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ABSTRACT

Objective: A web-based radiotherapy incident analysis system was developed and tested for safer radiotherapy implementation. Radiation dose incidence reporting is a known evaluation method for learning from the errors that occur during the radiotherapy procedure. Established as a safety-critical, non-punitive, just-culture system, the waterfall model was employed in the construction process of the system to identify and learn from incidents, non - conformance, and near-misses in radiotherapy settings.

Method: The theoretical framework of the thesis was based on the Systems-Theoretic Accident Model and Processes (STAMP). The system algorithms were designed to identify sixty-two (62) radiotherapy errors.

Results: The results of system implementation require patient test data that was selected based on the PRISMA 2009 method. Records identified through the radiotherapy manual database were 4479 patient data set. The system reported 1215 treatment sessional errors which are equivalent to 219 patient errors when analyzed with simple descriptive statistics. Incident data were identified directly by the system, in terms of incident level, form and patient incident, year dependent, site-specific, primary site incident, and treatment status. Frequency of error types were 10% incidents, 85% non-conformance and 5% near-misses. Patient error types identified 58.447% incidents, 13.699% non-conformance and 27.854% near-misses.

Conclusion and Recommendation: Treatment status gave an overview of the quality of clinical decisions and implementation in the management of the patient. In future iterations, error tagging and solution recommendation parts with supervised machine learning algorithms would be made available to show the types of errors captured and chances of mitigating risks in terms of percentages for incident learning.

Keywords: *Incidents, Near-misses, Non-Conformance, Error, Radiotherapy Settings.*

INTRODUCTION

Incident Reporting and Learning System (IRLS) is an outstanding, empirical safety mechanism in the practice of radiotherapy. It thoroughly addresses patient and personnel protection as well as high-quality practice in the Radiotherapy setting in all facets of the radiotherapy community as a necessary condition for safer radiotherapy care. Numerous organisations advise on this (Kohn, Corrigan, and Donaldson, 2000). Currently, therapeutic and diagnostic procedures are dynamic and sophisticated, requiring that each stage of diagnosis and therapy be prepared, coordinated, and monitored to ensure the quality of the services rendered (Bogusz-Osawa et al., 2002). (Fong *et al.*, 2012) reported that globally developed Incident Reporting and Learning Systems (IRLS), provided the appropriate forum for reporting safety incidents (errors), evaluating them, and designing strategies to avoid repeat occurrences. In highly reliable industries, such as oncology, patient safety and quality of care are crucial and incident learning is also widely recognized as paramount. Incident learning provides a complete feedback loop mechanism for documenting an incident, reviewing the report for missing information, and taking measures to prevent it from occurring again (Williams, 2007), as well as learning from near misses, accidents, and mistakes (Dale *et al.*, 2007). Despite a lack of evidence from low- and middle-income countries such as Ghana. It is believed that the prevalence is higher than in high-income countries due to factors such as insufficient access to treatment and diagnostic testing facilities, which harm the diagnostic procedure (Singh et al., 2017).

Since a misdiagnosis leads to ineffective treatment of patients, diagnostic radiology and radiation are tightly interconnected fields. Other diagnostic radiological hospitals have a high incidence rate, and this is a problem in Ghana. Radiation mistakes include, among other things, overexposure to radiation, the wrong patient or location. The Incident Learning System (ILS) is an excellent option for improving patient safety and treatment quality (Ford et al., 2012). There is a lack of public statistics on the nature and frequency of radiation incidents in developing countries, compared to many in developed countries (Shafiq et al., 2009). (Ganesha, 2014). Between industrialized and underdeveloped nations, there are differences in treatment methods, staff resources, equipment, and other infrastructures when comparing radiation conditions (Cunningham et al., 2010). Many impoverished nations, on the other hand, are implementing more and more modern technology and treatment techniques. The transition to a learning culture (Cunningham et al., 2010) and the need of having an incident learning system in place are therefore equally important (Ganesh, 2014). It was thus decided to develop an Institutional Incident Learning System (ILS) and analyze the frequency and severity of radiation events reported over a period.

Accident causality models are theories of how accidents occur. These models support the analytical methodologies and can influence the results of the study significantly. The causes of injuries have become proportionally complex as the procedures have become more complicated. Simple linear event chain models cannot consistently represent the dynamism of current radiotherapy incidents. Unless any of the device's components fail, accidents can occur which necessitate a new accident cause model. Leveson used system theory to explain these non-linearities in a novel accident cause model called System theoretical Accident Model and Mechanism (STAMP). (Leveson, 2011). STAMP focuses on the following three basic principles: safety restrictions, hierarchical control structures, and process models, all of which are derived from system theory. Safe administration of radiation therapy is mainly dependent on interaction with patients and employees at various levels. Several healthcare providers, regulators, and accreditation agencies are demanding awareness of incidents, including the Ghana Nuclear Regulatory Authority (NRA), WHO, Accreditation Canada, United Kingdom

