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ERROR IN THE DELIVERY OF RADIATION THERAPY: RESULTS OF A QUALITY ASSURANCE REVIEW

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Purpose: To examine error rates in the delivery of radiation therapy (RT), technical factors associated with RT errors, and the influence of a quality improvement intervention on the RT error rate.
Methods and Materials: We undertook a review of all RT errors that occurred at the Princess Margaret Hospital (Toronto) from January 1, 1997, to December 31, 2002. Errors were identified according to incident report forms that were completed at the time the error occurred. Error rates were calculated per patient, per treated volume (≥1 volume per patient), and per fraction delivered. The association between tumor site and error was analyzed. Logistic regression was used to examine the association between technical factors and the risk of error.
Results: Over the study interval, there were 555 errors among 28,136 patient treatments delivered (error rate per patient = 1.97%, 95% confidence interval [CI], 1.81–2.14%) and among 43,302 treated volumes (error rate per volume = 1.28%, 95% CI, 1.18–1.39%). The proportion of fractions with errors from July 1, 2000, to December 31, 2002, was 0.29% (95% CI, 0.27–0.32%). Patients with sarcoma or head-and-neck tumors experienced error rates significantly higher than average (5.54% and 4.58%, respectively); however, when the number of treated volumes was taken into account, the head-and-neck error rate was no longer higher than average (1.43%). The use of accessories was associated with an increased risk of error, and internal wedges were more likely to be associated with an error than external wedges (relative risk = 2.04; 95% CI, 1.11–3.77%). Eighty-seven errors (15.6%) were directly attributed to incorrect programming of the "record and verify" system. Changes to planning and treatment processes aimed at reducing errors within the head-and-neck site group produced a substantial reduction in the error rate.
Conclusions: Errors in the delivery of RT are uncommon and usually of little clinical significance. Patient subgroups and technical factors associated with errors can be identified. The introduction of new technology can produce new ways for errors to occur, necessitating ongoing evaluation of RT errors for quality assurance. Modifications to processes of care can produce important reductions in error rates. © 2005 Elsevier Inc.

Medical errors, Quality assurance, Radiotherapy.

INTRODUCTION

Over the last decade, the rapid development of new technology has significantly changed the way in which radiation therapy (RT) is planned and delivered. Three-dimensional computed tomography (CT)–based planning, multileaf collimation, improved immobilization, and more sophisticated planning software now permit complex, highly conformal treatment plans to be developed for many patients. However, as RT hardware and software become increasingly complex, understanding the detailed workings of these systems, and their potential limitations, becomes more difficult. Furthermore, many radiation oncology departments are under increasing pressure to adopt these technological innovations while simultaneously treating more patients with greater efficiency.

The rapid adoption of new technologies in the setting of increasing patient volume might create an environment in which treatment errors are prone to occur. Even technology intended to reduce the risk of RT errors might paradoxically act as a new source of errors (1, 2). Regardless of how accurately treatment is planned, errors in the delivery of RT not only might increase treatment toxicity and reduce effectiveness but can also undermine patients' confidence that their treatment is being delivered correctly. Careful imple-

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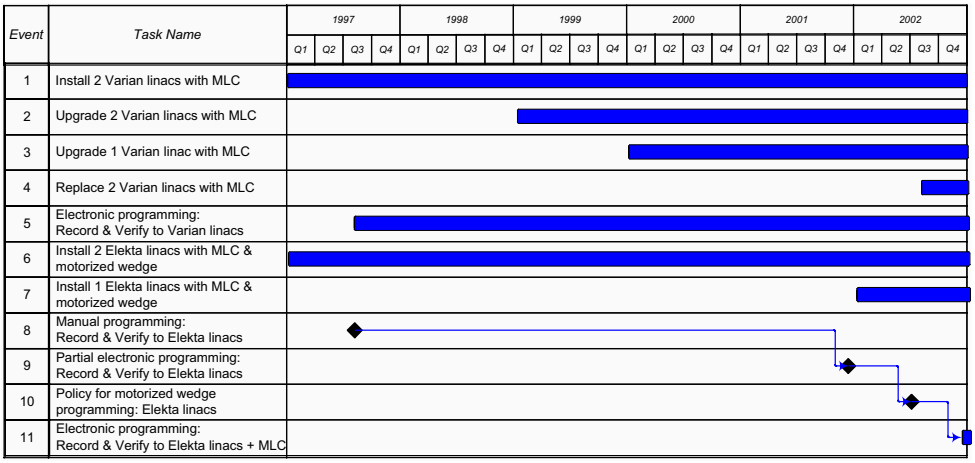

