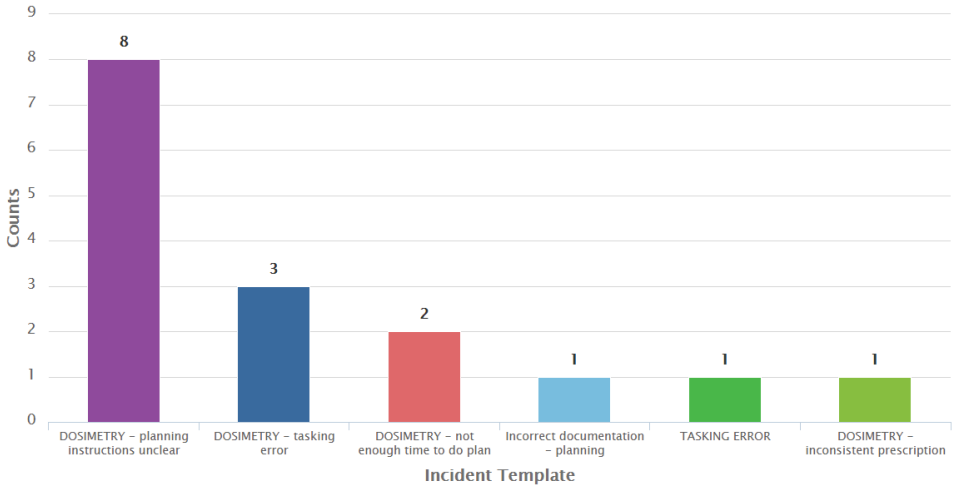


Figure 4.7: Incident templates created by investigators and the number of times used. Counts do not include the incident with which the template was created.

The time taken to complete investigations for incidents submitted near the date SaILS was deployed was compared against the time taken for incidents submitted in the more recent months. Because the workflow optimization features were added gradually over the months following the deployment of SaILS, quicker turnaround time on completion of investigations in the latter months could be used to gauge effectiveness of these features. A histogram is presented in Fig. 4.8 that shows the fraction of incidents that went uninvestigated for more than 30 days after being submitted to SaILS, sorted by the month they were submitted. Note that the date an incident was submitted is not necessarily the same as the date it was reported, if it was initially reported using a paper form. The number of incidents submitted per month is shown in the denominator of the data label above the corresponding column. A threshold of 30 days was chosen because the histogram was generated at the beginning of August. This way, all of the incidents submitted in June had been submitted more than 30 days ago and were thus subjected to the same evaluation criteria as incidents submitted in earlier months.

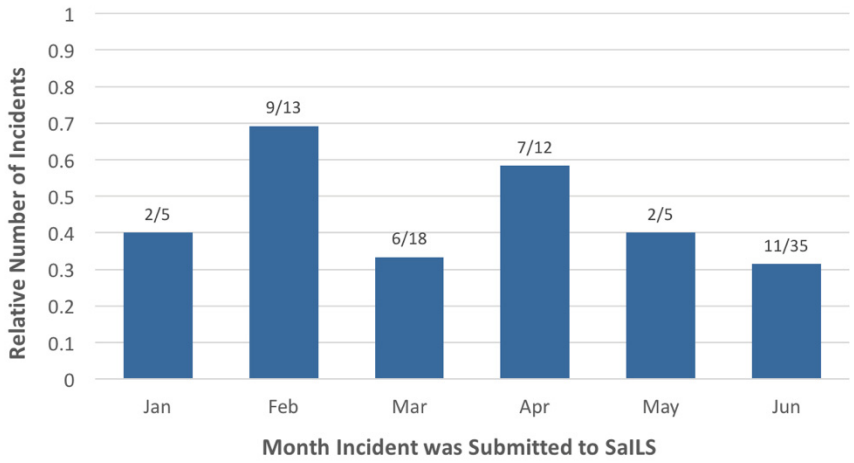


Figure 4.8: Relative number of incidents that took more than 30 days to complete the corresponding investigation after being submitted to SaILS, sorted by the month they were submitted. The data label above each column displays the number of incidents that were uninvestigated for more than 30 days out of the total number submitted that month.

4.3.2 – Tasked Actions

A total of 24 actions were created and tasked within SaILS from March (when the feature was introduced) until June of 2016. Twenty of these actions have been completed at the time of writing, in August 2016. An examination of the "taskable actions" revealed that they have been used primarily as a communication tool between members of the RMC. Several actions were assigned by the assistant chief RTT to one of the technical coordinators, requesting education or debriefing sessions with RTTs following certain incidents for which the learnings should be disseminated. Other actions have included tasks to develop checklists, to send reminders for proper completion of prescription documents, as well as to schedule meetings.

4.4 – Radiation Therapist Survey Results

Twenty-six of 37 radiation therapists employed at the Department of Radiation Oncology (including three technical coordinators and the assistant chief RTT) responded to the survey that was circulated, yielding a response rate of 70%. A copy of the survey is available in the Appendix. The five questions that prompted respondents for a yes or no answer, proportions of responses, and answer rates among respondents are provided in Table 4.9.

Table 4.9. Responses to Yes/No questions posed in the departmental incident reporting and learning survey of radiation therapists (n=26 out of 37).

Question (paraphrased)	Yes	No	Answer rate among survey respondents
Q1) Are you aware of the departmental incident reporting system?	100%	0%	100% (26)
Q2) Have you reported an incident in the last 6 months?	80%	20%	96% (25)
Q4) Have you used SaILS to follow-up on any incidents?	16%	84%	96% (25)
Q5) If yes to the previous question, have you found the feedback to be useful/informative?	40%	60%	19% (5)
Q8) Would you like to receive newsletters that highlight particular anonymized incidents and resulting actions?	100%	0%	85% (22)

All respondents were aware of the incident reporting system, and the majority had submitted a report within the last six months. However, 84% of responding RTTs had not used the feedback feature of SaILS, and the majority of those that had used it did not find the feedback useful. All respondents who answered question eight indicated that they would like to receive newsletters that present anonymized incidents and associated learning outcomes.

Additionally, regarding questions not summarized in Table 4.9, 87% of respondents who answered question three (answer rate 88%) indicated they prefer the new system, SaILS with revised paper form, over the previous system. Interestingly, 78% of respondents who answered question seven (answer rate 88%) indicated they would prefer to submit incident reports electronically instead of via paper forms. The responses obtained when participants were asked how well they believe (on a scale of 1 to 10) that the department can learn from incidents and make positive system changes are shown in Fig. 4.9. A rank of 10 indicated that the respondent felt that the department demonstrated the ability to learn from incidents, whereas a rank of 1 indicated they felt that the department was unable to learn from previous incidents. The answer rate was 92% and the average response was 5.7.

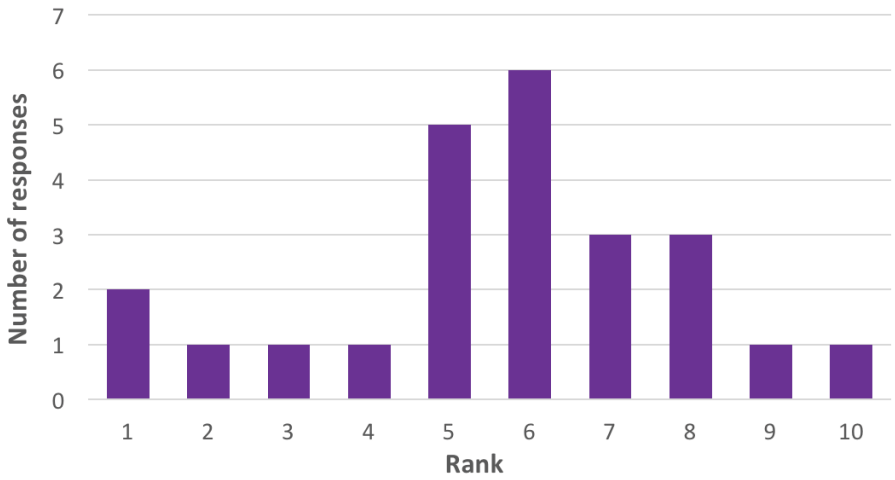


Figure 4.9: How well radiation therapists believe the department can learn from incidents and make positive system changes, on a scale from 1 to 10.

