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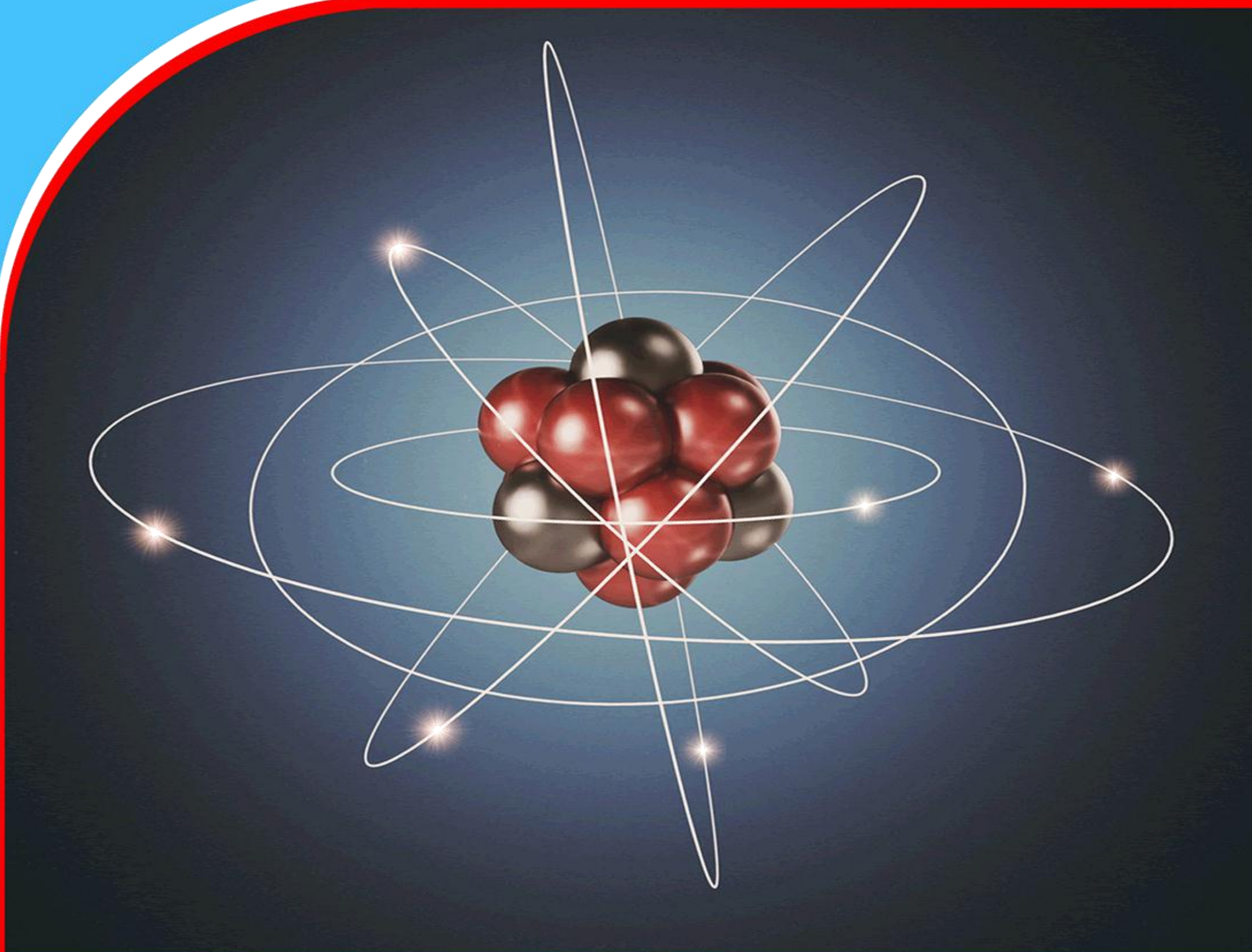

USING INCIDENT LEARNING IN RADIATION THERAPY: THE FIRST-HAND EXPERIENCE IN A LOW-INCOME SETTING USING CUTTING-EDGE TECHNOLOGY

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USING INCIDENT LEARNING IN RADIATION THERAPY: THE FIRST-HAND EXPERIENCE IN A LOW-INCOME SETTING USING CUTTING-EDGE TECHNOLOGY

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ABSTRACT

Objective: To explore the implementation of an incident learning system for quality management of radiotherapy in a low-income radiotherapy setting.

Materials and Methods: An incident learning system was specifically designed using the human-centred design, the waterfall model was implemented for error identification and learning of individual incidents. The incidents that occurred in external beam radiotherapy for 8 years, were reported.

Results and Discussion: A total of 122 incidents, 49 Near-misses and 28 non-conformance were identified with 4465 patients treated within the 8 years. The total average percentage of 2.73, 1.10, 0.63 and 4.46 were detected for incidents, near miss and non-conformance respectively. The average incident, near miss and non-conformance rate per 100 patients treated were 2.73, 1.10 and 0.63 respectively over the 8-years review period. The highest wrong total dose error of 79 occurred in the eighth year. Trend analysis identifies major improvements in clinical practice by measuring and analyzing patterns of incidents over time. The trending incident levels for each treatment site were in decreasing order of level 4, level 1, level 2, level 5, and level 3.