Fig. 1. Introduction of MLC and R&V systems at the Princess Margaret Hospital, 1997–2002.

mentation of quality assurance protocols can detect random or systematic errors that might otherwise go unnoticed (3). The investigation of these errors can facilitate the improvement of existing quality assurance procedures to minimize or avert future treatment errors.

This study was undertaken to examine error rates in the delivery of RT, technical factors associated with RT errors, and the influence of a quality improvement intervention on the RT error rate.

METHODS AND MATERIALS

Setting

Errors in the delivery of RT over the period January 1, 1997, through December 31, 2002, were analyzed retrospectively. The Princess Margaret Hospital is the largest radiation therapy center in Canada and over the study period operated 17 radiation therapy units (10 Varian linear accelerators [600C, 21EX, 2100C, 2100CD; Varian Medical Systems, Palo Alto, CA], 4 Elekta linear accelerators [Elekta Precise Digital 6/18; Elekta Oncology Systems, Crawley, UK; Philips SL-25 6/25], 2 Cobalt-60 units [Theratronics Theratron 780C; Theratronics, Inc., Kanata, Canada], and 1 orthovoltage unit). The Cobalt-60 units were replaced by 2 Varian units (Clinac 21EX) in 2000. For most of the study period, Elekta units used internal motorized wedges, whereas manually placed external wedges were used on Varian units. Multileaf collimators (MLCs) were installed or upgraded on several treatment units over the course of the study, a "record and verify" (R&V) system was introduced, and the department put into operation three CT-simulators during this time (Fig. 1). Approximately 125 radiation therapists and 27 radiation oncologists were employed during this period. Each radiation oncologist typically worked in two "site groups" (e.g., breast cancer and lung cancer), and individual treatment machines were generally assigned comparable patients with respect to the anatomic site requiring treatment.

Identification and characterization of errors and patients at risk

Detected radiation treatment errors were documented on a comprehensive "Record of Treatment Incident" form by the radiation therapists treating the patient at the time the error occurred. Errors were defined as an unintended deviation from the prescribed treatment resulting in any one of the following: (*1*) ≥0.5 cm deviation from the intended treatment field, (*2*) variation of 5% or more on the intended prescribed daily or total dose, or (*3*) any omission or incorrect placement of accessories (e.g., shields, compensators, wedges, bolus, or electron filter). Changes in treatment fields or shielding that occurred as a result of routine portal imaging were not considered as errors.

The incident report included the patient's name, diagnosis, attending doctor, time and place of treatment, and reporting therapist. Recommendations were made by a senior radiotherapist and a physicist regarding ways to rectify any dose discrepancies where needed and to avoid such errors in the future. The clinical significance of the error and any corrective actions were indicated by the attending radiation oncologist as none, minor, moderate, or severe; however, there was no standard definition of these severity grades.

The study cohort comprised all patients who underwent external beam RT during the study period. These patients were identified through the electronic R&V software used during the study period (Multi-ACCESS Oncology Management System; IMPAC Medical Systems, Mountain View, CA). Patients treated exclusively with brachytherapy or with orthovoltage were excluded from the analysis.

Calculation of error rate

The error rate per patient was calculated with one incident report equal to one error in the numerator. The denominator was the number of patients completing a course of RT. Patients treated more than once were reincluded in the denominator for each course; however, to avoid double counting those with planned breaks, a completed RT treatment course was defined as all the radiation treatments given to 1 patient within a 3-month period.