A few radiation therapists responded to the final question that probed for additional recommendations, or he/she provided comments alongside other questions in the survey. All responses indicated that the RTTs would like incidents to be discussed regularly at technical meetings in order to better disseminate learnings among staff.

4.5 – *Other-event* Analysis

4.5.1 – Aggregate Observations

The number of incidents that were characterized with at least one *Other* option, for incidents reported to SaILS and to the NSIR-RT pilot system are provided in Table 4.10. A breakdown of the relative number of incidents with *Other* selected for each pertinent data element in the NSIR-RT taxonomy for both systems is shown in Fig. 4.10. All 75 investigation-complete incidents submitted to SaILS between January and June 2016 were included in the analysis. Incident data from the NSIR-RT pilot system were gathered on June 3rd 2016, including all incidents submitted as far back as the launch of the system in September 2015.

Table 4.10. Prevalence of *Other-events* reported to SaILS and the NSIR-RT pilot system.

Parameter	SaILS	NSIR-RT pilot	Aggregate
Number of investigation-complete incidents	75	412	487
Number of *Other-events*	57	305	362
Percentage of *Other-events*	76%	74%	74%

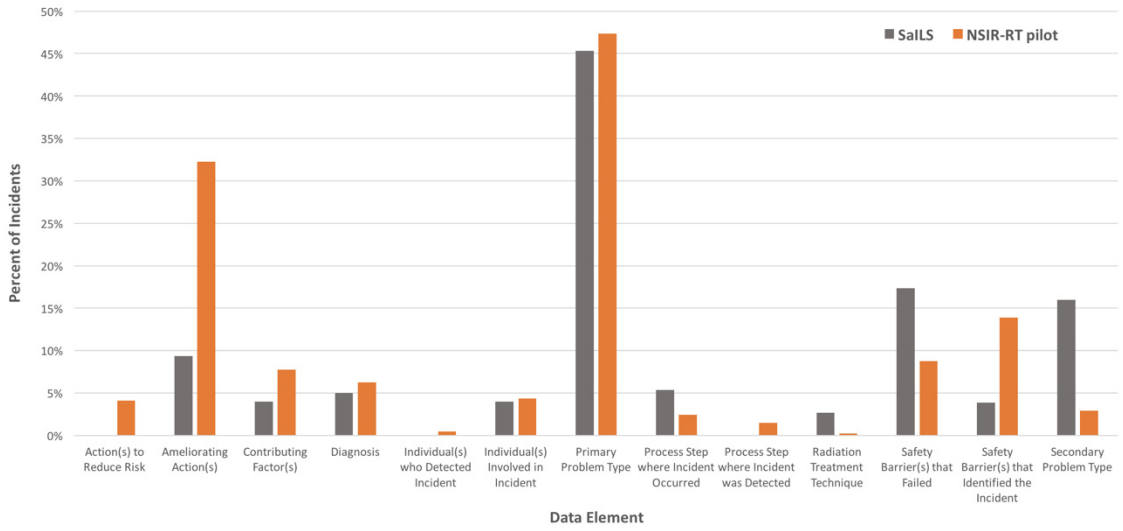


Figure 4.10: Relative number of incidents with *Other* selected by NSIR-RT data element. Incident counts for each data element were normalized by the total number of investigation-complete incidents reported to the corresponding ILS that included the data element.

4.5.2 – Word Frequency Analysis: *Other-events*

A histogram displaying words (excluding "stopwords") that occurred in at least 10% of *Other-events*, across both SaILS and the NSIR-RT pilot system, is shown in Fig. 4.11. There were 362 *Other-events* out of 487 total incidents, and the remaining 125 incidents were included in the control group. The difference in occurrence frequency for each word, between *Other-events* and the control group, is shown in Fig. 4.12 and an interpretation of these data is presented at the end of the next chapter.

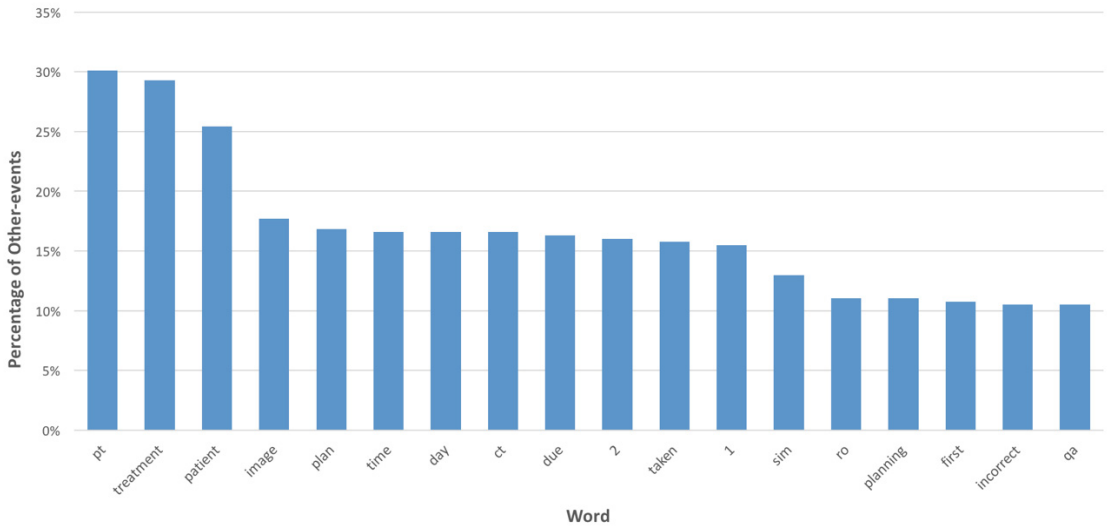


Figure 4.11: Occurrence frequency for words that occurred in at least 10% of *Other-events* reported to either SaILS or the NSIR-RT pilot system.

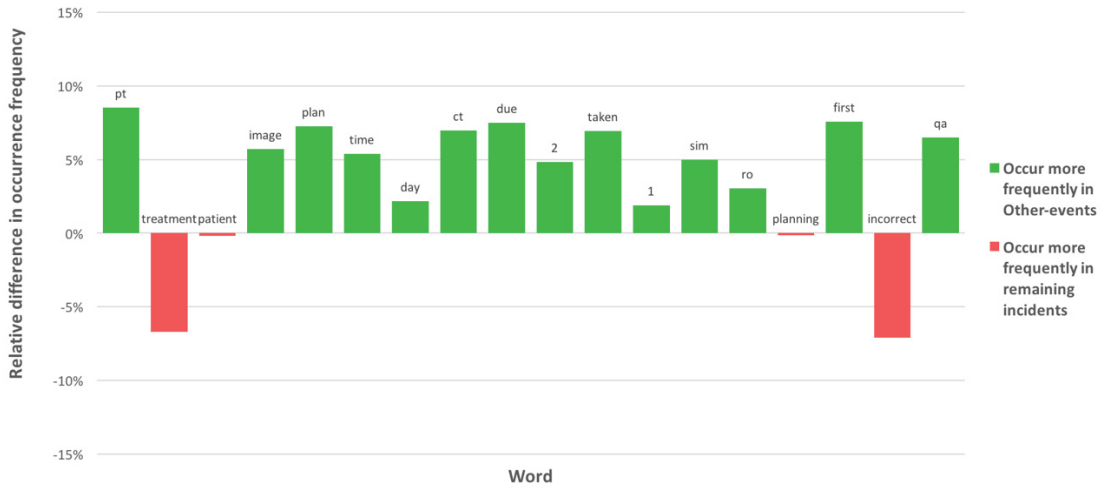


Figure 4.12: Difference in occurrence frequency for the most frequently occurred words among *Other-events*, compared to all remaining incidents. Differences shown in green correspond to words that occurred proportionally more frequently in *Other-events*, while those in red correspond to words that occurred more frequently in the remaining incidents.

4.5.3 – Word Frequency Analysis: Incidents with *Problem Type: Other*

Plots were generated equivalent to those presented in the previous section, but specifically for incidents with *Primary Problem Type: Other*, and with all remaining incidents in the control group. These plots are displayed in Fig. 4.13 and Fig. 4.14 below. There were 229 incidents with *Primary Problem Type: Other* and thus 258 incidents in the control group.