Conclusion: Treatment status gave an overview of the quality of clinical decisions and implementation in the management of radiotherapy patients. Effective implementation of incident learning can reduce the occurrence of near misses/incidents and enhance the culture of safety.

Recommendation: Future iterations, would improve the error tagging and solution recommendation parts, and extend the implementation all radiotherapy centres in the country.

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

INTRODUCTION

With the fast advancement of radiotherapy equipment and technology in Ghana, radiation techniques grow more complex. The planning and delivery of radiation is a very complicated, multi-step procedure involving numerous professional groups. Every stage of the radiation oncology treatment process requires expertise in the management of cancer and certain benign diseases, radiobiology, medical physics, and radiation safety, which can only be obtained via systematic and organized training. There are several stages where problems might occur, yet significant radiation events are uncommon. Furthermore, determining the real mistake rate in radiation is difficult. Radiotherapy incident learning is critical to ensuring radiotherapy's appropriateness, quality, and safety. Incident learning has shown its audit worth in a variety of sectors as a systematic tool and approach to quality management (Pronovost et al., 2009). It has also been used effectively in various radiation oncology clinics for numerous years. For the last nine years, a voluntary worldwide reporting system (Radiation Oncology Safety Information System (ROSIS)) has been available online (Cunningham et al., 2010). As part of its six-point "target safely" strategy to enhance patient safety in radiation, the American Society for Radiation Oncology (ASTRO) has asked for a nationwide event reporting/learning system.

The Work Group on the Prevention of Errors (WGPE) of the American Association of Physicists in Medicine (AAPM) issued consensus guidelines for incident learning database architectures in radiation oncology in 2012 (Ford et al., 2012). Learning from radiation mishaps or near misses through incident reporting systems has the potential to enhance patient safety and clinical service quality (Williams, 2007). Reporting, responding to, and learning from events and near misses may also give an evaluation of the quality assurance program's success or failure in avoiding a mistake. Sharing incident information enables for improved process optimization by providing information about the expected severity and frequency of certain mistakes, as well as aiding in the prioritization of quality management activities (Huq et al., 2008; Rath, 2008; Ford et al., 2012; Peters et al., 2010). A variety of sources recommend reporting and learning from radiation events or near misses. While event learning is widely acknowledged to be beneficial in the radiation treatment context, adopting incident reporting and learning poses a significant barrier. It needs more clinical resources as well as a well-designed system for reporting, analysis, and reaction. What matters more is the creation of a more open mentality and fair culture for reporting near misses and events, with a greater focus on incident learning to find hidden mistake pathways. There have been few studies that look at the impact of event learning on patient safety and quality in specific clinics, even though various departments have described their experiences (Arnold et al., 2010; Clark et al., 2010; Ekaette et al., 2006; Yeung et al., 2005; Bissonnette and Medlam, 2010). The goal of this study is to investigate the application and efficacy of event learning in a freshly created radiation oncology program with sophisticated equipment utilizing a system designed based on AAPM approved database structure.

MATERIALS AND METHODS

Radiotherapy Site

The oncology directorate of the Komfo Anokye Teaching Hospital is a comprehensive clinical and academic department with a newly established external beam radiotherapy programme that treats about 1100 patients per year. Oncology Directorate, Komfo Anokye Teaching Hospital, currently operates one Varian Clinac ix linear accelerator (Linac) system (installed, accepted, and commissioned in 2019), one Cirus cobalt – 60 teletherapy machine (commissioned in 2004), one Varian Acuity conventional simulator, and Low-dose-rate Curietron brachytherapy system. The PROWESS PATHER treatment planning system is used for patients scheduled for the cobalt-60 machine whereas Varian Eclipse 15.6 is used for patients scheduled for the linear accelerator. The ARIA oncology information system (Version 15.5.0, Varian Medical Systems, Inc., Palo Alto, CA, USA) contains the patient and treatment EMR for the Linac, while manual medical records are used for the cobalt system. Radiation Oncology Directorate has employed 8 medical physicists, 4 radiation therapy technologists (RTT), 8 radiation oncologists, 42 oncology nurses, 2 biostatisticians, and 4 administrative personnel.

Development of the Reporting and Analysis System.

In the radiotherapy department, an incident learning system was specifically designed and developed for reporting, investigating, and learning individual external beam radiotherapy incidents. Prototyping is the experimental process of building initial interfaces of the application excluding their full functionality. Prototypes were built in varying degrees of fidelity to capture design concepts and allow users to test and measure the extent to which the system meets their needs. Without a pre-existing system in Ghana as such, prototyping proved to be essentially supportive. The prototype enabled both users and developers of the system to agree on the requirements specification after thorough testing, (Interaction Design Foundation, 2020). The architecture of the system (Figure 1) throws light on the radiotherapy workflow path of a patient undergoing a routine radiotherapy service with a network of scientific infrastructure, equipment-specific activities, patient-specific activities, and other activities contributing to protocol violation. The Waterfall Model was the first process model and the first Software Development Life Cycle methodology utilized for software development. It depicts a plan-driven process in which all project modules and process activities were planned and scheduled before any work could be done on them. The whole software development process was separated into phases, with each phase being finished before the start of the next, and no phase overlapping another. Sequentially, the output of one phase served as the input for the following step. Unplanned occurrences and unpredictability were not accommodated due to strict adherence to the phases of the waterfall model. Angular, laravel, Ant design, visual studio, Node package manager, Web application, PHP and Database were development and implementation tools for the waterfall model.