For some tumor sites, RT plans were more likely to involve multiple treatment regions, thereby increasing the opportunity for error. For example, patients with head-and-neck tumors undergoing radical RT often had three or more distinct volumes within a single treatment plan, whereas most palliative treatments generally had a single volume treated. To adjust for this, the error rate was recalculated with the number of treatment regions as the denominator. A treatment region was defined as any treated volume that was prescribed a separate dose and fractionation schedule. This would generally occur if an RT plan had more than one phase or

Table 1. Radiation therapy error rates from 1997–2002

Year	Errors* (*n*)	Patient treatments (*n*)	Error rate per patient (%) (95% CI)†	Treatment volumes (*n*)	Error rate per treated volume (%) (95% CI)†	Fractions (*n*)	Error rate per fraction (%) (95% CI)‡
1997	63	4,880	1.29 (1.00–1.66)	5,935	1.06 (0.82–1.37)		
1998	65	4,967	1.31 (1.02–1.68)	7,400	0.88 (0.68–1.13)		
1999	85	4,492	1.89 (1.52–2.35)	6,959	1.22 (0.98–1.52)		
2000	91	4,179	2.18 (1.77–2.68)	7,018	1.30 (1.05–1.60)	41,548	0.29 (0.24–0.35)
2001	145	4,624	3.14 (2.66–3.69)	7,835	1.85 (1.57–2.18)	97,858	0.38 (0.34–0.42)
2002	106	4,994	2.12 (1.75–2.57)	8,155	1.30 (1.07–1.58)	101,781	0.21 (0.19–0.25)
Total	555	28,136	1.97 (1.81–2.14)	43,302	1.28 (1.18–1.39)	241,187	0.29 (0.27–0.32)

Abbreviation: CI = confidence interval.
* The same technical error occurring over >1 fraction is counted as one error.
† Significant increase in error rate over time ($p < 0.001$).
‡ Each fraction delivered with an error is counted as a separate error.

had adjacent volumes treated with different fields. This meant that a patient with a single RT treatment course could have more than one treatment region, so that the denominator for this error rate calculation is necessarily greater than for the error rate per patient calculation.

In a small proportion of cases, errors might be repeated for more than one fraction of a multifraction RT treatment course. Data regarding the number of fractions in a course for which there was an error were collected from July 1, 2000, through December 31, 2002. For this period we calculated the error rate per fraction, using the number of fractions delivered with an error as the numerator and the total number of fractions delivered to all patients at risk as the denominator.

Identification of patient and treatment factors associated with errors

We investigated whether tumor site played a role in the frequency of error. Error rates were calculated for individual tumor sites, classified according to the departmental site groups (e.g., head and neck, lung, breast, lymphoma).

The linear accelerators in use differed in their technical specifications, particularly as they relate to the use of shielding and beam-modifying devices. For some units, external shielding was placed manually in the head of the machine, whereas for others shielding was electronically programmed and MLCs within the head of the machine acted as shielding. Similarly, some units required manual placement of beam-modifying devices, such as lead wedges, whereas others had motorized internal wedges. The significance is that external shields and wedges were placed manually each day; thus, placement was subject to the daily risk of human error. However, incorrect programming of MLC shielding or internal wedges could also produce errors that might have been more difficult to detect because they were not visible to the radiation therapists. Therefore, we collected data regarding the use of MLC shielding, external shielding, internal wedges, and external wedges on all error cases and an equal number of controls randomly sampled from the population at risk.

Error reduction intervention

In July 2001, the Departmental Quality Assurance Team reported that the head-and-neck site group's quarterly error frequency had risen from two errors during October–December 2000 to 30 errors during January–March 2001 and 60 errors during April–June 2001. A multidisciplinary site-specific working group met weekly throughout August 2001 and identified the following concerns: (*1*) there was significant interpatient variation with regard to simulation technique (fluoroscopy, CT scanner, or CT simulator), patient immobilization, and the use of beam-modifying devices within the site group, (*2*) patients were often moved between treatment units owing to machine service, (*3*) therapists frequently moved between treatment machines, and (*4*) charting of treatment techniques was partially paper-based and partially electronic, creating uncertainty regarding where information was charted.