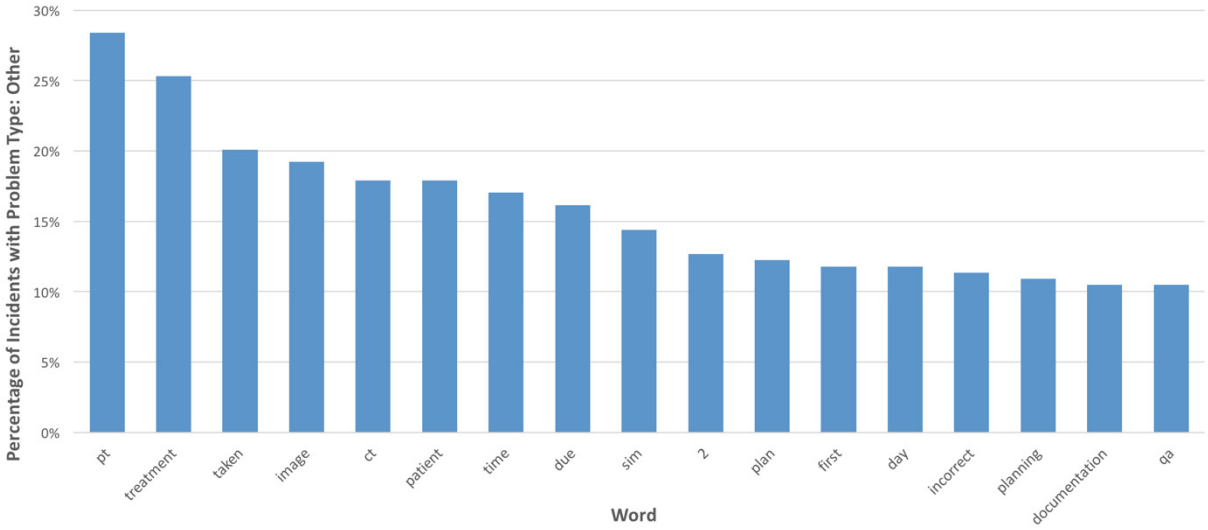


Figure 4.13: Occurrence frequency for words that occurred in at least 10% of incidents with *Problem Type: Other*, reported to either SaILS or the NSIR-RT pilot system.

Figure 4.14: Difference in occurrence frequency for the most frequently occurred words among incidents with *Problem Type: Other*, as compared to all remaining incidents. Differences shown in green correspond to words that occurred proportionally more frequently in incidents with *Problem Type: Other*, while those in red correspond to words that occurred more frequently in the remaining incidents.

Notably, the words "image", "ct", "sim", and "documentation" appeared at least 5% more frequently in incidents with *Primary Problem Type: Other*. These findings are discussed in relation to the findings depicted in Fig. 4.5 and 4.6 in the next chapter.

Chapter 5 – Discussion

A number of interesting findings were noted among the results presented in the previous chapter and will be discussed throughout this chapter. In Section 5.1 the types of incidents reported to SaILS will be analyzed, the effectiveness of the workflow optimization features will be evaluated, and several clinical outcomes of the system will be presented. The successes and ongoing challenges pertaining to staff engagement with the ILS and the departmental incident learning culture will be discussed in Section 5.2. As a significant component of the current work was to evaluate the NSIR-RT taxonomy through analysis of clinical incident data, recommendations to improve the taxonomy for future use are presented in Section 5.3 with accompanying rationale. Finally, a brief discussion on the applicability and role of word frequency analysis in the ongoing revision of the NSIR-RT taxonomy is presented in Section 5.4.

Other publications on radiotherapy incident learning have emphasized the importance of participation of management in order to achieve a successful ILS [33] [40] [63]. This sentiment is supported by the current work because much of the success of SaILS may be attributed to involvement and time-investment of the chief and assistant chief radiation therapists, chief of medical physics, and chief of radiation oncology. They have also provided consistent access to departmental meetings to present SaILS throughout the deployment process, and have opened feedback channels to staff of all professions.

5.1 – Reflection on Incident Learning

5.1.1 – Analysis of Incidents Reported to SaILS

The majority of incidents reported to SaILS, about two-thirds, were identified as actual incidents as opposed to reportable circumstances or near-misses, as shown in Table 4.3. The distribution among event types is notably different from the equivalent result published in the 2016 "Year in Review" document that summarized incidents submitted to RO-ILS over the first two years [60]. Table 5.1 provides the proportion of incidents of each type for both systems.

Table 5.1. Distribution of incidents by event type as reported to SaILS and RO-ILS.

SaILS		RO-ILS [60]	
Event type	% of Incidents	Event classification	% of Incidents
Reportable circumstance	25.3%	Unsafe condition	29.8%
Near-miss	8.8%	Near-miss	33.9%
Actual incident	65.9%	Incident that reached patient	36.3%

In particular, the fraction of actual incidents was much higher in SaILS than the equivalent in RO-ILS, whereas the opposite was true for near-misses. While this result could be indicative of a truly higher proportion of actual incidents at the MUHC, it is more likely due to under-reporting of near-misses and confusion regarding definitions of each event type. The confusion stems at least partially from limitations in the application of the NSIR-RT taxonomy to no-harm, incidents; of which many were reported as actual incidents within SaILS and are described in more detail in the following paragraph. First however, recall that not all incidents that are reported using RO-ILS are uploaded to the national database, and thus are not included in the distribution presented in Table 5.1. It is possible that no-harm incidents reported as actual incidents using RO-ILS were not uploaded to the national database, thus causing the discrepancy in the number of incidents submitted as actual incidents between the two systems. The RO-ILS 2016 Year in Review report states explicitly that the recent revision of their taxonomy to include *Operational/process Improvement incidents* was to accommodate institutions using RO-ILS "for multiple purposes" [60]. It is unlikely that the very slight differences in phrasing of the definitions of event types across the two systems are responsible for the observed discrepancy.

The no-harm incidents mentioned above refer to a number of reported incidents that did not have an obvious medical impact on the patient, but affected the patient (and/or staff) in other ways. Such incidents and their impact included:

- Improper treatment planning documentation or prescriptions that led to treatment planning delays and thus delay of patient treatment.
- Scheduling and communication errors, particularly for patients receiving concurrent chemotherapy, that caused confusion to the patient and treatment delays.

- Failure to account for limitations on arc treatments during setup of patient at simulation, that was not detected until collision check on first treatment fraction. Such incidents caused treatment to be postponed and inconvenienced the patient.

These types of incidents offer significant learning opportunities but are not well categorized in some areas of the NSIR-RT taxonomy. Usually these incidents were reported as actual incidents, but in most cases may have been better classified as no-harm incidents that impacted patients in a non-medical capacity. Regardless of the event type assigned, the non-medical impact of the incidents indicated above should have been formally captured within the ILS. A suggested expansion of available event types and of the *Incident Impact* domain is presented in Section 5.3.1 to address these potential shortcomings in the taxonomy.

An increased or stable rate of reporting that, over time, shifts towards a higher ratio of near-misses to actual incidents is typically cited in the literature as a good metric to gauge the success of an ILS [33] [63] [64]. Publications often present a trend plot depicting this behaviour that spans a period of two or more years. However, a preliminary trend was identified among incidents reported to SaILS over six months, as shown in Fig. 4.2. A relatively stable number of incidents were reported per month, with a notable increase in May and June. While the number of actual incidents was actually constant at 10 per month from March to June, the number of reportable circumstances and near-misses increased during the last two months. Numerous education and debriefing sessions among RTTs were scheduled using tasked actions following incorporation of the feature in late March. These sessions may have played a role in motivating staff to report more near-misses and reportable circumstances in the following months. Or the increase in near-misses and reportable circumstances could be reflective of a higher incident occurrence rate, as there were no other commonalities identified among those events. The proportion of incidents by event type will continue to be monitored in the coming months.

Table 4.4 showed that all actual incidents, except for one, were assigned no or minor severity across all three medical-impact fields in the NSIR-RT taxonomy. At the national level, the NSIR-RT system will aid greatly in aggregating higher-impact incidents across all participating institutions as sufficient data are accrued over the coming months and years. However, as there are

no previous studies of large quantities of higher severity radiotherapy incidents, to the author's knowledge, it is difficult to predict whether or not such an aggregate analysis will reveal much useful, generalizable information.