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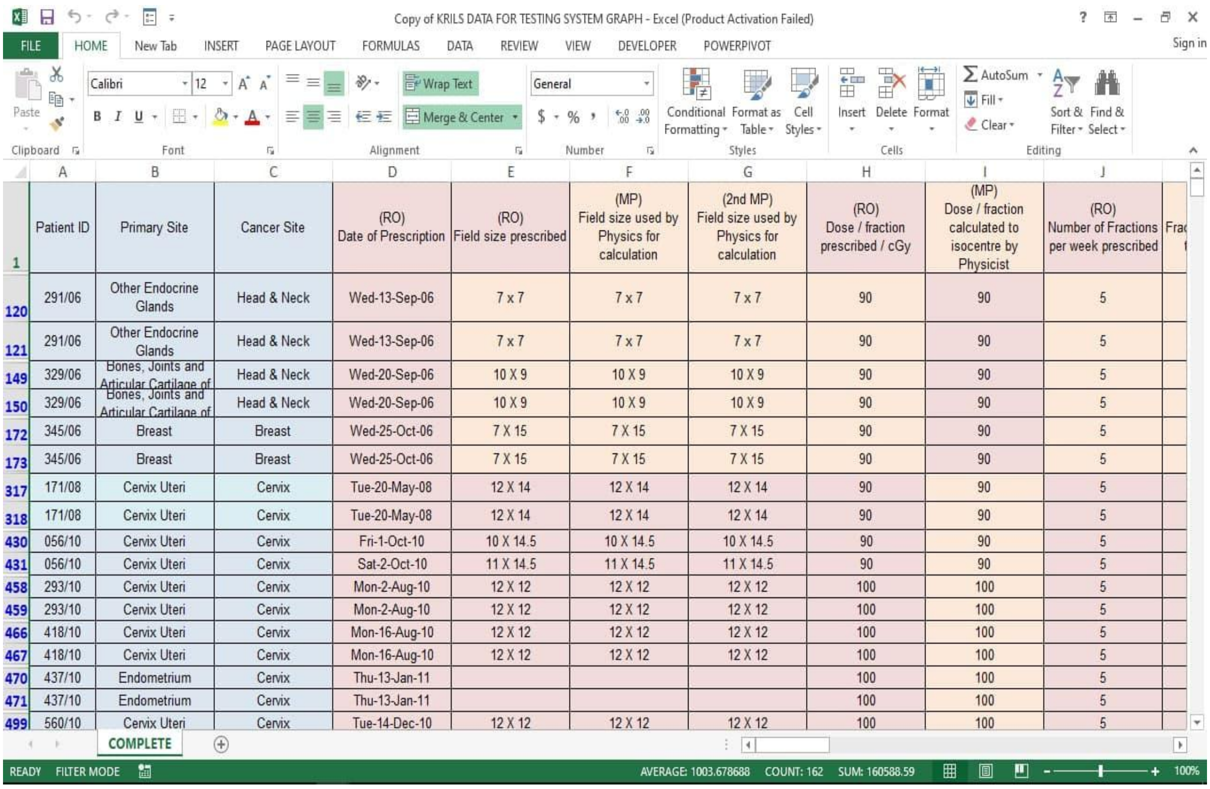
National Patient Safety Agency, and United States (Larizgoitia, Bouesseau, & Kelley, 2013), (Donaldson, 2008), and the United States Joint Commission for Hospital Accreditation (WHO, 2005), (Ford *et al.*, 2017). Distinguished incident learning systems modelled and implemented across the globe is the Safety in Radiation Oncology (SAFRON) system, the Radiation Oncology Incident Learning System (RO-ILS) system, the National System for Incident Reporting (NSIR-RT), and the Radiotherapy Incident Reporting and Review System (RIRAS).

METHODOLOGY

Prototype Overview

The web-based radiotherapy incident analysis system (WRIAS) is a sub-system incorporated into the Addison Radiotherapy Incident Reporting and Learning System. It was developed using the Angular TypeScript and Laravel PHP frameworks for the user interface and backend respectively. Angular is a component-based framework for building scalable web applications that offer a collection of well-integrated libraries that cover a wide variety of features, including routing, forms management, client-server communication, while ensuring privacy and security of software code from the frontend. The dependency injection, queues, unit-testing, real-time events, and highly scalable capabilities of Laravel made it ideal for the maiden version of the WRIAS. The database was constructed using MySQL, a Relational Database Management System (RDBMS) to store, retrieve, modify and administrate a database. MySQL enables storing the data that exists in a database to be structured and organized. The attributes of the incident analysis database as well as its representation on the user interface were made similar to that of the excel file containing radiotherapy treatment records to be analysed. This required all subsequent analysable patient records to follow the same format. Also, form validators were duly used for verifying user input. Finally, records of radiotherapy patient treatment such as that in figure 1 can be uploaded into the WRIAS database for incident analysis.



	Patient ID	Primary Site	Cancer Site	(RO) Date of Prescription	(RO) Field size prescribed	(MP) Field size used by Physics for calculation	(2nd MP) Field size used by Physics for calculation	(RO) Dose / fraction prescribed / cGy	(MP) Dose / fraction calculated to isocentre by Physicist	(RO) Number of Fractions per week prescribed
120	291/06	Other Endocrine Glands	Head & Neck	Wed-13-Sep-06	7 x 7	7 x 7	7 x 7	90	90	5
121	291/06	Other Endocrine Glands	Head & Neck	Wed-13-Sep-06	7 x 7	7 x 7	7 x 7	90	90	5
149	329/06	Bones, Joints and Articular Cartilage of	Head & Neck	Wed-20-Sep-06	10 X 9	10 X 9	10 X 9	90	90	5
150	329/06	Bones, Joints and Articular Cartilage of	Head & Neck	Wed-20-Sep-06	10 X 9	10 X 9	10 X 9	90	90	5
172	345/06	Breast	Breast	Wed-25-Oct-06	7 X 15	7 X 15	7 X 15	90	90	5
173	345/06	Breast	Breast	Wed-25-Oct-06	7 X 15	7 X 15	7 X 15	90	90	5
317	171/08	Cervix Uteri	Cervix	Tue-20-May-08	12 X 14	12 X 14	12 X 14	90	90	5
318	171/08	Cervix Uteri	Cervix	Tue-20-May-08	12 X 14	12 X 14	12 X 14	90	90	5
430	056/10	Cervix Uteri	Cervix	Fri-1-Oct-10	10 X 14.5	10 X 14.5	10 X 14.5	90	90	5
431	056/10	Cervix Uteri	Cervix	Sat-2-Oct-10	11 X 14.5	11 X 14.5	11 X 14.5	90	90	5
458	293/10	Cervix Uteri	Cervix	Mon-2-Aug-10	12 X 12	12 X 12	12 X 12	100	100	5
459	293/10	Cervix Uteri	Cervix	Mon-2-Aug-10	12 X 12	12 X 12	12 X 12	100	100	5
466	418/10	Cervix Uteri	Cervix	Mon-16-Aug-10	12 X 12	12 X 12	12 X 12	100	100	5
467	418/10	Cervix Uteri	Cervix	Mon-16-Aug-10	12 X 12	12 X 12	12 X 12	100	100	5
470	437/10	Endometrium	Cervix	Thu-13-Jan-11				100	100	5
471	437/10	Endometrium	Cervix	Thu-13-Jan-11				100	100	5
499	560/10	Cervix Uteri	Cervix	Tue-14-Dec-10	12 X 12	12 X 12	12 X 12	100	100	5

