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Adoption of an incident learning system in a regionally expanding academic radiation oncology department☆

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ABSTRACT

Aim and Background: We describe a successful implementation of a departmental incident learning system (ILS) across a regionally expanding academic radiation oncology department, dovetailing with a structured integration of the safety and quality program across clinical sites.

Materials and methods m: Over 6 years between 2011 and 2017, a long-standing departmental ILS was deployed to 4 clinical locations beyond the primary clinical location where it had been established. We queried all events reported to the ILS during this period and analyzed trends in reporting by clinical site. The chi-square test was used to determine whether differences over time in the rate of reporting were statistically significant. We describe a synchronous development of a common safety and quality program over the same period.

Results: There was an overall increase in the number of event reports from each location over the time period from 2011 to 2017. The percentage increase in reported events from the first year of implementation to 2017 was 457% in site 1, 166.7% in site 2, 194.3% in site 3, 1025% in site 4, and 633.3% in site 5, with an overall increase of 677.7%. A statistically significant increase in the rate of reporting was seen from the first year of implementation to 2017 ($p < 0.001$ for all sites).

Conclusions: We observed significant increases in event reporting over a 6-year period across 5 regional sites within a large academic radiation oncology department, during which time we expanded and enhanced our safety and quality program, including regional integration. Implementing an ILS and structuring a safety and quality program together result in the successful integration of the ILS into existing departmental infrastructure.

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1. Aim and background

The safe and efficient delivery of radiation therapy is a complex, multi-step process requiring the alignment of multiple professional disciplines, software systems, and highly sophisticated equipment. There is potential for error or inefficiency at all points across this process, and systems designed to detect and address real or potential problems are critical. One well-established method for improving safety in medicine[1] and in radiation oncology[2–5] specifically is the utilization of an incident learning system (ILS). There are a variety of types of ILS that may be utilized in radiation oncology departments, including the national system, RO-ILS, as well as local hospital or departmental systems that may be unique to a given center. Regardless of the specific system used, the success of an ILS depends on the reporting of events that may affect patient safety and/or efficient workflow. Comprehensive reporting allows for the identification of safety or process gaps, and for interventions directed at addressing those gaps to prevent future events. Thus, the more comprehensive the reported events in a department, the greater the opportunity for improvement.

Despite awareness of the benefits of reporting, there are also barriers to reporting, including time spent in entering reports, fear of repercussions, antipathy to change in culture, and concern that reporting will not lead to change or improvement.[6,7] The development of a common safety culture across disparate sites is one of the greatest challenges expanding departments face, and we feel the utilization of a common ILS may be a key factor in successful integration.

Like many academic departments, our clinical footprint has expanded over the last decade, with the incorporation of regional clinical sites at a relatively rapid pace. In this manuscript we describe the implementation of a departmental (in-house) ILS across multiple clinical sites operating within a single academic radiation oncology department. The departmental ILS has been in use for many years at the primary clinical location, and was deployed to regional sites as they have been added. The current version of the ILS began in 2011 at the primary clinical site, site 1. In 2012, the ILS was deployed in clinical site 2, a new location which was developed by the primary clinical location, and in clinical site 3, a pre-existing department which was acquired by the primary academic department. In 2013, the ILS was deployed in clinical sites 4, another pre-existing department that was acquired by the primary academic department. Finally, in 2015, the ILS was deployed in site 5, a new location developed by the department.

Over the same period, a structured approach to developing a common safety and quality (SAQ) program across the sites was undertaken. In this manuscript we describe our approach, and provide a temporal description of the key elements of the program. We believe that the robust uptake of the ILS is reflective of the successful development of common safety culture established by the SAQ program. It is our hope that this experience can provide a basic roadmap for other departments facing the challenges associated with the development of a unified safety culture during rapid regional expansion and integration.