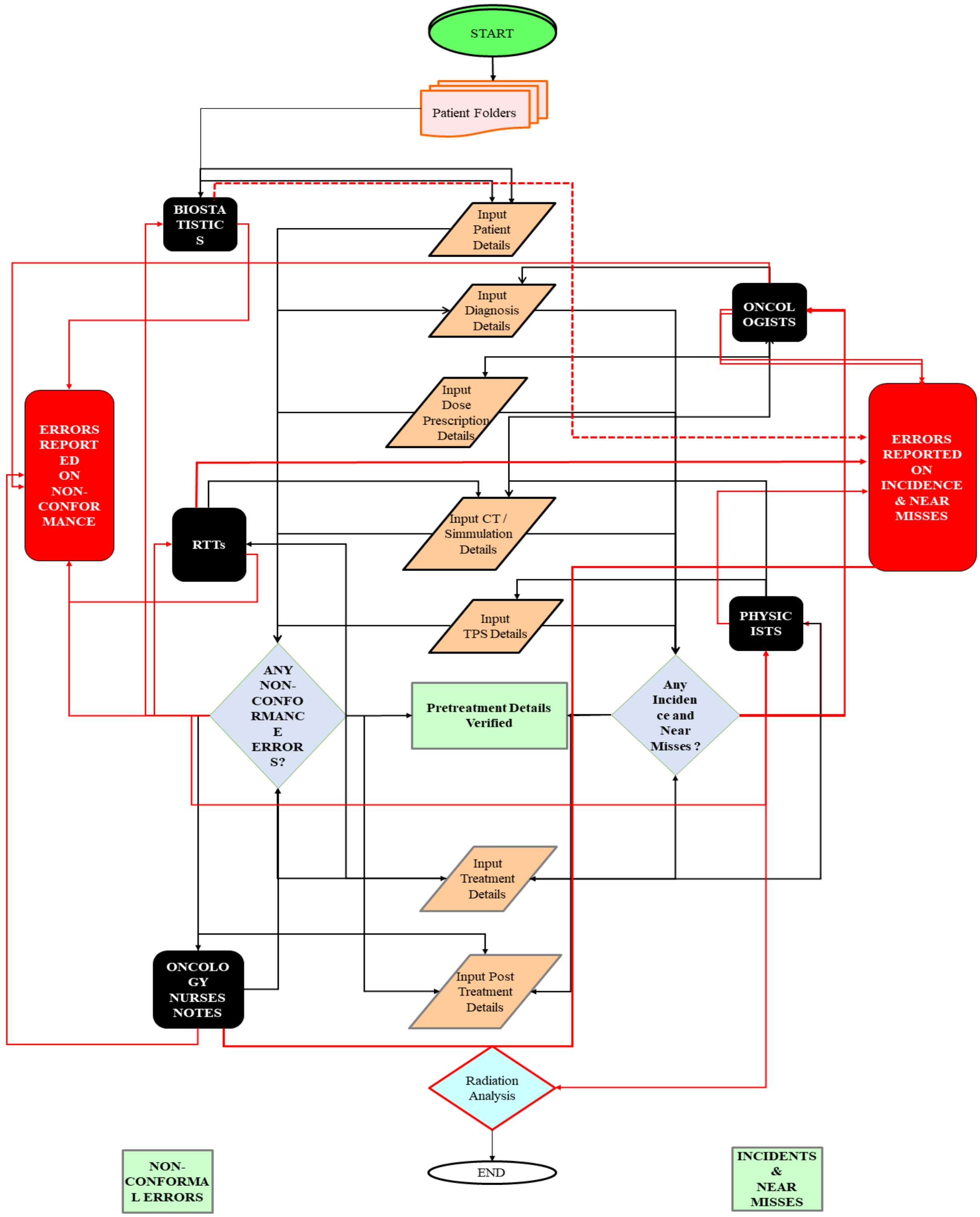

Figure 1. Flow chart Diagram depicting the Architecture of the system.

***Software Implementation*.**

Following pilot testing, clinical personnel began using the system to report occurrences that happened in clinical practice. An interdisciplinary team comprised of radiation oncology, radiation physics, and technologists studied, evaluated, and learnt from the occurrences recorded in the system. Our implementation strategy's top aim was to vigorously encourage employee acceptance and engagement by emphasizing senior management participation and expectations about the construction of a fair workplace. It was intended to encourage openness about reporting occurrences, a focus on learning and assistance, and a duty to act so that all staff members felt comfortable sharing incidents while retaining professional accountability. The results of the system implementation require test data that is selected based on the PRISMA 2009 method. Records identified through the radiotherapy manual database were 4506 patient data set. Careful screening to remove duplicates produced a record of 4506 patients. For eligibility, studies included in the quantitative analysis (meta-analysis) were 194 patients with 657 treatment sessions, whiles 4506 were used for qualitative analysis. The test incident data require validation by checking for correctness and completeness.