5.1.2 – Impact of Workflow Optimization Features

SaILS was deployed into the clinic in a stable state with a complete set of core features. However, a number of additional features were suggested in the months following its deployment. In this regard, use of an internally-developed and customizable system was highly beneficial. A steady improvement in the ratio of completed investigations may be inferred from Fig. 4.8, where the proportion of uninvestigated incidents for more than 30 days decreased consistently over the last three months. This indicates that the suggested workflow optimization features that were implemented have played a role in the observed improvement, as justified below.

Sixteen incident investigations were completed using a template, as shown in Fig. 4.7, which accounts for 21% of completed investigations. With regards to Fig. 4.8, seven of 13 investigations that were submitted in February were completed using a template, but exceeded the 30-day threshold because the template feature was not added until May 2016. Four templates were also applied to incidents submitted in June, and one or two more for each of the remaining months. Investigation of an incident using a template takes only about one or two minutes compared to around 10 or 15 minutes for most typical incidents, as indicated by investigators who have used the feature. This improvement in processing time allowed investigators to quickly process the lingering investigations of similar events that previously would have taken an unjustifiably long time to complete.

Despite the fact that more incidents were submitted to SaILS in June than any other month, June was the month for which the highest proportion of incidents were completed within 30 days; also shown in Fig. 4.8. Ten incidents were completed within one day of being submitted (out of 35 total submitted in June) and cannot be directly attributed to workflow optimization features. It must be noted that the three technical coordinators were given investigator roles at the beginning of June, and were responsible for the timely completion of several incident investigations. However, the dates that most remaining investigations were completed were clustered around the dates that

automatic investigation reminders were sent to the investigator. Seven incidents were completed within 24 hours after the first automatic investigation reminder was sent (a week after electronic submission) and a few more were completed within a day or two after the subsequent reminder was sent (three weeks after electronic submission). This quantitative evidence of the usefulness of the automated reminders was supported qualitatively by verbal feedback provided by investigators.

5.1.3 – Clinical Outcomes Facilitated by Incident Learning

Overall, as evidenced by the number of reports submitted and the results of the staff survey, the implementation of SaILS in the Department of Radiation Oncology at the MUHC has had a positive impact on incident learning and communication. SaILS has aided in rejuvenating the department's Risk Management Committee and has begun the process of including frontline staff in the incident learning feedback loop. The assistant chief RTT and chief of medical physics have also indicated that SaILS is a useful tool for keeping abreast of departmental activity.

The majority of tasked actions and ameliorating actions identified within SaILS were related to staff education or reminders as presented in the Table 4.8. As indicated previously, these may have had a role in improving reporting compliance for near-misses and reportable circumstances. Soft actions such as these are typically viewed as being less effective at realizing long term change, but are more easily implemented in a short timeframe. More severe actual incidents should result in firmer actions, but as was shown in Table 4.4, only one incident had a dosimetric impact of moderate or greater and no incidents resulted in moderate or higher acute medical harm. On its own, a single reportable circumstance, near-miss, or low severity actual incident usually will not warrant a firm follow-up action. Over time however, trends in these incidents are more likely to reveal system-level issues that warrant stronger action(s). Two examples of process-related actions regarding the use of treatment accessories are discussed below, and the need for which became evident after multiple similar incidents were reported.

Firstly, the issues involving unidentified vacuum cushions arose because the cushions were previously labeled with masking tape that fell off between simulation and treatment. New tags have been purchased to attach to each cushion using an existing hole (that is used to hang it). These

tags will allow each cushion to be labeled without risk of falling off, but can be easily cut-off once the corresponding patient's treatments are finished, so that the cushion may be reused.

Secondly, additional patient alerts entered into the electronic medical record will be added to require RTTs to sign off on the inclusion of bolus for each treatment fraction. These alerts will act as an additional reminder to include the bolus at the time the patient's plan is loaded into the treatment unit, just before setting up the patient. A firmer interlock will be strived for in the future, but this interim solution will hopefully reduce the number of forgotten bolus incidents.

5.2 – Evaluation and Improvement of Incident Learning Culture

The results of the radiation therapist incident reporting and learning survey have aided greatly in determining the next steps to be taken with SaILS and incident learning in the department. Preeminently, as motivated by the unanimous feedback provided in the survey, a newsletter will be drafted and circulated among staff within the next couple of months. The report will discuss the successes and challenges of SaILS and incident learning in the department and will present a number of incident case studies. Incidents will be anonymized to respect confidentiality of the incident report, and will focus on sharing what was learned from the incident.

Additionally, therapists will be encouraged to submit future incident reports online using SaILS. To maintain immediate discussion about the incident, which was the rationale to require a paper report in the first place, a technical coordinator will be required to review the incident report, assign an investigator, and provide their SaILS credentials before the report submission is finalized. The assistant chief therapist will be automatically notified via email of all such reports, so that he may still keep track of all incidents reported by the RTTs. Alleviating his incident report transcription duties will also free up some time to focus on incident investigations. These modifications should facilitate faster turnaround on submission of incident reports electronically and completion of investigations. It is expected that the negative responses regarding usefulness of the feedback provided to RTTs on the incident summary pages may have been due to the incident not having been electronically submitted or investigated yet. With the expected faster turnaround on report submission and investigations, the summary pages that provide feedback to frontline staff will become more useful. Once the incident reporting process is revised, and RTTs are provided with

clearer evidence of the successes of the system, they will be re-surveyed regarding their confidence in the departmental incident learning process.

As indicated in Table 4.5, the majority of incidents (about two thirds) were detected by RTTs and the overall engagement of RTTs with the incident reporting process has been very good. 80% of RTTs who responded to the survey indicated they had submitted an incident report since SaILS was deployed. Also, as shown in the distribution of reports by functional work area (Fig. 4.2), RTTs have submitted reports from all seven linear accelerators, all three simulation suites, and from brachytherapy. A high proportion of incident reports submitted by RTTs is similar to findings published about other incident learning systems. The proportion of incidents detected by RTTs, physicists, dosimetrists, and radiation oncologists in SaILS and other incident learning systems is shown in Table 5.2.

Table 5.2. Proportion of incidents detected by various staffing groups for several incident learning systems.

Staff group	SaILS	RO-ILS [57]	Gabriel et al. [33]	ROSIS [53]
Radiation therapist	69.6%	48.6%	46.9%	61%
Medical physicist	0%	27.5%	32.8%	9%
Dosimetrist	26.8%	7.6%	4.1%	4%
Radiation oncologist	3.6%	8.3%	5.2%	8%

Table 5.2 shows that the proportion of incidents detected by physicists was much lower in SaILS than for other incident learning systems considered. However, it was noted that a couple reports were submitted by Physics in July 2016 that were not considered in the distributions and trends presented in the previous chapter. Additionally, it may be possible that some investigation-complete incidents for which the *Individual who Detected the Incident* data element was not provided, were detected by a physicist. This serves as motivation to make the data element mandatory within the NSIR-RT taxonomy. Regardless, improved engagement of physicists with SaILS will be pursued in the coming months. The majority of investigations completed by Physics are done by the chief physicist. Distribution of investigations among more of the clinical physics staff will improve awareness of the system and possibly result in additional reports generated by physicists.

5.3 – Feedback on the NSIR-RT Taxonomy

Implementation of the NSIR-RT taxonomy has improved the quality of incident learning in the department compared to the previous incident reporting system that had an unstandardized in-house taxonomy. The NSIR-RT taxonomy encompasses many important aspects of incidents that have been submitted to SaILS over a six-month period. The numerous select-type data elements allow for robust plotting of incident distributions and trends as shown in the previous chapter. Going forward, it will be very beneficial to share incident data with other centres in a common and unambiguous manner. However, based on the data presented in the previous chapter, a number of recommendations to further improve the taxonomy for future use are suggested here. The recommendations are grouped into two significant expansions of the taxonomy, as well as a collection of smaller modifications.

5.3.1 – Inclusion of No-harm Incidents and Expansion of the *Incident Impact* Domain

As mentioned in Section 5.1.1, a number of no-harm incidents submitted to SaILS, that involved a patient or patient's treatment plan, were not well characterized in some areas of the NSIR-RT taxonomy. These incidents were characterized as actual incidents or near-misses with no medical impact to the patient, but there was no way to systematically capture the potential impact to workflow or patient experience. Thus it is recommended here that a new event type, *No-harm incident*, be added to the taxonomy. This event type is defined as:

- *No-harm incident*: An incident that did not medically impact a patient, but had an impact on radiotherapy treatment workflow and/or patient experience.