2. Materials and methods

We queried event reports to the departmental ILS from January 1, 2011, to December 2017, excluding only reports that were noted to be duplicate or erroneous. Events were categorized by the location of origin, and date of report. We also queried our treatment and patient volume during the same time frame to determine whether a change in reporting trends was linked to the volume of treatment planning and patients. Unique patients were identified by their individualized system-wide medical record number, and unique treatments were identified by billed treatment event. We plotted the number of reported events per year, broken down by clinical site beginning in the year that the ILS was deployed at that site. We then plotted the number of reports by volume of unique patients and treatments. For ease of interpretation, these values were normalized by assuming a value of "1" for the lowest number and adjusting other values based on the appropriate ratio.

The chi-square test was used to determine whether differences over time in the rate of reporting (number of event reports per unique patient and per unique treatment, normalized to the lowest rate) were statistically significant. Comparisons were made between the rates of reporting in the first year the ILS was used in a given location versus the most recent year.

We also undertook a descriptive review of the key changes in the SAQ program over this time frame, and developed a temporal map of the key elements of the program.

3. Results

3.1. *Incident learning system*

Table 1 summarizes the 5 clinical locations, including the year in which the ILS was deployed, whether it was a new versus acquired site, and the number of linear accelerators in each site. During 2011, 193 events were reported in the primary clinical location (site 1). In 2012, 244 events were reported in site 1, 24 in site 2, and 70 in site 3. In 2013, site 4, another longstanding clinical facility that was acquired by the main center, was added to the system. In that year, 583 events were reported in site 1, 36 in site 2, 89 in site 3, and 8 in site 4. In 2014, 685 events were reported in site 1, 42 in site 2, 293 in site 3, and 27 in site 4. The most recent clinical location, site 5, a newly opened regional location, was opened in 2015 and that year 802 events were reported in site 1, 53 in site 2, 405 in site 3, 44 in site 4, and 9 in site 5. In 2016, 868 events were reported in site 1, 47 in site 2, 362 in site 3, 89 in site 4, and 34 in site 5. In 2017, 1075 events were reported in site 1, 64 in site 2, 206 in site 3, 90 in site 4, and 66 in site 5. In total, the number of events reported rose from 193 in 2011 to 1501 in 2017. Table 2 summarizes the number of reports by clinical site during years 2011–2017, and Fig. 1 visually depicts the pattern of increase in reports across all clinical locations during this time frame.

While the crude number of reports in each location fluctuated over time, there is an overall increase in the number

Table 1 – Summary of clinical sites.

	Site 1	Site 2	Site 3	Site 4	Site 5
Description	Primary site	New site	Acquired site	Acquired site	New site
Year ILS deployed	2011	2012	2012	2013	2015
Number of linear accelerators	$n=6$	$n=1$	$n=3$	$n=2$	$n=1$

Table 2 – Reports by clinical site. All values are absolute number, other than the bottom row which presents the percentage increase in absolute number of reported events from the first year of reporting for that site to the most recent year, 2017.

Year	Site 1	Site 2	Site 3	Site 4	Site 5	Grand total
2011	$n=193$					$n=193$
2012	$n=244$	$n=24$	$n=70$			$n=338$
2013	$n=583$	$n=36$	$n=89$	$n=8$		$n=716$
2014	$n=685$	$n=42$	$n=293$	$n=27$		$n=1047$
2015	$n=802$	$n=53$	$n=406$	$n=44$	$n=9$	$n=1314$
2016	$n=868$	$n=47$	$n=362$	$n=89$	$n=34$	$n=1400$
2017	$n=1075$	$n=64$	$n=206$	$n=90$	$n=66$	$n=1501$
Grand total	$n=4450$	$n=266$	$n=1426$	$n=258$	$n=109$	$n=6142$
Percentage increase – first to last year	457%	166.7%	194.3%	1025%	633.3%	677.67%

