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Original article

Patient safety is improved with an incident learning system—Clinical evidence in brachytherapy

Christopher L. Deufel *, Luke B. McLemore, Luis E. Fong de los Santos, Kelly L. Classic, Sean S. Park, Keith M. Furutani

Departments of Radiation Oncology and Radiation Safety, Mayo Clinic, Rochester, United States

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ABSTRACT

Background and purpose: Health leaders have advocated for incident learning systems (ILSs) to prevent errors, but there is limited evidence demonstrating that ILSs improve cancer patient safety. Herein, we report a long-term retrospective review of ILS reports for the brachytherapy practice at a large academic institution.

Material and methods: Over a nine-year period, the brachytherapy practice was encouraged to report all standard operating procedure deviations, including low risk deviations. A multidisciplinary committee assigned root causes and risk scores to all incidents. Evidence based practice changes were made using ILS data, and relevant incidents were communicated to all staff in order to reduce recurrence rates.

Results: 5258 brachytherapy procedures were performed and 2238 incidents were reported from 2007 to 2015. A ramp-up period was observed in ILS participation between 2007 (0.12 submissions/procedures) and 2011 (1.55 submissions/procedures). Participation remained stable between 2011 and 2015, and we achieved a 60% ($p < 0.001$) decrease in the risk of dose error or violation of radiation safety policy and a 70% ($p < 0.001$) decrease in frequency of high composite-risk scores. Significant decreases were also observed in incidents with root causes of poor communication (60% decrease, $p < 0.001$) and poor quality of written procedures (59% decrease, $p < 0.001$).

Conclusions: Implementation of an ILS in brachytherapy significantly reduced risk during cancer patient care. Safety improvements have been sustained over several years.

Seventeen years have elapsed since the Institute of Medicine (IOM) concluded that "tens of thousands of Americans die each year from errors..., and hundreds of thousands suffer or barely escape from nonfatal injuries" [1]. The IOM concluded that patient safety should be a priority in the healthcare system and greater attention paid to systems that reduce risk and prevent errors. That report generated strong reactions—supporting and opposing—and many centers instituted mandatory reporting systems for serious events [2,3].

Progress in improving patient safety has been made since the IOM report, however medical errors are still thought to be the third leading cause of death in the United States and procedural deviations in radiation oncology have been found to adversely impact tumor control and patient overall survival [4–6].

Some reluctance remains on the part of hospital leaders to report moderate and minor incidents, and widespread adoption of ILSs would benefit from studies that demonstrate successful interventions [7–13]. Unfortunately, few studies have reported on the effectiveness of an ILS in radiation oncology, and none isolate the brachytherapy practice [14,15]. This is despite the fact that numerous radiation centers have adopted ILSs for reporting procedural deviations and sharing lessons with all staff [14,16–20].

In this review of the brachytherapy practice at a large academic institution, we found that implementation of an ILS that captured all deviations from standard operating procedure, including low risk incidents, was associated with a reduction in risk to patients and improvements in communication among staff members and quality of written procedures. This supports the broader campaign for use of ILS in radiation oncology.

Methods and materials

Setting

This retrospective review, at a large academic medical center, evaluates the impact that implementing an incident learning

* Corresponding author at: Mayo Clinic, 200 1st St. SW, Rochester, MN 55905, United States.

E-mail address: deufel.christopher@mayo.edu (C.L. Deufel).

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system had on patient safety and safety culture. Patient safety was measured using scores that were generated for each incident by a multidisciplinary committee. All brachytherapy staff participated in incident reporting, including physicians, physicists, radiation therapy technologists, nurse practitioners, physician assistants, nurses, medical residents, and medical physics fellows. Between January 1, 2007 and December 31, 2015, 5258 brachytherapy procedures were performed. The low-dose-rate (LDR) brachytherapy practice included treatments for ocular melanoma with eye plaques, biliary cancer with the intraluminal-endoscopic-retrograde-cholangiopancreatography (ERCP) technique, prostate cancer using permanent radioactive seeds, and the spinal dura with beta-emitting planar sources. The high-dose-rate (HDR) brachytherapy practice, with two remote after loaders and two treatment suites equipped with in-room computed tomography (CT), performed treatments for cancers of the cervix with the tandem and ovoid, tandem and ring, multi-tandem, and interstitial techniques; prostate with template and needles; esophagus with a Bougie applicator; bile duct with percutaneous and ERCP techniques; breast with a strut-based applicator; vagina and vaginal cuff with single and multi-channel cylinders; rectum with a shielded cylinder; soft tissue sarcomas with interstitial needles; and surgical tumor beds for various types of cancer with an intraoperative HDR technique.