This definition was adapted from the existing definition for no-harm incidents published in the CPSI Incident analysis framework, but more explicitly states the types of impact that could be involved with such an incident [35]. Also, recall that a key objective of the NSIR-RT initiative is to establish an incident reporting and learning system that is compatible with other national and international systems [13]. Given that a new analogous incident type, *Operational/process improvement incidents,* is being added to RO-ILS, this addition will aid in keeping the two systems synchronized [60].

Correspondingly to the above suggestion, an expansion of the *Incident Impact* domain of the NSIR-RT taxonomy is proposed whereby two new data elements are added. The proposed elements and choices within each are:

1. *Workflow Impact* [mandatory for no-harm incidents and actual incidents]
    - *None* – No change to the treatment schedule due to this event.
    - *Treatment delayed* – Treatment was delayed to later the same day, due to this event.
    - *Treatment postponed* – Treatment was postponed to a later date due to this event.
    - *Treatment cancelled* – Treatment was cancelled due to this event.
2. *Patient Experience Impact* [mandatory for no-harm incidents and actual incidents]
    - *None* – Patient experience was not impacted by this event.
    - *Patient inconvenienced* – Patient was inconvenienced due to this event.
    - *Patient upset* – Patient was visibly upset due to this event.
    - *Patient enraged* – Patient was enraged due to this event.

These modifications will broaden the type of impact captured by the taxonomy, and should not add significant workload to the investigation process. Consideration of the patient experience also provides better alignment with the desired outcomes of quality improvement initiatives in radiotherapy as discussed in Chapter 2. The *NSIR-RT Algorithm for Categorizing Impact of Radiation Treatment Incidents* was updated in this project to reflect this proposed expansion, and is shown in Fig. 5.1 (the original version was provided in Fig. 2.9).

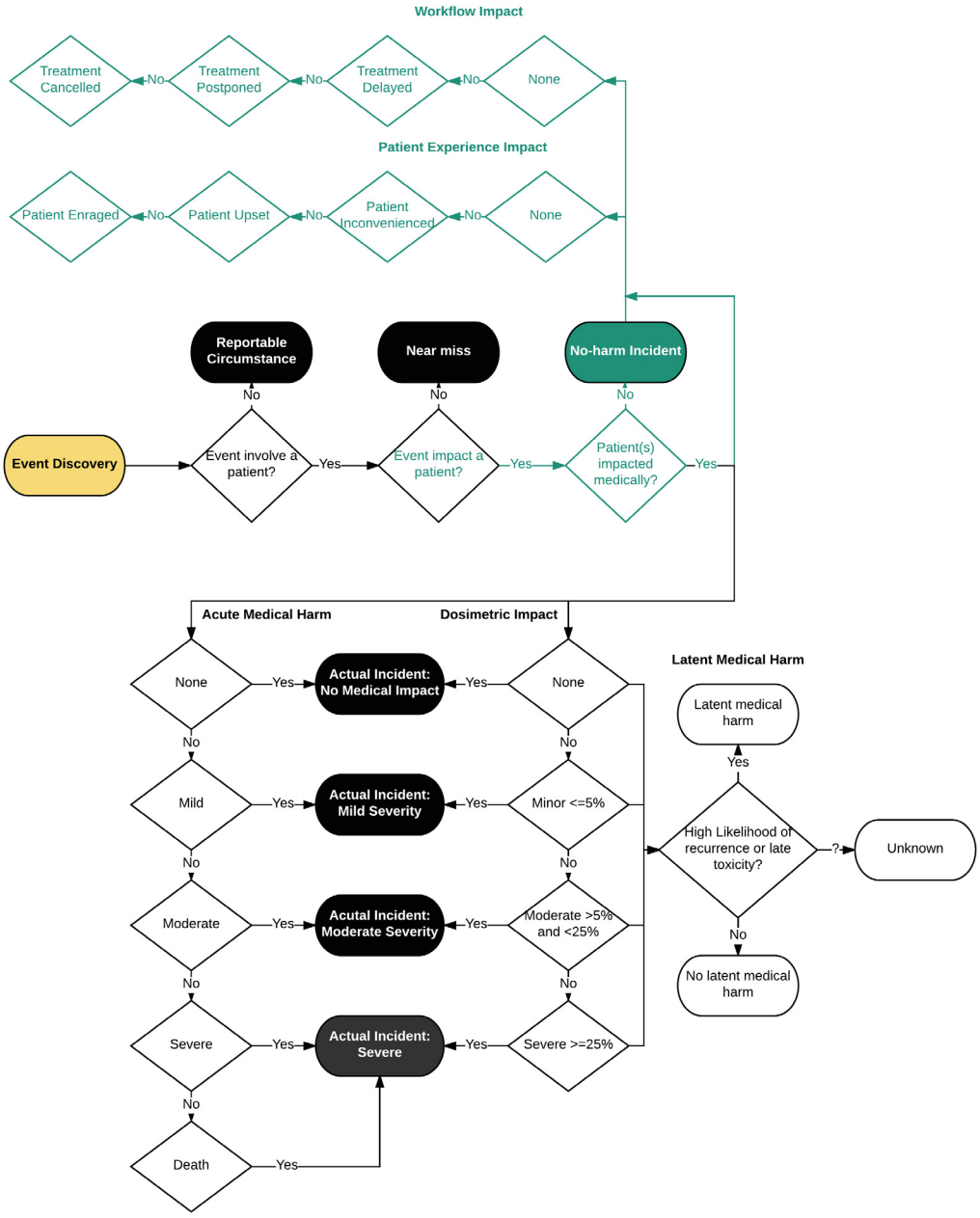


Figure 5.1: Proposed expansion of the NSIR-RT Algorithm for Categorizing Impact of Radiation Treatment Incidents. Proposed updates are highlighted in green.

5.3.2 – Expansion of *Primary Problem Type*

Almost 50% of investigated incidents in SaILS were assigned a value of *Other* for the *Primary Problem Type*, as shown in Fig. 4.4 and Fig. 4.10. Evidence that such incidents often occurred in treatment planning and imaging for radiotherapy planning was provided in Section 4.2.2. Because

most of those incidents were reported in the latter months considered (May and June), this relationship cannot be explained by users' initial lack of familiarity with the taxonomy. Thus, the incidents categorized with a problem type of *Other* were reviewed. This review prompted a number of additional choices to be added to the *Primary Problem Type* data element. A table showing the proposed expansion of *Primary Problem Type* is shown in Fig. 5.2. The large proportion of incidents that occurred in planning or imaging would be well characterized by two new categories: *Setup/Positioning* and *Excessive Imaging*. Sub-options within each category are shown in Fig. 5.2

4.3	Problem Type (Problem that is MOST responsible for the incident)	Patient related circumstance or accident	Allergic reaction	
			Infection	
			Interventional procedure error	
			Fall or other accident	
			Prosthesis involvement	
			Dental involvement	
			Cardiac device involvement	
		Hardware/Software		
		Improper documentation		
		Dose	Wrong prescription dose	
			Wrong plan dose	
			Calculation error	
			Calibration error	
		Treatment volume	Wrong patient	
			Wrong anatomical site	
			Wrong side (laterality)	
			~~Wrong patient position~~ [Replaced]	
			~~Wrong shift from setup point~~ [Moved]	
			Wrong target or OAR contours, or wrong planning margins	
			Patient movement during simulation or treatment	
			~~Wrong treatment accessories~~ [Replaced]	
		Scheduling	Radiation treatment scheduling error	
			Combined modality treatment scheduling error	
		Setup/Positioning	Patient not setup as planned	
			Wrong shift from setup point	
			Planned setup would cause collision	
			Planned setup did cause collision	
			Treatment accessories	Wrong treatment accessories
				Forgotten treatment accessories
				Lost/damaged treatment accessories
		Excessive imaging	Imaging unnecessarily repeated in error	
			Wrong anatomy imaged	
			Poor image quality	
		Other		

Figure 5.2: Proposed updates to the *Primary Problem Type* data element. New options are highlighted in green, removed/replaced options in red, and moved options in orange.

Review of the remaining incidents categorized with *Primary Problem Type: Other* led to suggestion of a few more options. Firstly, as shown in Table 4.7, 15% of incidents arose due to failure to verify proper treatment accessories. As discussed in Section 4.2.3, many of these incidents involved forgotten bolus or lost vacuum cushions and were assigned a problem type of *Other* or *Wrong treatment accessories*. Based on the review, it is recommended that the existing *Wrong treatment accessories* option be decomposed into a new *Treatment accessories* category with three sub-options, as shown in Fig. 5.2.