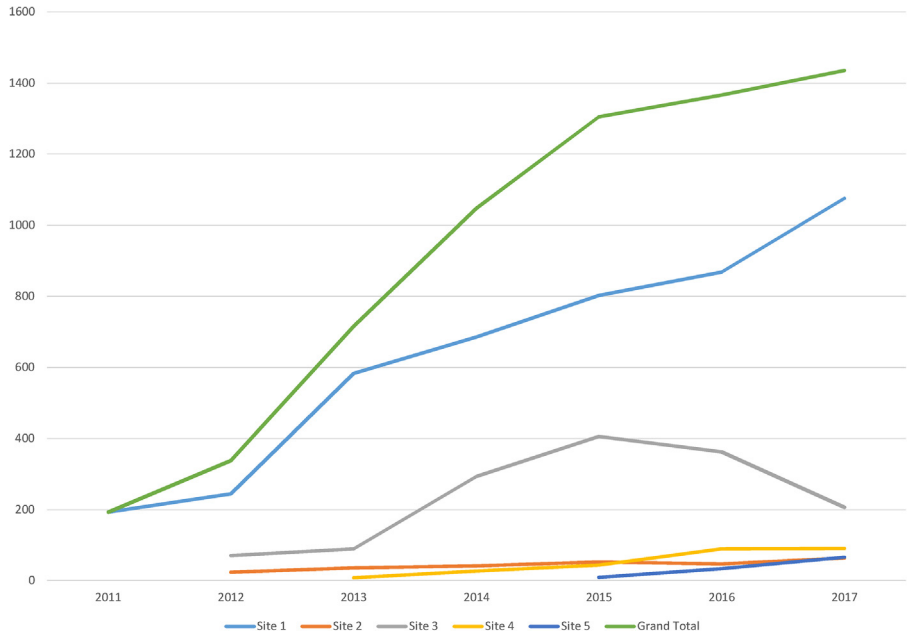

Fig. 1 – Events reported per year by clinical site from the first year of ILS use to 2017. The Y-axis represents absolute number of events reported per year by site.

of reports from each location over the time period from 2011 to 2017. The percentage increase in reported events from the first year of implementation to 2017 was 457% in site 1, 166.7% in site 2, 194.3% in site 3, 1025% in site 4, and 633.3% in site 5, with an overall increase of 677.7%, as shown in Table 2.

The patient and treatment volume is highly variable at each of the clinical locations, as is the number of linear accelerators in use (shown in Table 1). The volume of patients treated at each site during this period is shown in Fig. 2a, and demonstrates that site 1 has the greatest clinical volume over the entire time frame, consistent with the largest number of treatment machines, while the number of patients treated at the other clinical sites is substantially lower, consistent with fewer treatment machines. During this time frame there have been modest fluctuations in the patient volume at each site but the overall trend has been relatively stable.

Fig. 2b depicts the volume of individual radiation treatments performed at each location. Growth has generally occurred by shifting patient volume to new clinical sites, and thus the overall volume at each site has been relatively stable. In keeping with the relatively stable number of patients treated at each clinical location, the number of individual treatments has also remained stable, with the exception of the primary clinical location, site 1, where the majority of the stereotactic and hypofractionated treatments are delivered; in site 1, the number of individual treatments delivered has declined during this time frame while the patient volume has remained stable as a result of increasing use in hypofractionated treatment approaches.