Figure 1: Excel file showing the radiotherapy patient record test data uploaded for analysis.

Automated Error Capturing Algorithms

The system is currently capable of automatically detecting more than 62 types of radiotherapy treatment errors. Some common errors identified by the system are as follows, but not limited to; wrong field size as a near miss or an incident, wrong total dose incident, wrong depth incident, and inaccurate biological effective dose incident.The principle of the wrong field size algorithm captures the field sizes specified by the radiation oncologist and is used by the first medical physicist to calculate the dose prescribed to that point in the centre of the tumor. The second medical physicist is supposed to cross-check the field size prescribed by the radiation oncologist and calculated by the first medical physicist. The field sizes are then compared, and in case the field size specified by the second Medical Physicist, is the same as the prescribed field size by the radiation oncologist and used in the dose calculation, then no error exists. If the field size specified by the first Medical Physicist, is not the same as that of the second Medical Physicist, but the same as that of the radiation oncologist, a wrong field size error is thrown as a near miss. In the situation where the field size specified by the second Medical Physicist, is not the same as the prescribed field size by the Medical Oncologist, a wrong field size error is thrown as an incident. Patient treatment planning is paused until the error is corrected; otherwise, the patient is allowed to go on with treatment.

To catch a wrong total dose incident, dose per fraction prescribed by the radiation oncologist, dose per fraction calculated by Medical Physicist, and the dose per fraction used by the RTT for patient treatment are accepted as inputs. To catch a wrong total dose incident, a comparison is made between the dose per fraction prescribed by the radiation oncologist, the dose per fraction calculated by Medical Physicist, and the dose per fraction used by the RTT for patient treatment. If the dose per fraction prescribed by the radiation oncologist, and the dose per fraction calculated by Medical Physicist are equal, and the dose per fraction prescribed by the radiation oncologist is equal to the dose per fraction used by the RTT for treatment, then patient treatment is allowed. Otherwise flag the wrong total dose as an incident.To catch the wrong depth as an incident, the depth prescribed by the radiation oncologist and the depth used by the Physicist is accepted as input. In case the depth prescribed by the radiation oncologist is equal to the depth used by the Medical Physicist, then patient treatment proceeds as normal. Otherwise, wrong depth used, wrong dose per fraction, wrong depth of tumor, wrong total dose, and wrong SSD/SAD are flagged as incidents.The biological effective dose (BED) incident capturing algorithm returns false, pointing out the occurrence of a BED incident, if the treatment gap entered is greater than zero and the biological effective dose compensation was not compensated for treatment to continue.

Implementation Testing

For a single dose analysis test case, hypothetical patient information was first keyed into the Addison Radiotherapy incident learning system via the New Patient interface of the Biostatistics dashboard. The patient's treatment record was then keyed into the system via the 'New Dose Analysis' modal form as shown by figure 2. The patient's name can be selected from the first form field and suitable values entered via subsequent fields labelled as follows: Dose/# treated by therapist. (RTT), Date of Prescription (RO), Number of fractions per week prescribed (RO), Date of initial treatment (RTT), Fractions entered by the physicist (MP), Field size prescribed (RO), Depth prescribed (RO), Field size used by Physics for calculation (MP), Depth used by Physicist (MP), Dose / fraction prescribed (RO), total fractions treated (RTT), Dose / fraction calculated to isocentre by Physicist, Total treatment time (days), total fractions prescribed (#) (RO), Treatment gaps (RTT, MP) (days), total physical dose prescribed = dose/# x # (RO), Biological effective dose compensation (MP), Incomplete (partial) treatment (RTT,