Most of the remaining incidents with *Primary Problem Type: Other* related to documentation errors and patient characteristics including cardiac devices and dental implants. Thus, an *Improper documentation* option is proposed, as well as three new options in the existing *Patient related circumstance or accident* category. These are shown in Fig. 5.2.

The word frequency analysis for incidents with *Primary Problem Type: Other*, shown in Fig. 4.14, provided evidence that the limitations in available choices for *Primary Problem Type* identified using SaILS were common among other participants of the NSIR-RT pilot system. In particular, the notably higher occurrence frequency of the words “image”, “ct”, “sim”, and “documentation” among incidents with *Primary Problem Type: Other* emphasized the need for the *Excessive Imaging* category and *Improper documentation* option. The relatively even distribution of incidents between the two groups, and significant sample size (229 incidents with *Primary Problem Type: Other* and 258 without) strengthens this evidence. The remaining words depicted in Fig. 4.13 and 4.14, as well as the corresponding differences in occurrence frequency, are discussed further in section 5.4.

5.3.3 – Additional Recommendations

Additional recommendations regarding the NSIR-RT taxonomy are summarized in Table 5.3 and a brief rationale for each is discussed below.

Table 5.3. Recommended modifications to the NSIR-RT taxonomy.

Data element / domain	Recommendation
Individuals Involved in the Incident & who Detected the Incident	- Add *Nutritionist* option - Add *Social worker* option - Make both data elements mandatory
Patient Diagnosis	- Add checkbox for metastatic disease
Secondary Problem Type	- Remove from taxonomy
Treatment Delivery	- Make data elements within this domain mandatory only for actual incidents that caused acute or latent medical harm, or had a dosimetric impact
Investigation Narrative	- Add this free-text data element to the *Incident Investigation* domain of the NSIR-RT taxonomy

There were several incidents reported to SaILS with no selection for either the individual(s) who detected the incident or were involved with an incident. Most could have been answered using existing options, however there were a couple for which *Other* would have been the appropriate selection. Addition of a nutritionist and social worker option would have removed the need for the *Other* option. Additionally, as noted previously, these two data elements should be mandatory as they are easily filled out, provide useful information about participation in the incident learning system, and there is an *Unknown* option for cases where the information is truly unknown.

The three incidents for which *Other* was selected for *Patient Diagnosis* were both identified as involving patients being treated for metastases of malignant neoplasms of the breast or lung. Adding a checkbox to indicate metastatic disease would have removed the need for them to be characterized with an *Other* diagnosis, and remain general for use with metastases of other primary cancers.

The *Secondary Problem Type* was only provided for 40% of incidents, and little meaningful information was gleaned from those which did provide a value. Thus, it is recommended to be removed from the taxonomy, which will reduce the number of data elements.

Investigators noted the deemed-unnecessarily long time required to specify values for the mandatory elements in the *Treatment Delivery* domain of the NSIR-RT taxonomy, particularly for near-misses and incidents that could have been classified as no-harm incidents. The treatment delivery information is relatively uninformative for such incidents and is burdensome on investigators. Thus, this information should be mandatory for actual incidents that caused acute or latent medical harm, or had dosimetric impact, but should be optional for all remaining incidents.

Finally, an *Investigation Narrative* is proposed to be added to the taxonomy. This free-text element complements the existing *Incident Description* data element, but is to be filled at the end of the investigation rather than the beginning of the report. It provides an opportunity for the investigator to clearly communicate the investigation that was undertaken and summarize key findings that are more difficult to ascertain from reviewing inputs into dropdown menus. The narrative provided is also displayed on the Incident Summary pages that are displayed to RTTs. The *Investigation Narrative* data element was added to SaILS in February 2016 and is mandatory for all incidents.

The proposed changes, including that to *Primary Problem Type* discussed in the previous section, should significantly reduce the number of incidents classified as *Other-events*. The proportions of *Other* selections by data element should be monitored following these changes. Unless incidents with other recurring characteristics are noted, in which case additional modifications to the taxonomy should be incorporated, the *Other* options for several data elements should be removed. Pending further analysis, these will include:

- *Individual(s) who Detected the Incident*
- *Individual(s) who were Involved in the Incident*
- *Patient Diagnosis*
- *Primary Problem Type*

Although a significant portion of incidents were submitted with *Other* for the *Ameliorating Action* field, particularly in the NSIR-RT pilot system, there are many possible outcomes of an investigation that would be difficult to completely characterize without an *Other* option. “Taskable actions” can also clarify *Other* selections for ameliorating actions. A further analysis of incidents with *Other* selected for either failed or successful safety barriers will be performed to determine if

there are missing options that could be added, and thus remove the *Other* option from the taxonomy.

5.4 – The Role of Word Frequency Analysis in Evaluating NSIR-RT

The findings of the word frequency analysis of incident data reported to SaILS and the NSIR-RT pilot were reflective of the findings of a more detailed investigation of incidents with *Primary Problem Type: Other*, as discussed in Section 5.3.2. When analyzing Fig. 4.14, differences in word occurrence frequency of 5% or greater were deemed significant, albeit somewhat arbitrarily in correspondence with the aforementioned findings. However, a 5% difference in a sample size of approximately 250 incidents included in both groups (229 incidents with *Primary Problem Type: Other* and 258 remaining incidents) does equate to approximately 13 additional incidents in the corresponding group; a considerable number of incidents.

The additional words that were not discussed previously and appeared at least 5% more frequently in incidents with *Primary Problem Type: Other* were “taken”, “time”, and “first”. A survey of incident descriptions including the word “taken” revealed that the word was often preceded by “image(s)” or “CBCT”, and thus may also be indicative of incidents pertaining to excessive or poor quality imaging. Similar analysis for the word “time” indicated that the word was typically used in the context of delayed treatments due to late development of treatment plans, ultimately because of improper documentation. However, the author acknowledges that these correlations are tenuous and, at best, require additional context to be potentially useful. The higher occurrence frequency of the word “first” was interpreted as noise.

Conversely, it was found that “treatment” and “patient” occurred at least 5% more frequently in the group of remaining incidents, i.e. those without *Other* selected for *Primary Problem Type*. Due to the various abbreviations and tenses with which these words could also be used (e.g. “treating”, “treated”, “pt”, “patient’s”), these findings were interpreted as noise. The relatively large difference in occurrence frequency for the word “day” was also interpreted as noise.

No meaningful interpretations could be gleaned from the results presented in Fig. 4.12, comparing all 362 *Other-events* to all 125 remaining incidents. Some similar signals that were identified in

Fig. 4.14 can also be observed in Fig. 4.12, most notably the frequent presence of "ct", "sim", and "image" among *Other-incidents*. However, these signals are largely attributed to incidents with *Primary Problem Type: Other*, as about two thirds of *Other-events* fall into the former category. After implementing the suggested modifications to the *Primary Problem Type* data element, presented in Fig. 5.2, the number of incidents with *Primary Problem Type: Other* should be reduced. Repeating this word frequency analysis on all *Other-events* in the future, with fewer incidents with *Primary Problem Type: Other*, may unveil new meaningful signals and prompt additional revisions to other data elements in the NSIR-RT taxonomy.

It may also be useful to undertake similar word frequency analyses for all incidents with *Other* selected for alternative data elements, instead of *Primary Problem Type*. Potential candidates for this would be *Ameliorating Action(s)*, *Safety Barrier(s) that Failed*, and *Safety Barrier(s) that Identified the Incident*, given the relatively large number of incidents with *Other* selected for each. However, in addition to yielding two groups of roughly equivalent sample sizes, *Primary Problem Type* was a uniquely suitable candidate for word frequency analysis because it is a single-select data element. The three data elements identified above all permit multiple selections, which could confound the word frequency analysis. Additionally, from the *Incident Descriptions* alone, it may be difficult to establish ties between word frequency and the types of actions or safety barriers that are missing from the taxonomy. A possible alternative, would be to do word frequency analysis on the *Investigation Narrative* text, or text of any associated *Taskable Actions*. However, in the current state of the NSIR-RT taxonomy, this level of analysis would only be possible with incidents reported to SaILS.