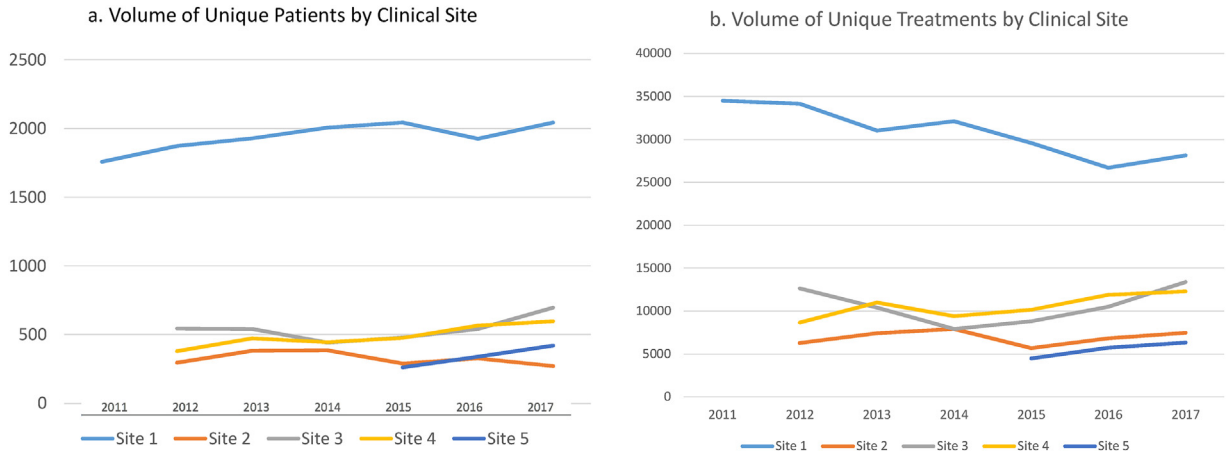

Fig. 2 – Volume of unique patients by clinical site (a) and volume of unique treatments by clinical site (b) from the first year of ILS use to 2017. The Y-axes represent the absolute numbers of patients and unique treatments per year by site.

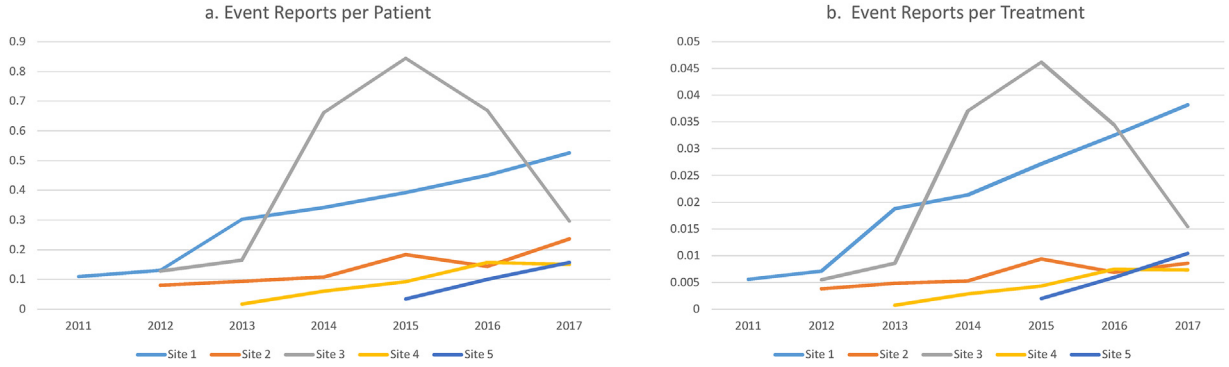

Fig. 3 – Variation in "reporting rate" over time. The event rate is calculated by dividing the number of event reports in a given year by the number of unique patients treated that year (a) and by the number of individual treatments delivered that year (b).

Table 3 – Total event reports and volume of treatments (column 4) and patients (column 6) in the first and most recent years of ILS use by clinical site. All values are written as absolute number. Accounting for both treatment patient volume, the increase in reporting rate from the first to most recent year of ILS use was statistically significant in all sites.