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MP). Errors captured by the system are then made available for analysis. Also, upon clicking the 'Upload dose analysis' button, the user is prompted with information on the various attributes or headings required in the excel file for a batch patient treatment record analysis. This can be seen in figures 3 and 4. The appropriate file can then be selected by clicking the 'Choose File' button. An excel file with the format and information as shown in figure 1 was uploaded into the patient treatment record analysis system for testing. The data headings comprised the Patient ID, primary site, cancer site, prescription date by radiation oncologist (RO), Field size prescribed by RO, field size used by the physicist for calculation, dose-per-fraction prescribed by RO, dose-per-fraction calculated to isocentre by physicist, number of fractional doses prescribed per week, fractions entered by Physicist, total fractions prescribed, total physical dose prescribed, number of fractions treated by Therapist (RTT), total physical dose delivered by therapist, total physical dose undelivered by therapist, patient treatment evaluation per physical dose delivered, depth prescribed, depth used by Physicist (MP), depth used by Physicist, date of initial treatment, date treatment ended, total treatment time (in days), RTT and MP treatment gaps (in days), MP biological effective dose compensation, fractions prescribed, dose per fraction, overall treatment time, pre-gap fraction, normal tissue, tumor, kick off time, potential doubling time, BED_{10} prescribed, BED_{10} pre-gap, BED_{10} required, BED_3 prescribed, BED_3 pre-gap, BED_3 required, remaining fractions, D_{10} dose per fraction, BED_3, therapeutic ratio prescribed, therapeutic ratio required, total physical dose delivered by therapist, therapeutic ratio prescribed, total dose delivered frequency, and maximum therapeutic ratio. For a check, error warnings are displayed to the user when the specified rules are unheeded as depicted by figure 5.