As good clinical data, the data set used in the system was attributable, eligible, contemporaneous, original, accurate, enduring, and consistent. All clinical available data was not used but selected dataset which shows the error detectable attributes of the system. Data used helped to detect the Personnel who made inputs into the system, not according to the rule, in addition to the error which occurred. This particular data was an earlier project of building Cancer Patient Registration exercise which was not functional as expected. The openness and active engagement of users in event processing considerably helped to the consistency of event processing by the system. The cases were analyzed individually by the system under the guidance of designated oncology professional. A comprehensive team inquiry is employed for more significant occurrences and when determining the core cause and identifying the most relevant learning component necessitates a more thorough review. Following that, events are handled depending on their severity categorization. More complicated incidents that need major remedial measures are sent to the department's Process Improvement Committee for additional review and processing. The investigating team analyzed and assigned all relevant cause/contributory variables from management, technique, people, equipment, and process, since it is a rare case in which just one single cause is at work, allowing a thorough root-cause analysis to be implemented.

Furthermore, each discipline reviewed or commented on the data within their specialization, concentrating on process breakdowns and system failures to develop ways to avoid recurrence. The department's no-blame principle was constantly publicized, encouraging employees to report instances without fear of retaliation. Blaming a single person or group as the only root cause may result in remedial activities that fail to address an underlying problem. When undertaking root-cause analysis, an individual's activities must be assessed in the context in which they occur. Each reporter is aware of all events that they have filed, as well as the supervisor's analysis and the final disposition of the events. Focused education sessions on a specific process to highlight error risk, process mapping, protocol changes, quality control measures and approaches to error prevention and continuous improvement, discussion with specific workgroups to make them aware of any error risk that has been identified, and presentations at chart rounds were among the learning actions. The incident learning was utilized to guide clinical process reengineering. The data and statistics gathered via the constructed database were presented together with corrective measures

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at the department quality improvement conference, enabling easier communication of issue specifics and appropriate process improvements.

RESULTS AND DISCUSSION

A total of four thousand four hundred and sixty-five patient treatments 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 1.

Table 1. Eight years statistics of types of error

	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

The third year recorded the highest level of incidence rate. Near miss had an unpredictable sequence from the previous year. Non-conformance showed the same characteristics as the near-miss. The incident category of identified error type is shown in Table 2. The highest wrong total dose error occurred in the eighth year. The highest incident rate for calculational error of the exposure time, wrong field size, wrong treatment depth and communicational errors occurred in the third year, sixth year and an eighth year respectively.

Table 2: Summary of identified incidents category

Category	1st year	2nd year	3rd year	4th year	5th year	6th year	7th year	8th year	Total
Wrong total dose	3	20	73	67	37	32	49	79	360
Calculational error of the exposure time or dose Error in commissioning of TPS	3	13	66	49	34	30	49	45	289
Wrong Field Size	3	3	4	1	11	15	10	10	57
Wrong Treatment Depth	3	2	4	6	10	8	9	18	60
Communication errors between clinical staff and patient	0	0	8	12	5	5	3	22	55
Incorrect field size (X,Y)	0	0	1	0	0	0	0	1	2
Total	12	38	156	135	97	80	120	175	823

An error type sequence refers to the order of error that 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 to several faults, such as organizational management, human behaviour involving staff, technical and procedural issues. These faults are also dependent on several factors. Possible factors which produce the wrong total dose are acting outside one's scope of practice, wrong communication, leadership and external issues, negligence, poor judgment, error in acceptance testing and commissioning, and training. The possible causes of these factors include but are 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, destruction, inadequate supervision and lack of independent reviewing. Trend analysis identifies major improvements in clinical practice by measuring and analyzing patterns of incidents over time, revealing new issues, or, if improving, that safety measures are working. Trend and cluster analysis were conducted using statistical control methodologies, such as check sheets, to collect data in an efficient and relevant manner. In a structured and coordinated manner, they develop efficient methods for incident reporting and learning data collection. Table 3 shows the definitions of the incident level pattern and cluster.

Table 3: Levels of incidents, notification and reporting definition

Incident level	Incident Level Definition
Level 1	A critical incident that has a significant impact on a patient (for example, a dose variation from the prescribed total dose of more than 25 per cent).
Level 2	A significant incident occurred that influenced a patient (e.g., dose deviation from a prescribed total dose of 5-25 per cent that could have led to serious side effects according to the irradiated organ)
Level 3	Minor events that have minimal impact on a patient (e.g., less than 5 per cent dose deviation from total intended prescription dose; 5 mm geometric variation except for a set-up fault, no shielding of normal tissue but below tolerance dose)
	Radiation incident that is compensable (e.g., the outcome, such as clinical significance, was not different radiobiologically from that which was intended)
Level 4	Near miss found after the responsibility phase but before commencing the recommended treatment plan, or therapy carried out without sufficient check, but patient received appropriate treatment as a result of a subsequent check
Level 5	Non-conformance with some aspects of conventional protocols, however, had no direct impact on radiation therapy.