Intervention

An ILS was created in 2007 for the brachytherapy practice in the department of radiation oncology. The ILS extended reporting beyond the institutional pathway for medical events and near-misses, and encouraged the brachytherapy practice to report standard operating procedure deviations, including low risk deviations that did not reach the patient, but could indirectly impact patient care (e.g. missing initials on check-forms or documents). We anticipated the intervention would generate a large number of reports, the vast majority with very low risk scores, with the intention of obtaining a more comprehensive assessment of practice health and identifying practice areas that might be made more flexible, efficient, and safe.

The intervention was based on the ideology that many problems are systems-based and not primarily due to individual recklessness or poor performers [21]. The learning system aimed to identify and fix the 'as is' processes and conditions that enable minor and major deviations. The system included: 1) reporting mechanisms for identifying and communicating potential failure modes, 2) analysis mechanisms for quantifying incident recurrence and risk, and 3) modification mechanisms for changing the 'as is' process and measuring whether modifications reduced risk. The intervention applies a retrospective methodology for practice improvement, as compared with a prospective approach for evaluating safety such as failure mode and effects analysis (FMEA). The reporting mechanism was a web-based form accessible from any clinic or hospital computer by any staff in the department. Evidence-based safety practices were considered during the design of the reporting workflow [22]. The reporting form contained the submitter's name (an optional entry), submission date, procedure type, process step in which the incident occurred, process step where the incident was discovered, and a brief description of the incident. A checkbox was used to indicate whether the physician and physics staff had already been notified of the incident. The reporting form included a header clarifying that incident discussions are for internal analysis to improve the quality of our practice, and that the ILS does not replace the reporting of sentinel events, medical events, or reportable state violations. An example of the reporting form may be found in the online supplement.

The analysis mechanism was performed by a multidisciplinary committee that is comprised of physicians, physicists, and radiation therapy technicians who reviewed and scored each incident within 1–2 weeks. The scoring committee indicated the root cause and assigned a score from 1 (low) to 5 (high) to each of the following five categories: likelihood of recurrence, likelihood of quality assurance failure, likelihood of non-dose related severity, likelihood of dose related severity or radiation safety policy violation (including overdoses and under doses), and staff or patient time wasted. Although radiation safety policy violations are not the same as potential radiation dose deviations, they were grouped with dose risk because the intention of radiation safety policies is to prevent unnecessary exposures. A detailed description of the scoring scales for each category and definitions of risk are provided with the scoring form in the online supplement. All risk scores evaluate the potential risk of the incident as measured by what would have happened to the patient if the incident had not been detected. A composite-risk score was calculated from the multiplicative product of the aforementioned scores (minimum score = 1^5, maximum score = 5^5). Reports were automatically highlighted with a red color in the online viewer if the composite-risk score exceeded 50. This threshold captured approximately the 5% highest scoring incidents. The scoring committee also could choose to manually highlight entries with scores lower than 50 if they were perceived as relevant.

The modification mechanism was conducted for all highlighted reports, as well as reports with recurring causes. The scoring committee shared results with all brachytherapy staff at monthly meetings. Staff discussed incident causes, proposed solutions to the recurring or high scoring events, and enacted practice changes to prevent recurrence (e.g. changes to procedure, documentation, equipment, etc.)

Data and statistical analysis

A retrospective analysis was performed of incident reports that were collected and scored at the time of the incident between 2007 and 2015. Reports were binned in one year increments in order to assess general trends in safety (e.g. 2007, 2008, etc.).

Decreases in the frequency of dose risk scores, composite-risk scores, and root causes are desirable outcomes. Baseline dose risk, composite-risk score, and root cause levels were collected from 2011, which was the first year that staff participation in the ILS, as measured by reporting frequency, achieved stable levels.

A comparison of dose risk score, composite-risk score, and root cause frequency was performed for 2015 versus 2011 using chi-squared methods. Chi-squared tests were performed with $\alpha = 0.05$. The relationships between reporting frequency and the number of procedures performed each year were measured with Spearman correlations.

We define a safety metric which we call the Risk Frequency Histogram (RFH). The RFH is a complementary cumulative distribution function (CCDF) and was used to evaluate the distribution of dose risk and composite-risk score for the years 2011–2015.

$$RFH(S) = \frac{Number\ of\ Incidents\ with\ Score\ \geqslant\ S}{Total\ Number\ of\ Incidents} \quad (1)$$

Readers who are unfamiliar with statistical metrics such as CCDF may be familiar with the dose-volume-histogram (DVH) used in radiation oncology. The RFH is a metric that is similar to the DVH, using cumulative risk score instead of dose, and frequency of incidents instead of contour volume. A feature of the CCDF is that the integral, or area below the curve, represents the expectation value. Hence, the area below the RFH curve can be interpreted as the total practice risk (in arbitrary units).