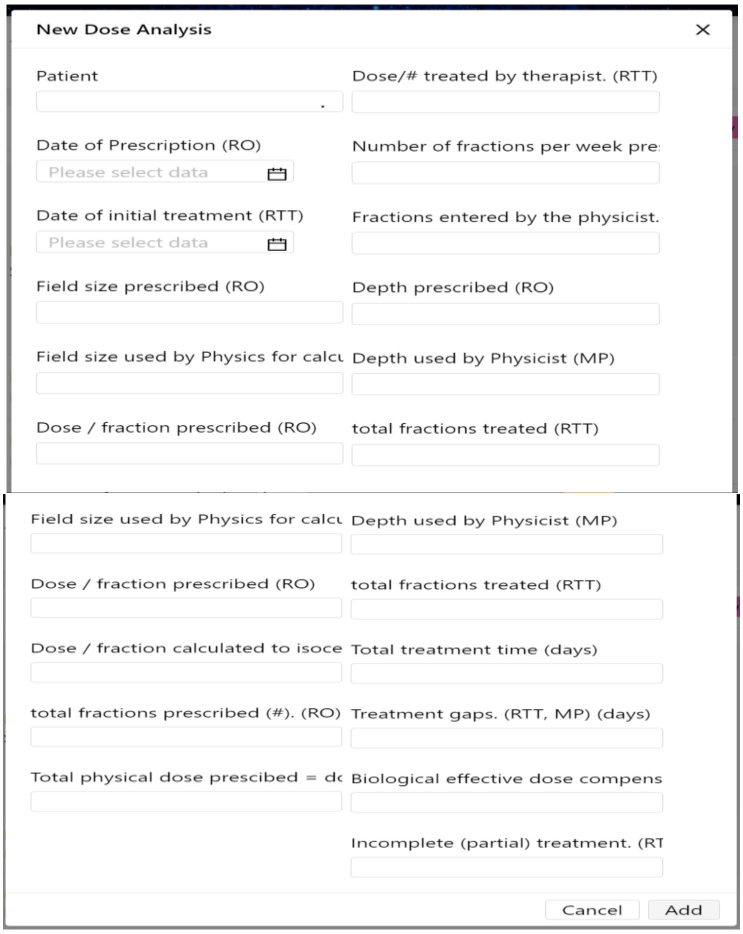

Figure 2: New Dose Analysis form for a single patient

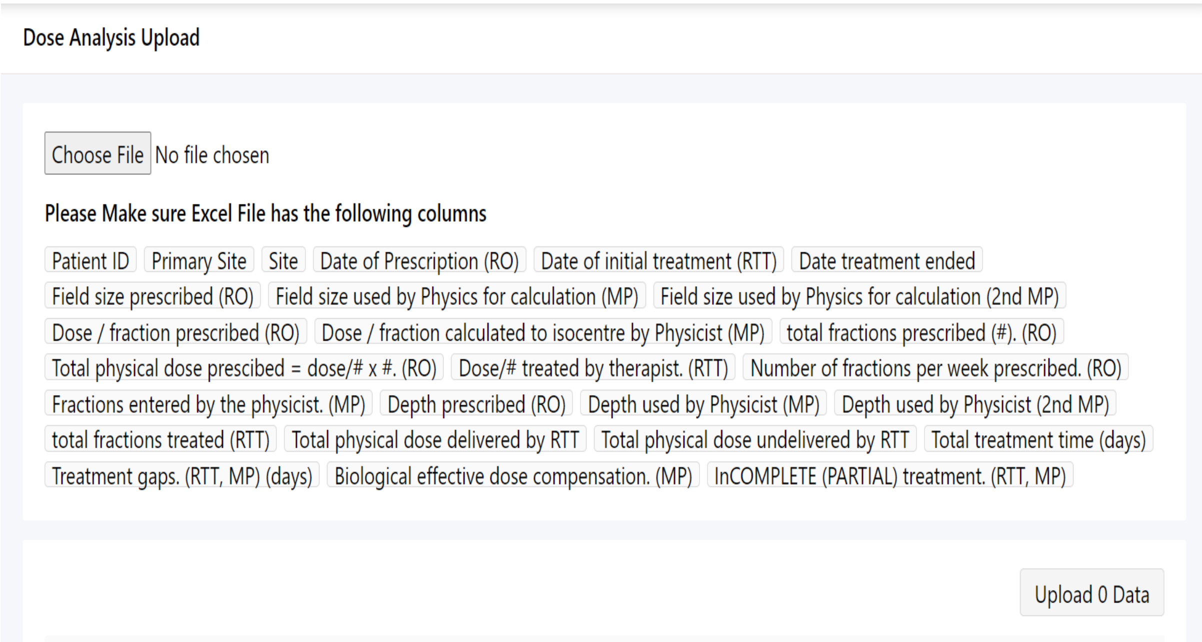

Figure 3: Excel file culumn headers specification

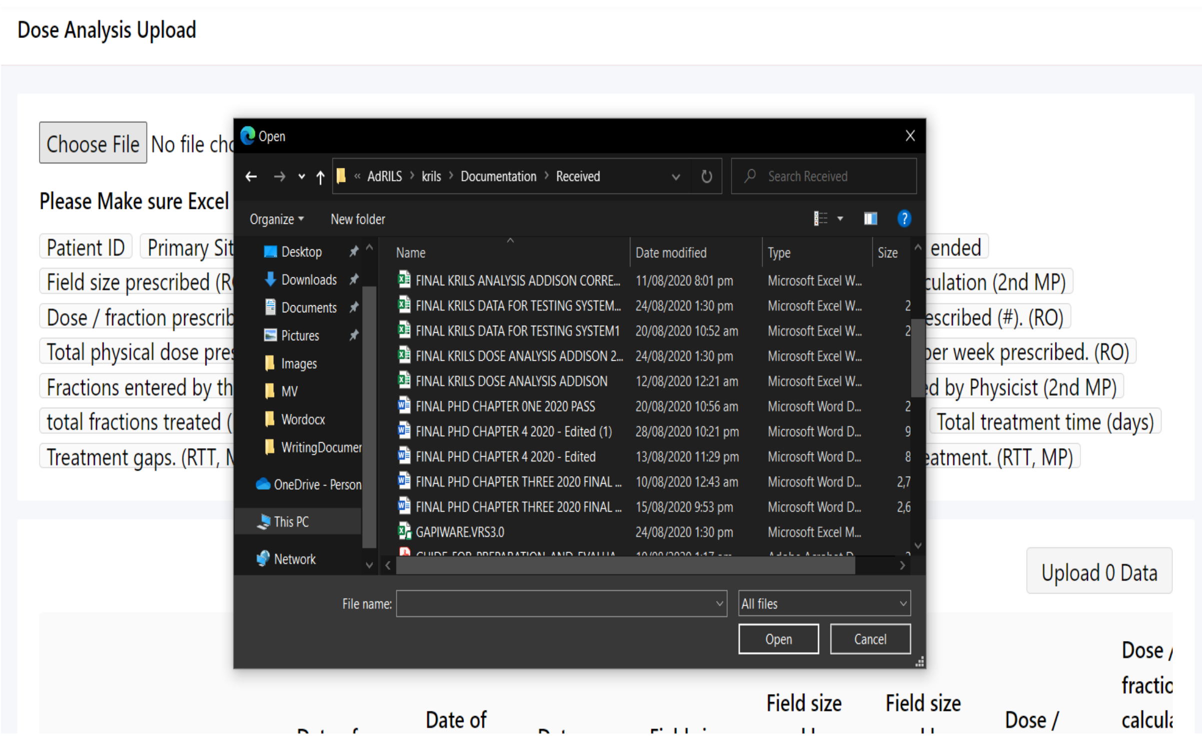

Figure 4: Patient treatment record file upload process

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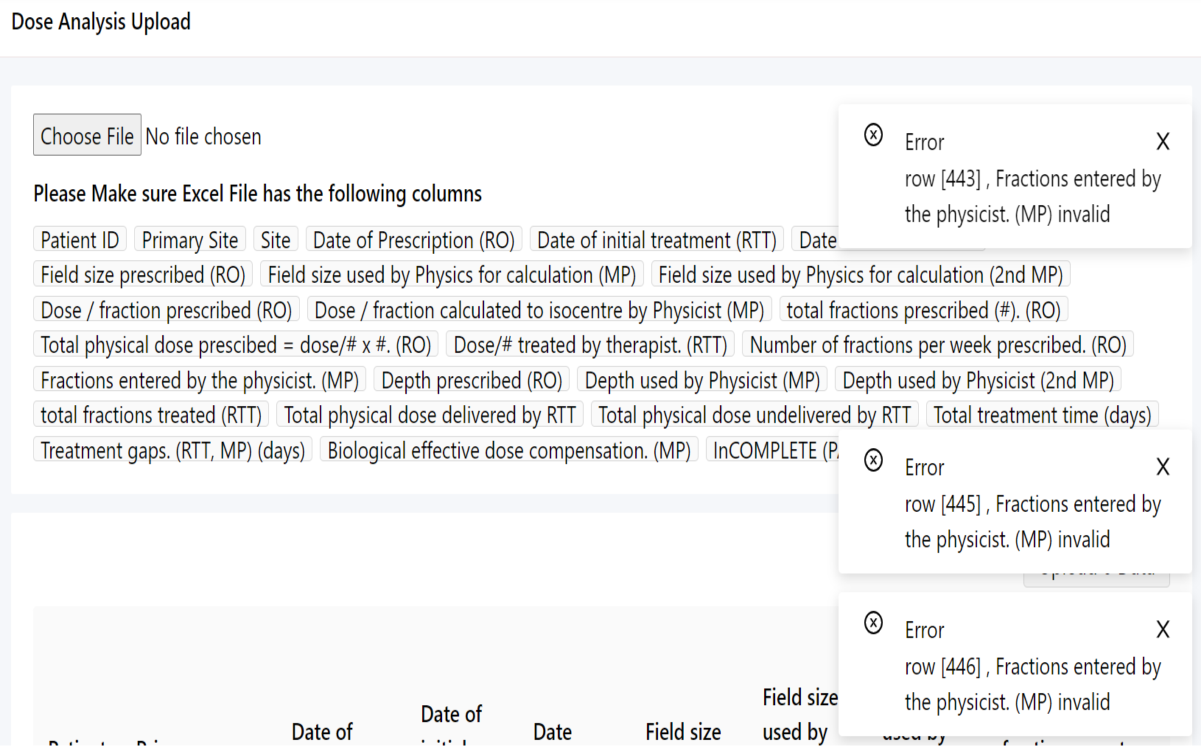

Figure 5: System displays error messages when a file without the specified column headers is uploaded

The number of patient data recorded is displayed on the 'Upload' button when the excel file is uploaded into the system, figure 6. The results of this process yields table 1, which shows the patient treatment records uploaded for incidence analysis.