A packed bubble chart of common cancer-treated sites and their corresponding number of treatment incident courses is shown in figure 2. A bubble chart requires three dimensions of data: the x- and y-values (to place the bubble along the value axes), as well as a third value for its volume. The volume is proportional to the total number of incident courses.

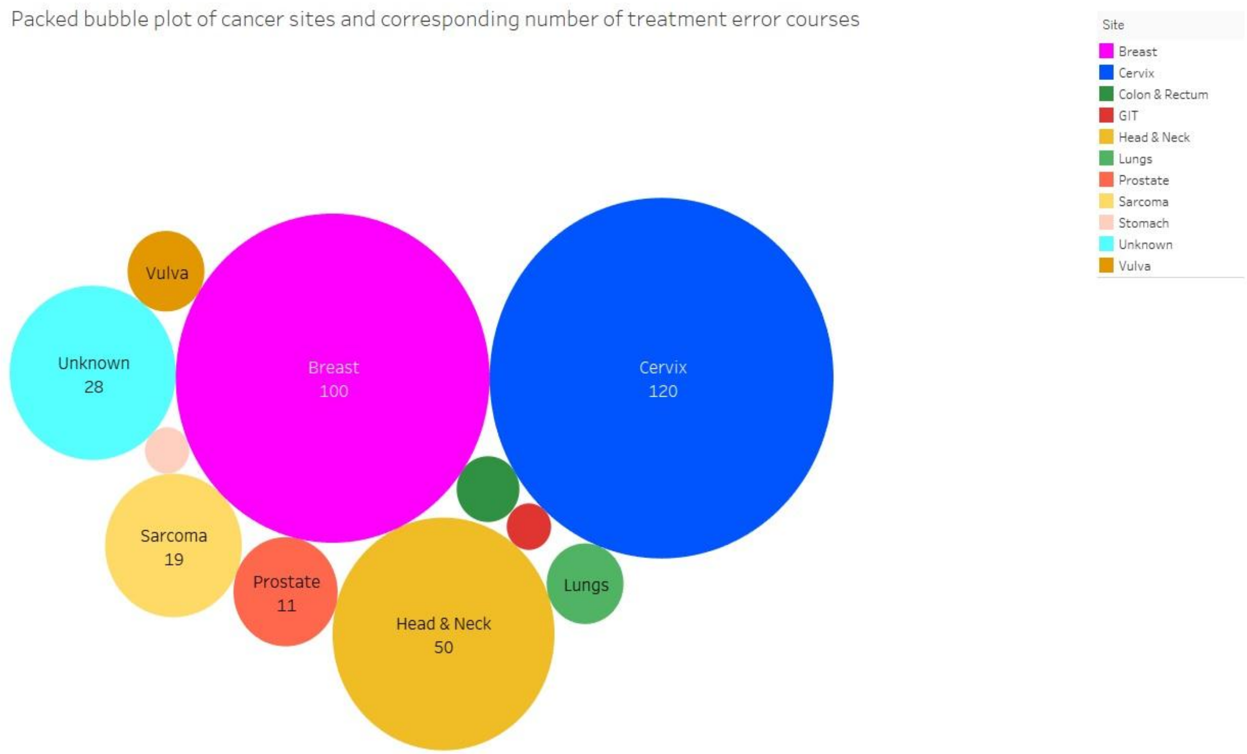

Figure 2: Packed Bubble Chart of Incident Cluster Analysis

Analysis of figure 2 shows that the number of treatment sessions and the number of incidents are strongly correlated. The trending incident levels for each treatment site are in decreasing order of level 4, level 1, level 2, level 5, and level 3. Near misses (level 4, figure 3) form the highest level of the incident in the treatment path of patients. This is preferable because the mistake was discovered before treating the patient. Level 1 (figure 4) is a critical event that had a significant impact on a patient with a dosage variation of more than 25%, whereas level 2 (figure 5) is an incident with an excess dose between 5 and 25% of the radiation oncologist's prescription dose. Figure 6 identifies a cluster trend incidents of non-conformance error. There was no Incident trend for level 3, a dose variation of less than 5% of the prescribed dose.