Site	Year	Total reports (n)	Volume of treatments (n)	p value	Volume of patients (n)	p value
Site 1	2011	$n=193$	$n=34{,}513$		$n=1759$	
	2017	$n=1075$	$n=28{,}161$	$p<0.001$	$n=2044$	$p<0.001$
Site 2	2012	$n=24$	$n=6296$		$n=297$	
	2017	$n=64$	$n=7486$	$p<0.001$	$n=271$	$p<0.001$
Site 3	2012	$n=70$	$n=12{,}651$		$n=546$	
	2017	$n=206$	$n=13{,}372$	$p<0.001$	$n=696$	$p<0.001$
Site 4	2013	$n=8$	$n=8678$		$n=380$	
	2017	$n=90$	$n=12{,}272$	$p<0.001$	$n=598$	$p<0.001$
Site 5	2015	$n=9$	$n=4496$		$n=262$	
	2017	$n=66$	$n=6334$	$p<0.001$	$n=421$	$p<0.001$

To account for the variability in patient and treatment volume across sites, we then calculated a "reporting rate" in each location. This was done by dividing the number of event reports in a given year by the number of unique patients treated that year (normalized to the lowest rate, shown in Fig. 3a), and also by the number of individual treatments delivered that year (again normalized to the lowest rate, shown in Fig. 3b). There has been an overall increase in event reports per patient and per treatment over time in all sites, when comparing the first and last years of reporting in each site. This increase was statistically significant in all locations, as shown in Table 3. It is notable that though the reporting rate in site 3 increased on average, there were dramatic fluctuations in the reporting rate over the period assessed as seen in Fig. 1.

3.2. *Safety and quality program*

During the period reviewed, our department also began the process of establishing a department-wide safety and quality

program. Here we summarize the key elements of this program:

2011:	* SAQ program in place in primary clinical location, managed primarily by physics and clinical director. * ILS in use only at site 1 (primary).
2012:	* Introduction of ILS at sites 2 (newly opened) and 3 (acquired). * SAQ activities continue to be conducted at individual locations without structured communication across sites. ILS reports from each location reviewed separately at that location.
2013:	* Introduction of ILS at site 4 (acquired).
2014:	* SAQ structure formalized as a unique committee (separated from ongoing operations committees with overlapping membership) to include dedicated physics and physician leadership, and membership from all disciplines (nursing, physician, physics, dosimetry, administration, information technology, radiation therapy), and representation from physics and physician leadership at all clinical locations (ongoing). * Monthly meeting with structured agenda including review of ILS reports at all clinical locations (ongoing). * Increased rotation of faculty and staff between the regional sites and the primary site, including nursing, dosimetry, therapy, physics, and physicians (ongoing).
2015:	* Introduction of ILS at site 5 (newly opened). * Simplification of the reporting tool within the ILS, to make reporting easier and more efficient for staff. * Establishment of a sub-committee responsible for reviewing and responding to event reports (ongoing). * Initiation of application for ASTRO's Accreditation Program for Excellence (APEx). * Implementation of effective audio and video conferencing system across campuses. * Initiation of development of system-wide policies applying to all clinical locations, unification of policies guided by APEx standards (ongoing). * Development and dissemination of department-wide SAQ policy document.
2016:	* Ongoing development of system-wide policies. * Adoption of hospital-based online policy development and housing website, allowing for version control, password-protecting editing and approval rights, and ready online access to policies for faculty and staff. * Upgrade of ILS system and initiation of prospective coding of event categories.
2017:	* APEx accreditation awarded at all 5 clinical locations. * Ongoing system-wide policy revision and development.

4. Discussion

We observed statistically significant increases in event reporting over a 6-year time period across 5 regional sites within a large academic radiation oncology department, during which a departmental ILS was deployed to all regional sites and a structured system-wide approach to safety and quality was developed. The expansion of academic radiation oncology departments with the addition of new facilities and/or incorporation of pre-existing facilities is increasingly common as health systems evolve. The challenge of establishing a cohesive culture of safety and quality over the course of such an expansion cannot be underestimated, particularly with respect to the merging of previously established entities. Various mechanisms to evaluate the integration of a culture of safety are available, including staff surveys and patient experience surveys, as well as event reporting. Given that event reporting requires a confidence in the system with respect to fear of repercussion and confidence that reporting can impact change, we have viewed event reporting rates as a meaningful measure of the success of our safety program. With this in mind, we evaluated patterns of event reporting across our clinical locations.