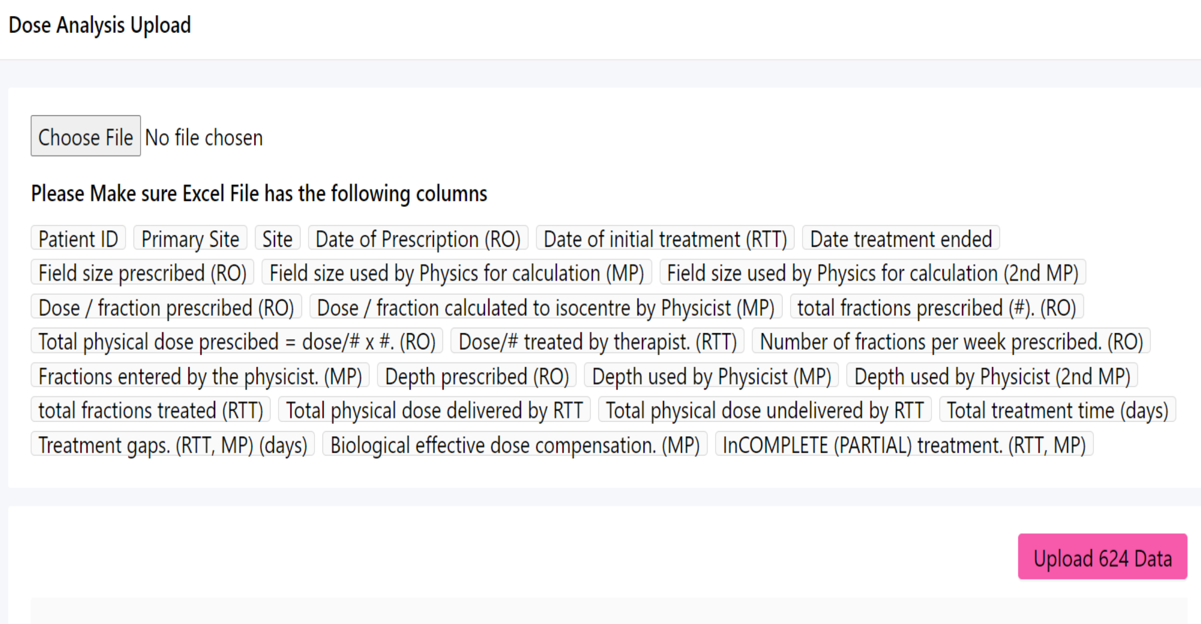

Figure 6: The number of patient data records is displayed when loaded

Table 1: Table of the patient treatment records uploaded for incidence analysis

Primary Site	Site	Date of Prescription (RO)	Date of initial treatment (RTT)	Date treatment ended	Field size prescribed (RO)	Field size used by Physics for calculation (MP)	Field size used by Physics for calculation (2nd MP)	Dose / fraction prescribed (RO)
Head & Neck	Head & Neck	5 May 2004	5 May 2004	18 May 2004	5 X 6	5 X 6	5 X 6	180
Head & Neck	Head & Neck	26 May 2004	26 May 2004	8 Jun 2004	7 X 14	7 X 14	7 X 14	300
Head & Neck	Head & Neck	10 Jun 2004	11 Jun 2004	18 Jun 2004	4 X 8	4 X 8	4 X 8	180
Head & Neck	Head & Neck	9 Aug 2004	9 Aug 2004	20 Aug 2004	5 X 6	6 X 6	5 X 6	100

Captured errors from the patient treatment record batch are then statistically represented by graphs for incidence analyses. This is further discussed in the Results section.

RESULTS AND DISCUSSION

The results of AdRILS implementation required test data that is selected based on the PRISMA 2009 method. Records identified through the radiotherapy manual database were 4479 patient data set, based on careful screening, since patients cannot be duplicated in the system. For eligibility, studies included in the quantitative analysis (meta-analysis) were 219 patients with 1215 treatment sessions, whiles 4479 were used for qualitative analysis. A total 219 patients had levels of incidence during their period of treatment. 27.854 percent of the patients had the error detected between treatment prescription and delivery. This was possible, because of the role of the second physicist. 58.447 percent were actual patients with levels of incidents based on dose delivered to target. As a single treatment unit, treatment gaps contributed to these effects. Incidents are sometimes described as patient safety events that happened on behalf of the patient, regardless of whether or not there was damage involved. It is an occurrence in which a therapeutic dosage is not administered as intended, with or without damage.