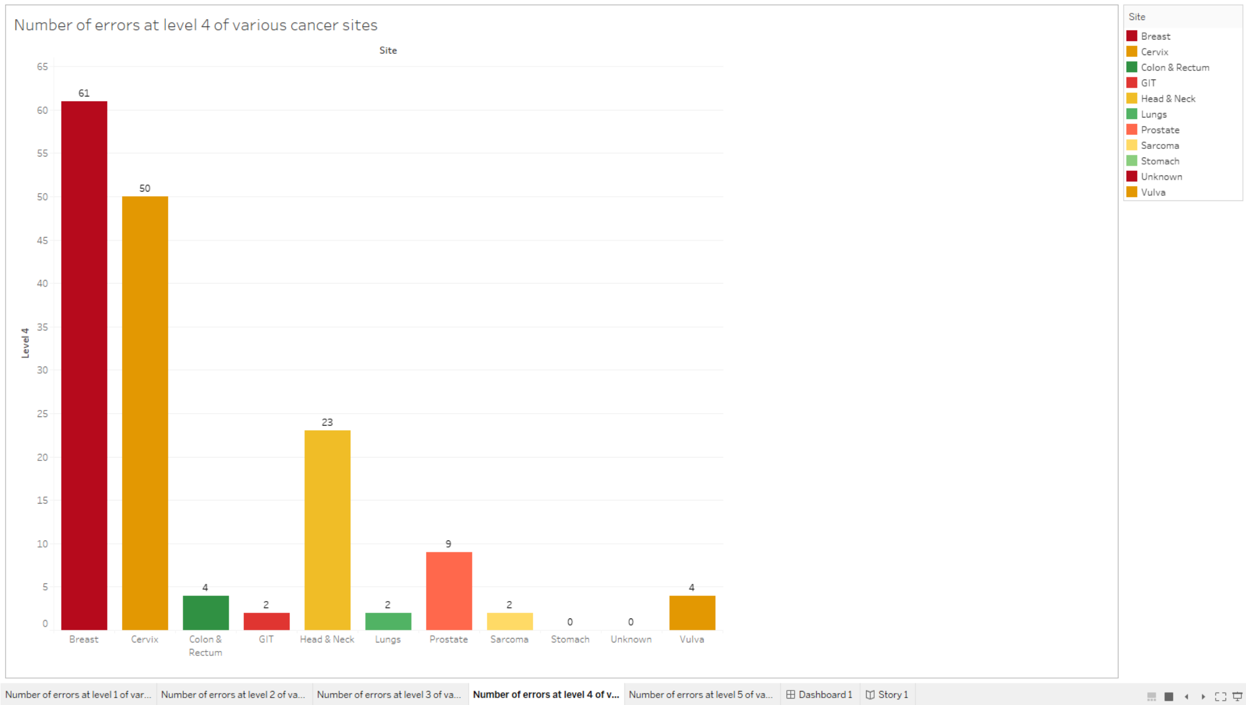

Figure 3: Level 4 Near – Misses Incident Trend

Breast, cervix, head and neck, and prostate were sites with pronounce near-misses. These sites are the most common cancer sites in the country.

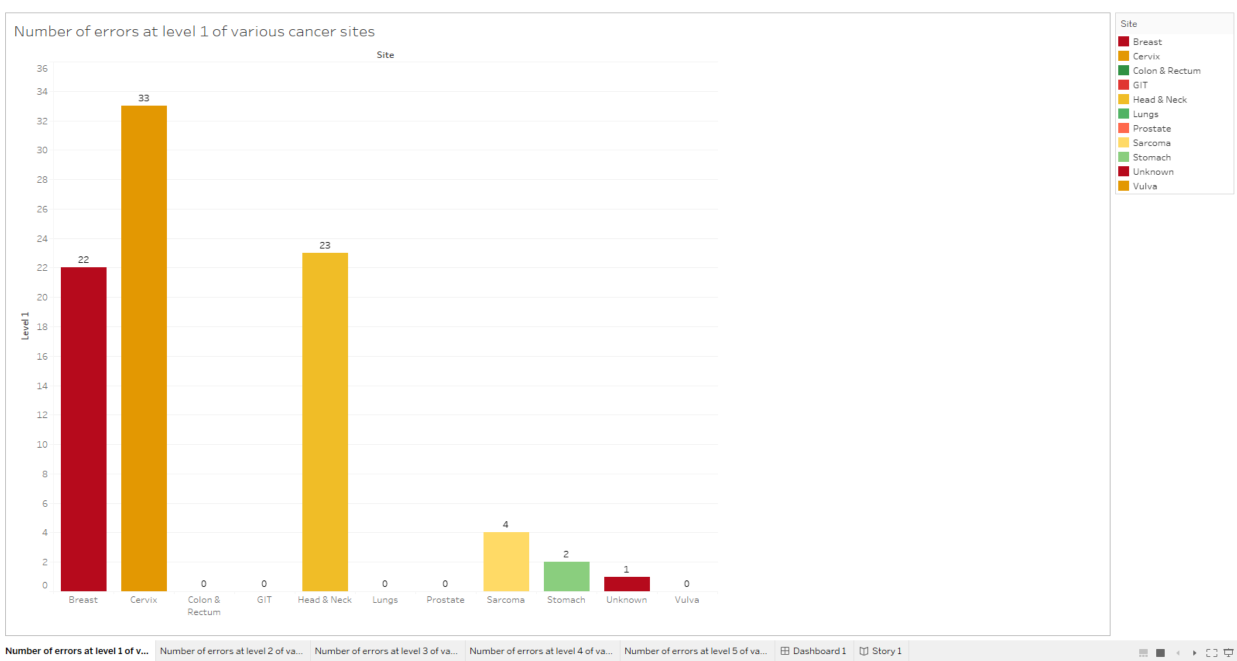

Figure 4: Level 1 Critical Incident of more than 25% of Prescribed Dose

Level 1 cluster incident analysis identified cervix, breast, head and neck, and sarcoma cancers as critical incident sites in the treatment of patients and therefore the need to review treatment protocols.