Finally, for any future word frequency analysis of incident data, the algorithm should be refined to better account for abbreviations, synonyms, and tense of words. Word "bins" with unique rules could be created to include any words meeting the specified criteria. This method of analysis may be less prone to prominent signals that are ultimately discarded as noise, as previously discussed in this section.

Chapter 6 – Conclusions and Future Work

The scope of this project was to develop and clinically integrate a radiotherapy incident learning system that is fully compatible with the Canadian National System for Incident Reporting – Radiation Treatment. The rationale for developing an internal system rather than simply adopting the NSIR-RT pilot system was to allow customizability to optimize workflow and accrue participation from all levels of staff; thus improving the departmental incident learning culture. Use of the NSIR-RT taxonomy also allowed participation in the ongoing evaluation of the data elements within the taxonomy using real clinical data.

SaILS, an open-source ILS originally deployed at TOHCC, was adapted for the current work and rebuilt from scratch, including an NSIR-RT-compatible MySQL database on the backend. The system was deployed into clinical use in January of 2016 and facilitates incident reports and investigations. There were 110 incidents reported to SaILS between January and the end of June 2016, 91 of which were deemed valid by the investigator, and 75 of which have been fully investigated. A built-in incident plotting toolkit was used to analyze these incidents via incident distribution and trend plots. Notably, two-thirds of incidents were reported as actual incidents as opposed to near-misses or reportable circumstances. This result differs significantly from the most recent annual report on RO-ILS incident data, and is expected to be due to ambiguity in the NSIR-RT taxonomy for characterization of no-harm incidents.

Incident investigations, analysis, and trending have revealed issues within the department regarding treatment accessories, documentation, and communication. Education sessions, staff reminders, new checklists, new treatment accessory labels, and new alerts incorporated into the electronic medical record comprise the efforts taken to reduce incident occurrence thus far. Several of these outcomes have been facilitated using a "taskable actions" feature within SaILS, which allows staff to explicitly assign outcome responsibility to other staff members. Additional features that were incorporated to improve communication and efficiency of data processing include incident templates, data retrieval and field population using the departmental electronic medical record, and periodic/automatic investigation email reminders.

Engagement of radiation therapists with the incident reporting and learning process has been a crucial factor in the successes of SaILS. RTTs have submitted over two-thirds of reports, from all treatment units and simulation suites within the department. Incident summary webpages are produced within SaILS for each reported incident and provide a feedback channel to the RTTs who report incidents. The RTTs of the department were also surveyed to gauge engagement and perceived-usefulness of the system. Results of the survey have motivated the development of a newsletter to highlight the successes and challenges of SaILS thus far, and will be circulated within the next couple months. The incident reporting process will also be modified as a result of the survey to allow RTTs to submit reports electronically after sign-off by a technical coordinator.

Evaluation of incident data has also yielded several recommendations for the NSIR-RT taxonomy. Firstly, it is suggested that a fourth event type, *No-harm incident*, be added for incidents that did not medically affect any patient, but that may have impacted workflow or patient experience. Correspondingly, *Workflow Impact* and *Patient Experience Impact* data elements should be added to the taxonomy to capture these salient details. Secondly, it was found in SaILS and the NSIR-RT pilot system that many incidents were frequently submitted with *Other* specified for at least one of the 13 data elements allowing such a choice. The *Primary Problem Type* data element was most egregiously filled with *Other* in both systems. A word frequency analysis of incidents with a problem type of *Other* across both systems revealed deficiencies in the available options for this element, particularly when categorizing documentation errors and imaging or other simulation errors. Several additional options are suggested to be added to the data element for future use to significantly reduce the number of incidents reported with *Other*. A free-text data element, *Investigation Narrative*, is also suggested to complement the existing *Incident Description* and more explicitly summarize the investigation process.

These recommendations will be discussed with the CPQR and CIHI and may be incorporated into a future update of the taxonomy. SaILS will be updated accordingly to ensure continued compatibility with NSIR-RT. Additional word frequency analyses may have a role in devising new revisions to the NSIR-RT taxonomy as more incident data are accrued, if the number of incidents with *Other* selected in one or more data elements remains high.

There also remains an additional major feature to incorporate into SaILS: batch uploading of incident data from the SaILS database to the national registry. Implementation of such a connection would allow direct transfer of anonymized incidents reported at the MUHC to NSIR-RT without having to perform duplicate entry using the pilot system. This feature would greatly improve the broad appeal of SaILS and discussions are currently underway with CIHI to develop this feature in the near future. Also, continuing in the open-source spirit of SaILS, the software will be offered to the Canadian radiotherapy community along with backend implementation instructions and frontend user guides.

In the meantime, SaILS will continue to be used as the departmental radiotherapy ILS at the Departmental of Radiation Oncology at the Cedars Cancer Centre of the MUHC. Incident data will continue to be investigated and analyzed, and will be fed into a continuous quality improvement cycle with participation of staff of all disciplines.

References

[1] National Cancer Institute, "What is Cancer?," 9 February 2015. [Online]. Available: http://www.cancer.gov/about-cancer/understanding/what-is-cancer. [Accessed June 2016].

[2] Canadian Cancer Society's Advisory Committe on Cancer Statistics, "Canadian Cancer Statistics 2015," Canadian Cancer Society, Toronto, ON, 2015.

[3] Canadian Cancer Society, "Treatment," [Online]. Available: http://www.cancer.ca/en/cancer-information/diagnosis-and-treatment/treatment/?region=nl. [Accessed June 2016].

[4] RadiologyInfo.org, "Introduction to Cancer Therapy (Radiation Oncology)," RadiologyInfo.org, 25 June 2015. [Online]. Available: http://www.radiologyinfo.org/en/info.cfm?pg=intro_onco. [Accessed June 2016].

[5] E. B. Podgorsak, Radiation Physics for Medical Physicists, 2nd Edition ed., Springer-Verlag Berlin Heidelberg, 2010.

[6] R. C. Lee, "Overview of Risk Management," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 73-76.

[7] International Commission on Radiation Units & Measurements, "Prescribing, Recording, and Reporting Photon Beam Therapy (Report 50)," 2016. [Online]. Available: http://www.icru.org/home/reports/prescribing-recording-and-reporting-photon-beam-therapy-report-50. [Accessed June 2016].

[8] Rossy Cancer Network, *Radiotherapy at the Cedars Cancer Centre,* Montreal, Quebec: McGill University Health Centre, 2015.

[9] P. B. Dunscombe and D. L. Cooke, "Perspective on Quality and Safety in Radiotherapy," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 3-6.

[10] W. R. Hendee, "Past, Present, and Futre of Quality in Radiotherapy Physics," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 63-65.

[11] AAPM TG-1, "The Role of a Physicist in Radiation Oncology," American Institute of Physics, Inc., New York, 1993.

[12] D. L. Cooke, P. B. Dunscombe and R. C. Lee, "Using a survey of incident reporting and learning practices to improve organisational learning at a cancer care centre," *Qual Saf Health Care,* vol. 16, pp. 342-348, 2007.

[13] M. Milosevic et al. (in press), "The Canadian National System for Incident Reporting in Radiation Treatment (NSIR-RT) Taxonomy," *Pract Radiat Oncol,* 2016.

[14] M. Carrigan, "Quality Management: An Overview," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 11-14.

[15] F. Soum-Pouyalet, A. Hubert and G. Kantor, "Quality as Viewed and Lived by the Patient," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 7-10.

[16] M. Saiful Huq, "New Paradigm for Quality Management in Radiation Therapy Based on Risk Analysis," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 115-118.

[17] J. Øvretveit, "Quality Management: Radiotherapy," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 15-17.

[18] L. T. Kohn, J. M. Corrigan and M. S. Donaldson, Eds., "To Err is Human: Building a Safer Health System," National Academy Press, Washington, DC, 1999.

[19] M. Coffey, "Issues in Patient Safety," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 69-72.

[20] Y. Lievens and P. Dunscombe, "Cost of Quality: Health Technology Assessment," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 53-57.

[21] S. C. Erridge, "Access to Care: Perspectives from a Public Healthcare Environment," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 47-51.

[22] G. R. Baker et al., "The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada," *CAN MED ASSOC J,* vol. 170, no. 11, pp. 1678-1686, 2004.

[23] Canadian Patient Safety Institute, "The Economics of Patient Safety in Acute Care," Edmonton, 2012.