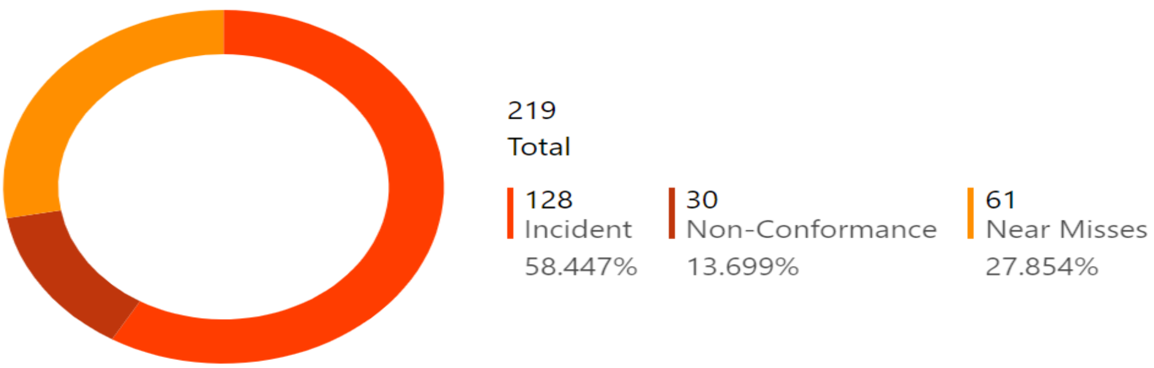

Figure 7: Real patient incidence statistics as an indicator for error types

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An overdose caused by a machine commissioning error and one fraction of a 25-fraction course administered at the incorrect SSD led to a 2 Gy difference between the anticipated and delivered dosages when a lung lesion was mistargeted. Non-conformance is defined as non-compliance with another component of a documented protocol that does not directly influence radiation treatment. A near miss is described as an occurrence or circumstance that could have resulted in an accident, damage, or illness but was not permitted due to chance or prompt action, such as a close call or a close hit. Close calls are occurrences that happened with a link to a certain patient but did not reach or influence the patient significantly as treatment procedure, figure 7 is converted into events in figure 8, showing the types of errors identified at the Clinic.

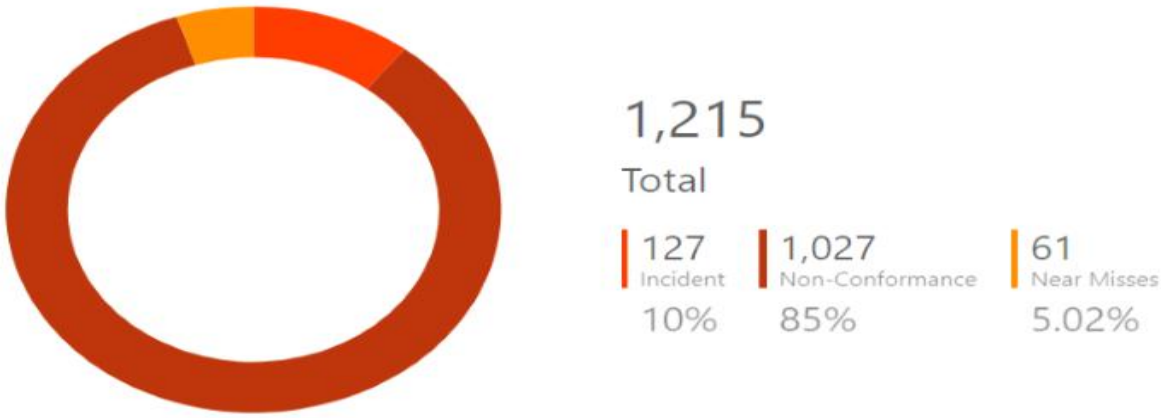

Figure 8: Total number of incidence types captured by the system according to patient treatment sessions

Patient treatment is dependent on the cancer type, site, stage, prognostic factors, and treatment technique. Some patients were treated with a single field, others with two fields (parallel opposed), three fields, four fields, and sometimes an extra number of fields. Non-conformance error was the lowest error type with near misses, as second highest type of error. The trend of error is reflected in both patient errors and type.

An error type sequence refers to the order of error occurred during a radiotherapy workflow showing a pattern of error determined by faults, factors, causes and sub-factors. Wrong total dose incidents, for example, is due a number of faults, such organizational management, human behaviour involving staff, technical, and procedural issues. These factors are also dependent on a number of factors. Possible factors which produce wrong total dose are acting outside one's scope of practice, wrong communication, leadership and external issues, negligence, poor judgement, error in acceptance testing and commissioning, and training. The possible causes of these factors include, but not limited to, failure to remedy past known shortcomings, inappropriate or misdirected communication, verbal instructions not supported by written documents, inadequate periodic assessment of staff competency, not following explicit referral to best – practice documentation, lack of review of pre-existing reports, poor or incomplete or unclear documentation, failure to request needed information, distraction, inadequate supervision, and lack of independent review. Each error identified in figure 9 and corresponding total errors per in table 2 are contributed by a number of faults, which are due to factors, causes and sub-factors.