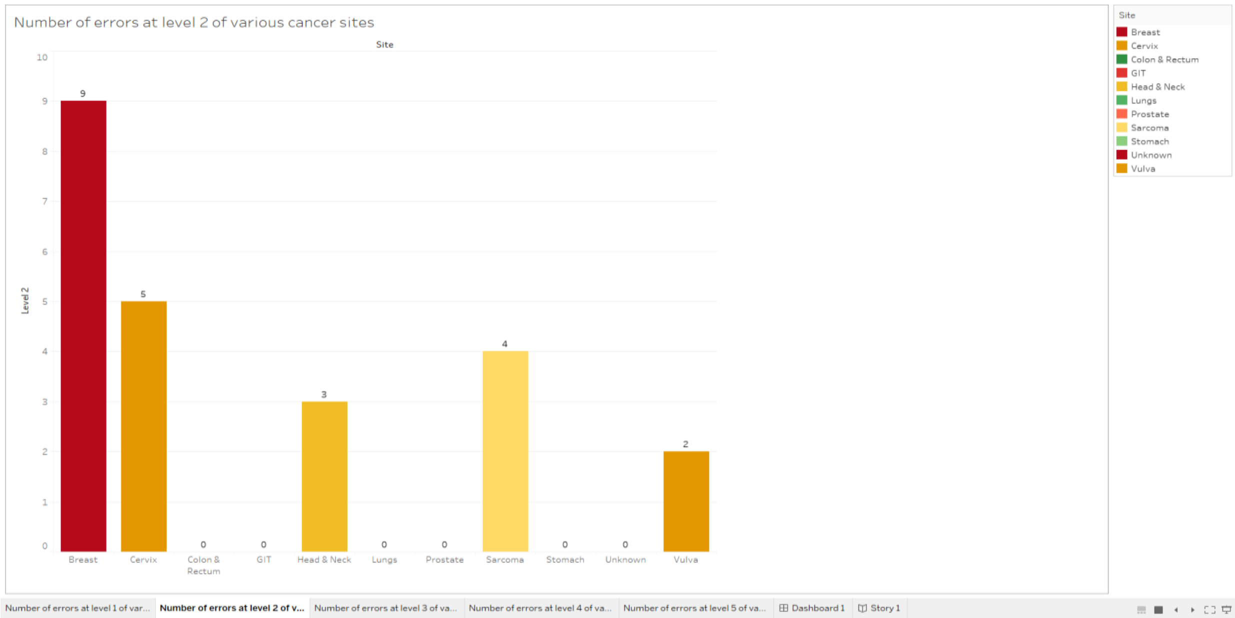

Figure 5: Level 2 Critical Incident of dose variation between 5 to 25% of Prescribed Dose

Level 2 cluster incident analysis identified breast, cervix, head and neck, sarcoma, and vulva cancers as critical incident sites in the treatment of patients and therefore the need to review their treatment protocols.