As described in Section 1, during the time period evaluated, two new facilities were added, both of which were at least partially staffed by team members who previously worked at the primary clinical site, or continued to rotate between clinical sites. These locations, therefore, did not have pre-existing cultures and instead were fully developed under the primary site. Two additional previously existing facilities joined the primary academic department; both were longstanding clinically focused departments with pre-established departmental cultures. Thus, we might expect to see different reporting patterns between sites 1, 2, and 5, as sites that have only existed as members of the primary department, and sites 3 and 4, which had pre-existing structures which adapted to the primary department over time. However, it does not appear that reporting between those clusters of sites is meaningfully different. It is interesting that site 3, one of the pre-existing (acquired) departments, has the most variable reporting over time while we observed, while the other locations had a more steady increase over time. During the time period evaluated there were significant changes in staffing and organizational structure at site 3, perhaps explaining the marked changes in the reporting rate at this site. In addition, 2015, the peak year of event reporting at site 3, also saw the most significant changes in the SAQ structure which likely impacted the culture at that time.

Despite the significant increases in reporting at all locations, it is notable that event reporting, even taking into account patient and treatment volume, remains highest at site 1; even those sites that were established under the primary department have a lower reporting rate as compared to the primary site 1. Our recent analysis of event reports[8] reveals that the vast majority of event reports at all sites including site 1 are "workflow" rather than safety events, and the greater

complexity of patient management in a high-volume center may explain the higher reporting rate there, although ongoing differences in safety and reporting culture are also likely. A weakness of the current analysis is the fact that we do not have detailed data on event type or detail prior to 2016, when we initiated a process of prospective event coding. Our process for event coding and details regarding event types and patterns are described in detail in other reports,[8,9] but we do not have detailed categorization of events prior to 2016 and thus are not able to report data for the full period reviewed in this analysis.

Over the time period reviewed, a more formal safety and quality program was established than had been in place previously, as described in Section 3. While it is not possible to establish causality between any specific intervention and the event reporting rate, we may infer that the more formal development of the safety and quality program likely contributed to increased reporting. ASTRO's accreditation program, APEx, requires participation in an event reporting system. A recent publication details the conditions that are required for the success of an ILS.[10] We have attempted to incorporate these elements in the management of our own ILS. ASTRO encourages participation in the national event reporting system, RO-ILS (radiation oncology-incident learning system).[11] A review of the available online quarterly reports similarly shows an increase in the utilization of RO-ILS since its inception in 2014 (https://www.astro.org/RO-ILS-Education.aspx), and over this time frame ASTRO has generated a great deal of educational materials and publicity regarding the system and its benefits. Thus, there appears to be a greater national buy-in of event reporting in recent years, and the increased utilization of our own system may relate to generalized awareness as to the importance of safety reporting in our field as well.

Event reporting at our institution is likely to continue to evolve as our system matures and develops. From the observed trends, it appears that reporting rates at each site continue to increase, even accounting for patient and treatment volume. In an effort to correlate event reporting patterns with specific safety and quality measures, we have re-tooled the system to prospectively code events since 2016 with the detail necessary to conduct such an analysis. Our long-term objective is to establish causality between specific interventions and long term safety and quality measures, such as the rate of near-miss events, patient experience, and staff safety culture surveys. We view this work as a key step toward our over-arching goal to demonstrate measurable impact on safety outcomes and culture, with robust utilization of the ILS as a backbone of that culture. We anticipate that the establishment of a culture of reporting that is shared over a high volume, geographically diverse and expanding academic department will lay the groundwork for such analyses going forward.

5. Conclusion

We observed significant increases in event reporting over a 6-year period across 5 regional sites within a large academic radiation oncology department, during which time we expanded and enhanced our safety and quality program, including regional integration. Implementing an ILS and structuring a safety and quality program together result in the successful integration of the ILS into existing departmental infrastructure.

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Conflicts of interest

The authors have no actual or potential conflicts of interest.

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