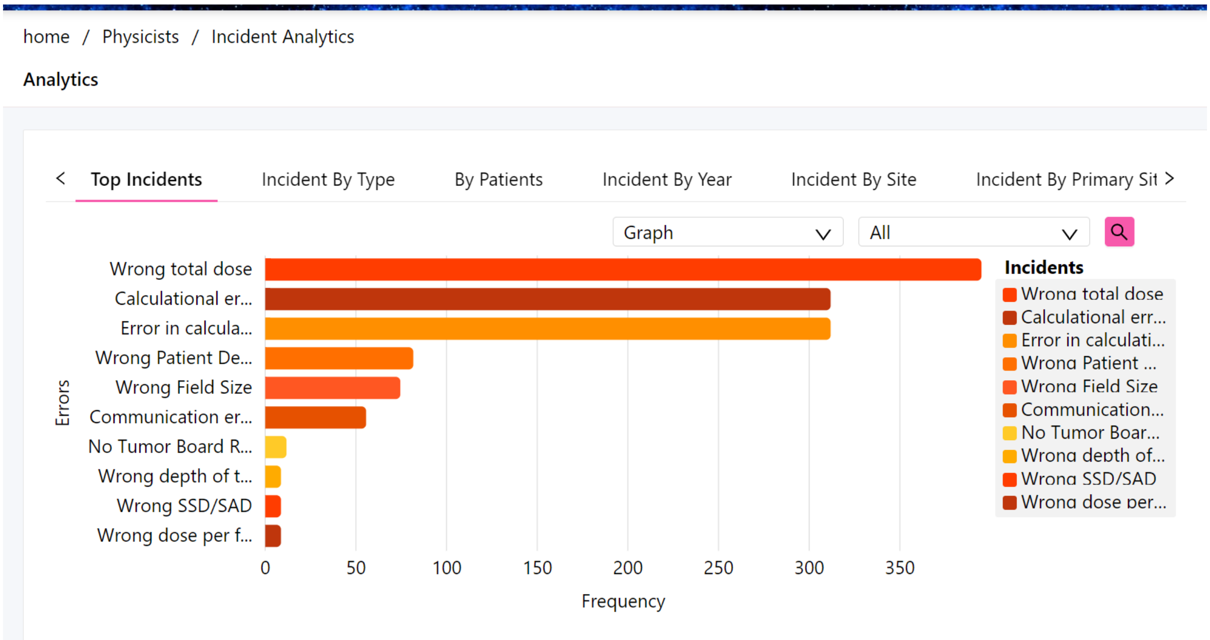

Figure 9: Frequency of error types captured by AdRILS in the test data, an indicator for treatment errors

Table 2: Incidents identified per year. Year-dependent radiotherapy patient incident analysis

	Incident	Near miss	Non-conformance	Patient treated	Incident (%)	Near miss (%)	Non-conformance (%)	Total (%)
1st year	1	3	0	462	0.22	0.65	0	0.87
2nd year	7	2	0	430	1.63	0.47	0	2.10
3rd year	28	4	5	492	5.69	0.81	1.02	7.52
4th year	20	4	2	511	3.91	0.78	2.35	7.04
5th year	13	8	3	630	2.06	1.27	0.48	3.81
6th year	12	7	4	613	1.96	1.14	0.65	3.75
7th year	21	9	1	684	3.07	1.32	0.15	4.54
8th year	20	12	13	643	3.11	1.89	2.02	7.02
Total	122	49	28	4465	2.73	1.10	0.63	4.46

Treatment modalities depend on the cancer site and the primary site. Prognostic factors determine the treatment parameters and the expected treatment outcome. A total of four thousand four hundred and sixty five patient treatment were reviewed, with a total incident of 4.46%. The average incidence rate per 100 patients treated is 0.22 for the first year of treatment. It increased to 1.63, 5.69, 3.91, 2.06, 1.96, 3.07 and 3.11 respectively for the subsequent years, as shown in table 2.

Limitations of the study

This research was limited to the development of patient treatment record analytical platform embedded on a major radiotherapy patient management system, the Addison Radiotherapy Incident Learning System. Apart from rule-based algorithms for error capturing, no other artificially intelligent technology was employed in the creation of the patient treatment record analytical system.

Regarding data privacy, the study has already been cleared for exemption by the university ethics committee as well as the Komfo Anokye Teaching Hospital's ethical board. The researchers took no special notice of patient names on the various medical records collated for the study as main focus was on dose analysis of patient treatment. Patient identities are duly hidden and all clues that might trace back to the patient as an individual were cleaned from the data. Hence their personal identities do not appear in any report or publication of this research.

CONCLUSION

In this research study, were able to build a web-based system that accepts as input; 1) a single patient treatment record; 2) a batch of patient treatment records over the years; and analyse them for errors (near misses, non-conformance, and incidents) which radiotherapy treatment staff can learn from for safer cancer treatment purposes. Captured errors are then analysed with graphs, and recommendations are made for learning purposes.

The main metrics for the electronic incident reporting and learning framework are in the areas of (1) number of recorded incidents, (2) reporter characteristics (health professionals as well as the public), (3) no time limits for reporting, (4) user satisfaction, (5) perceived benefits for users and (6) perceived disadvantages.

Several major benefits have been observed, including increased incident reporting, improved report completion increased reporting by non-healthcare workers, better management and quality management department notification, and greater reporting of near calls. There have also been certain challenges, such as reducing file close-out / sign-off time in particular locations. Radiotherapy staff members have expressed pleasure with new incident learning programs, in addition to reporting improvements.

Other advantages include (1) easy access to computers and paperwork, (2) greater reading, and (3) a better understanding of what constitutes an event and a near-miss. (4) less time required to complete reports, (5) availability of information on the status of individual managers' occurrences, (6) easier completion of forms, (7) less paper shuffling, (8) more accurate reporting information, (9) increased confidentiality (files not lying around in the dosimetry room for anyone to see), and (10) less lost files make tracking follow-up behaviour easier.

We realized that by utilizing supervised machine learning algorithms, automation of the error capturing process can be greatly enhanced.

Recommendations for Future Iterations

From the usability tests carried out, it was found that keeping the system updated with specific error types into the system at all times before they can be recognised and captured as errors in the patient treatment record analysis can be quite daunting. Manually giving recommendations every time for learning purposes too can get tedious. In future iterations, we intend to improve the error tagging and solution recommendation parts with supervised machine learning algorithms where an interface will be made available to show the types of errors captured and a summary of recommendations and their chances of mitigating risks in terms of percentages will be automatically made available for incident learning.

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