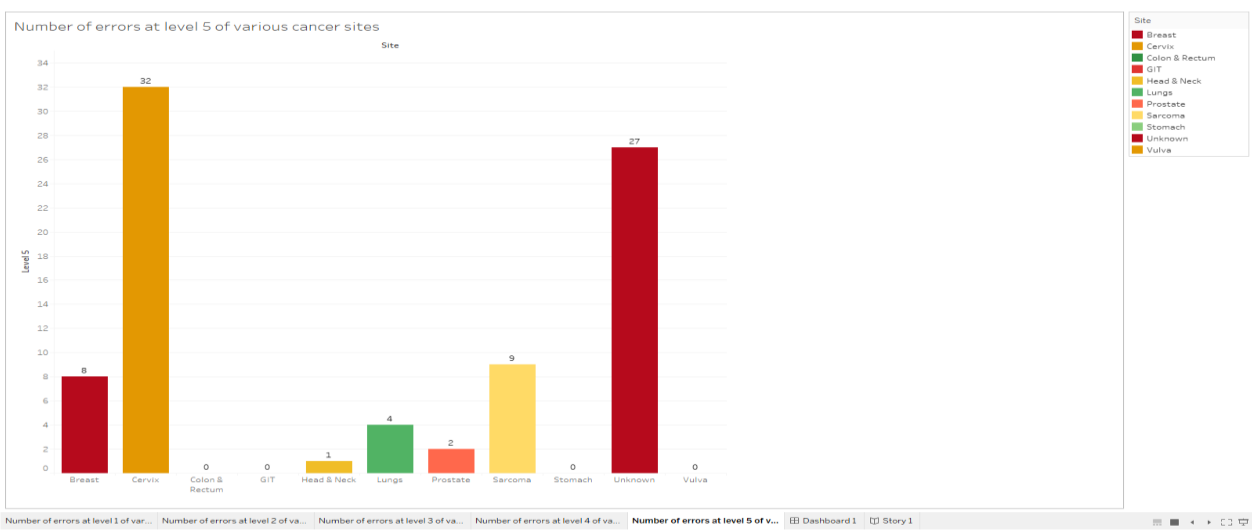

Figure 6: Level 5 Non-conformance errors

Non-conformance involves some parts of normal processes that do not directly influence radiation therapy, thus there is no incident on the patient's part. Cervix, unknown site, sarcoma breast, and lung cancers require review of standard treatment procedures. Cluster analysis of the trend of errors over the years justifies the need to identify and minimize errors when introducing new technology into the clinic. The centre started clinical practice with 2-dimensional radiotherapy treatment in the first year and transited to 3-dimensional radiotherapy with cobalt – 60 teletherapy in the third year, and therefore, an increase in the number of treatment errors courses. In the eighth year, computed tomography imaging was made mandatory for all patients and therefore the reason for an increase in workload and corresponding treatment incidents. Based on the individual levels of incidents, figure Level 3 which identifies dosimetric error of less than 5% of the prescribed dose was omitted since cluster analysis did not identify any error. Findings showed that incident learning may be applied for radiation safety and quality management in a department which is transiting from 2D to 3D technology by learning from incidents that occur in the old system and finding strategies to prevent them from reoccurrence. By addressing quality improvement initiatives collaboratively with transparent accountability, the implementation of an effective incident learning system may serve to reduce the occurrence of actual incidents and enhance the culture of safety at the individual health care professional and multidisciplinary team levels.

Incident learning also increased event communication and identified clinical areas that required process and safety changes, as well as promoted the reporting of prospective accidents as a proactive approach to improving safety and quality. The statistics presented were also beneficial for evaluating remedial steps and identifying unsuccessful tactics and attempts. Implementing incident learning in radiotherapy is a meticulous and time-consuming endeavour. For this strategy to have a real influence on patient care, a rigorous system of learning, feedback and action is necessary. Departmental infrastructure and facilities, organization and culture are required. By lobbying, regulation and legislation, the linked academic society, organization and state health administrative agency should promote and safeguard the reporting and learning of near misses/incidents. For incident learning to be completely adopted in radiotherapy, incremental improvements are required. This system database structure served as a great starting point for creating specialized databases for each radiotherapy hospital in the country. Based on that, a reporting system that is simple to use, report, reply to, and analyze might be built, taking into account the context of each department. Individual incidents might be reported fast and conveniently without interfering with therapeutic activity. In a radiation context, carefully built event reporting systems may give significant data for process and patient safety improvement. Assigning severity to a real incident or near miss is challenging, particularly for near misses, since one must assess the damage that would have been fall the patient many stages down the chain of events.

The dosimetric severity scale could not be adequately conveyed by dosage; it will be more accurate if assessed using the biologically effective dose. The amount of reports produced varies according to the report requirements, quality and safety culture, equipment, and methodologies used by various organizations. Mutic et al. discovered an incident report rate of 1 every 1.6 patients treated (this includes events that reach the patient as well as near-miss occurrences that are caught before reaching the patient) (Mutic et al., 2010). A significant number of occurrences was gathered, including near misses with little or no clinical effect on patients, such as plans with inferior plan quality, efficiency, beam energy, beam orientation, sensitivity to setup mistake, and organ motion that were discovered and modified before treatment. Such an approach enables continual proactive improvement, which may lead to the rectification of tiny or hidden system flaws before they result in far more serious occurrences, hence improving safety and quality of care by facilitating systematic learning from mistakes (Dunscombe, 2012; Williams, 2007). An essential element of the incident learning system is that it necessitates a thorough investigation to uncover the fundamental reasons of an occurrence based on a preset classification and therefore allow the identification of relevant remedial measures. An additional advantage of such an approach is that it allows for the discovery of system faults or fundamental reasons that might result in a variety of accidents. If the underlying reasons are addressed, it is reasonable to believe that overall system safety will improve rather than simply a specific weakness linked with a specific occurrence. The distribution of fundamental causes revealed that ignorance and training were the most important contributors to the mistakes. It is recognized for the newly formed program with new personnel. The reduction in the number of these variables also highlighted the impact of improved training and continued education. For radiation safety and quality management, a systematic, scientific, efficient, and practical management instrument and strategy are required. The goal of event learning was to capture both prospective and actual occurrences, foster a culture of safety, and enable process improvement in patient care and safety. Incident learning may be utilized alone or in conjunction with Failure Modes and Effects Analysis (FEMA). Incident learning enables the execution of both proactive and reactive error control measures, resulting in quality improvement in all parts of clinic operations and this approach. Thorough knowledge of the possible repercussions and linkages between event categories will drive incident reporting, resource allocation, and risk management initiatives. More effort is required to create strategies more efficiently using provided data for process improvement.

CONCLUSIONS

Findings indicate that implementing an effective incident learning system may assist to minimize the incidence of actual events, improve the safety culture, and promote the reporting of possible problems as a proactive approach to improving safety and quality in a radiation therapy programme. According to preliminary findings, incident learning was utilized to improve radiation safety and quality management.

RECOMMENDATION

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. Future iterations, would improve the error tagging and solution recommendation parts, and extend the implementation all radiotherapy centres in the country.

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