[24] P. F. Martelli and K. H. Roberts, "Primer on High Reliability Organizing," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 101-104.

[25] J. B. Conway and S. N. Weingart, "Organizational Change in the Face of Highly Public Errors—I. The Dana-Farber Cancer Institute Experience," Patient Safety Network, May 2015. [Online]. Available: https://psnet.ahrq.gov/perspectives/perspective/3/organizational-change-in-the-face-of-highly-public-errorsi-the-dana-farber-cancer-institute-experience. [Accessed July 2016].

[26] M. Murphy, *The Patient Experience as a Catalyst for Change,* Montebello: COMP Winter School 2016, 2016.

[27] British Institute of Radiology, "Towards Safer Radiotherapy," The Royal College of Radiologists, London, 2008.

[28] T. Pawlicki, *Improving the Organizations Aspects of Safety in Radiation Medicine,* Montebello: COMP Winter School 2016, 2016.

[29] J. Reason, "Human Error: Models and Management," *BMJ,* pp. 768-770, 2000.

[30] M. Udowicz, *Quality and Safety for Radiation Medicine,* Montebello: COMP Winter School 2016, 2016.

[31] S. Mutic and S. Brame, "Error and Near-Miss Reporting: View from North America," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 85-93.

[32] P. Scalliet, "Past, Present, and Future of Quality in Radiotherapy," in *Quality in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 59-61.

[33] P. E. Gabriel et al., "Incident Learning in Pursuit of High Reliability: Implementing a Comprehensive, Low-Threshold Reporting Program in a Large, Multisite Radiation Oncology Department," *Jt Comm J Qual Patient Saf,* vol. 41, no. 4, pp. 160-168, 2015.

[34] Candian Institute for Health Information, "National System for Incident Reporting — Radiation Treatment: Minimum Data Set," Ottawa, 2015.

[35] Canadian Patient Safety Institute, "Canadian Incident Analysis Framework," Edmonton, 2012.

[36] A. Wu, "Medical error: the second victim," *BMJ,* vol. 320, 2000.

[37] C. Connors, *Caring for the Caregiver,* Montebello: COMP Winter School 2016, 2016.

[38] W. Bogdanich, "Radiation Offers New Cures, and Ways to Do Harm," The New York Times, 23 January 2010. [Online]. Available: http://www.nytimes.com/2010/01/24/health/24radiation.html. [Accessed July 2016].

[39] T. Ohno, Toyota Production System: Beyond Large-Scale Production, New York: Productivity Press, 1988.

[40] D. A. Low, S. Mutic and T. Bostic, "The Impact of Cultural Biases on Safety," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 95-100.

[41] K. Weick and K. Sutcliffe, Managing the unexpected : resilient performance in an age of uncertainty, San Francisco: Jossey-Bass.

[42] K. E. Weick, K. M., Sutcliffe and D. Obstfield, "Organizing for high reliability: Processes of collective mindfulness," *Research in Organizational Behavior,* vol. 21, pp. 81-123, 1999.

[43] E. C. Ford et al., "Consensus recommendations for incident learning database structures in radiation oncology," *Med Phys,* vol. 39, no. 12, pp. 7272-7290, 2012.

[44] P. J. Pronovost et al., "Reducing Health Care Hazards: Lessons from the Commercial Aviation Safety Team," *Health Aff,* vol. 28, no. 3, pp. w479-w489, 2009.

[45] S. J. Singer et al., "The culture of safety: results of an organization-wide survey in 15 California hospitals," *Qual Saf Health Care,* vol. 12, pp. 112-118, 2003.

[46] P. O. López, "Tools for Risk Management," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 77-79.

[47] J. W. H. Leer, "Development and Operation of a Quality Management Program: A Case Study," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 19-21.

[48] A. Bolderston et al., "A Culture of Safety? An International Comparison of Radiation Therapists' Error Reporting," *J Med Imag Radiat Sci,* vol. 46, pp. 16-22, 2015.

[49] J. Zeng et al., "Best practices for safety improvement through high-volume institutional incident learning: lessons learned from 2 years," *J Radiat Oncol,* pp. 1-11, 2016.

[50] E. E. Klein, "Errors in Patient Information Flow," in *Quality and Safety in Radiotherapy*, T. Pawlicki, P. B. Dunscombe, A. J. Mundt and P. Scalliet, Eds., Boca Raton, CRC Press, 2011, pp. 105-110.

[51] S. A. Terezakis et al., "An Evaluation of Departmental Radiation Oncology Incident Reports: Anticipating a National Reporting System," *Int J Radiat Oncol,* vol. 85, no. 4, pp. 919-923, 2013.

[52] World Health Organization, "Radiotherapy Risk Profile," WHO Press, Geneva, 2008.

[53] J. Cunningham et al., "Radiation Oncology Safety Information System (ROSIS) – Profiles of participants and the first 1074 incident reports," *Radiother Oncol,* vol. 97, no. 3, pp. 601-607, 2010.

[54] ROSIS, "ROSIS: Radiation Oncology Safety Information System," 2015. [Online]. Available: http://rosis.info. [Accessed July 2016].

[55] SAFRON, "What is SAFRON," 2016. [Online]. Available: https://rpop.iaea.org/RPOP/RPoP/Modules/login/safron-register.htm. [Accessed July 2016].

[56] O. Holmberg, *International Reporting Systems,* Melbourne: Patient Safety in Radiation Oncology, 2012.

[57] ASTRO, "RO-ILS: Radiation Oncology Incident Learning System," 2016. [Online]. Available: https://www.astro.org/RO-ILS.aspx. [Accessed July 2016].

[58] S. B. Evans and E. C. Ford, "Radiation Oncology Incident Learning System: A Call to Participation," *Int J Radiat Oncol Biol,* vol. 90, no. 2, pp. 249-250, 2014.

[59] ASTRO and AAPM, "RO-ILS Participation Guide," American Society for Radiation Oncology, Fairfax, 2014.

[60] ASTRO and AAPM, "RO-ILS 2016 Year in Review," 2015.

[61] The Canadian Partnership for Quality Radiotherapy, "Why us? Why now?," 2013. [Online]. Available: http://www.cpqr.ca/about-us/. [Accessed July 2016].

[62] Django, "FAQ: General," 2015. [Online]. Available: https://docs.djangoproject.com/en/1.9/faq/general/. [Accessed July 2016].

[63] B. G. Clark et al., "The management of radiation treatment error through incident learning," *Radiother Oncol,* vol. 95, pp. 344-349, 2010.

[64] M. J. Nyloft et al., "Metrics of success: Measuring impact of a departmental near-miss incident learning system," *Pract Radiat Oncol,* vol. 5, no. 5, pp. e409-e416, 2015.

Appendix

Incident Reporting & Learning Survey

Please answer all questions

1. **Are you aware of the incident reporting system in our radiotherapy department?**
   Mark only one oval.
   - ◯ Yes
   - ◯ No

2. **Have you submitted an incident report within the last 6 months?**
   Mark only one oval.
   - ◯ Yes
   - ◯ No

3. **The current electronic incident reporting system (SaILS), as well as revised paper incident report forms, went live in January 2016. Do you prefer this new system or the previous system?**
   Mark only one oval.
   - ◯ New system
   - ◯ Old system

4. **Have you used the new electronic incident reporting system to follow-up on any of your reported incidents?**
   Mark only one oval.
   - ◯ Yes
   - ◯ No

5. **If you answered yes to the previous question, have you found the feedback provided to be useful/informative?**
   Mark only one oval.
   - ◯ Yes
   - ◯ No

6. **On a scale of 1 to 10, how well do you believe our radiotherapy centre is willing and able to learn from previous incidents and make positive system changes when necessary?**
Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
Unable to Learn from Previous Incidents	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	Demonstrated Ability to Learn from Previous Incidents

7. **Would you prefer to continue submitting paper incident reports, or would you rather submit incident reports electronically via a web page?**
Mark only one oval.

- ◯ Paper incident reports
- ◯ Electronic incident reports via a web page

8. **Would you like to receive periodic (quarterly or biannually) newsletters that highlight particular anonymized incidents as well as actions which have been taken to prevent their recurrence?**
Mark only one oval.

- ◯ Yes
- ◯ No

9. **Please make any suggestions as to what additional information/feedback you would like to have provided to you via the electronic incident reporting system:**

.....

.....

.....

.....

.....