In September 2001, steps were taken to standardize immobilization and RT techniques, with a move away from external blocks to the consistent use of MLCs. Identical treatment units were paired to allow movement of patients between units without changes in technology or staff familiarity. All planning was moved to a single CT simulator, and a standard policy for refluoroscopy for isocenter moves was established. All charting was moved to the electronic system. The length of routine staff rotations on the head-and-neck treatment units was extended. Additionally, technique-specific working groups within the head-and-neck site group were established to review all technical issues between September and December 2001, such that the planning and treatment procedures could be further standardized. To examine the effectiveness of these interventions, we calculated the quarterly error rate for head-and-neck patients before and after the date of implementation.

Statistical analysis

For the analysis of technical factors, logistic regression was used to estimate the relative risk (RR) of error associated with the use of external shielding, MLC shielding, internal wedging, and external wedging. A regression model was created that adjusted for each of these factors and also for the frequency of tumor types (entered in the model as breast, lung, head and neck, lymphoma, sarcoma, and other).

RESULTS

Overall error rates

During the study period, there were 28,136 patient treatments delivered to a total of 43,302 treatment regions. There

Table 2. Error rates according to tumor type

Site group	Errors (*n*)	Patient treatments (*n*)	Error rate per patient (%) (95% CI)	Treatment volumes (*n*)	Error rate per treated volume (%) (95% CI)
Sarcoma	49	884	5.54 (4.17–7.32)*	1,231	3.98 (2.99–5.27)*
Leukemia	4	86	4.65 (1.50–12.13)	98	4.08 (1.32–10.72)
Head-and-Neck	132	2,883	4.58 (3.86–5.42)*	9,204	1.43 (1.21–1.70)
Skin	18	560	3.21 (1.97–5.13)	735	2.45 (1.50–3.92)*
Pediatric	12	403	2.98 (1.62–5.29)	630	1.90 (1.04–3.40)
Lymphoma	56	2,079	2.69 (2.06–3.51)	2,686	2.08 (1.59–2.72)*
Gynae	36	1,602	2.25 (1.60–3.13)	2,188	1.65 (1.17–2.30)
GI	51	2,962	1.72 (1.30–2.28)	3,753	1.36 (1.02–1.80)
Lung	58	4,281	1.35 (1.04–1.76)†	5,702	1.02 (0.78–1.32)
Not classified	5	375	1.33 (0.49–3.27)	467	1.07 (0.39–2.63)
CNS	18	1,411	1.28 (0.78–2.05)	1,606	1.12 (0.69–1.80)
GU	49	3,897	1.26 (0.94–1.67)†	4,979	0.98 (0.74–1.31)
Breast	66	6,199	1.06 (0.83–1.36)†	9,395	0.70 (0.55–0.90)†
Endocrine	1	285	0.35 (0.02–2.25)	379	0.26 (0.01–1.70)

Abbreviations: CI = confidence interval; CNS = central nervous system; GI = gastrointestinal; GU = genitourinary.
* 95% CI higher than confidence interval of average rate.
† 95% CI lower than confidence interval of average rate.

were 555 treatments with detected treatment errors (Table 1). Over the 5-year period, the average error rate per patient was 1.97% (95% confidence interval [CI], 1.81–2.14%). The number of unique treatment volumes increased significantly faster than the number of treated patients (37.4% increase vs. 2.3%, $p < 0.001$). This indicates that over time, patients received more complex treatment, with multiple-phase RT plans treating different target volumes, or simultaneous treatment of adjacent volumes. There was a statistically significant increase in the error rate per patient per year during the study period ($p < 0.001$) and in the error rate per treated volume over time ($p < 0.001$). From July 1, 2000, through December 31, 2002, there were 241,187 fractions delivered, 711 with errors (0.29%; 95% CI, 0.27–0.32%).

Characterization of errors

The error rate classified by type was as follows: 44.3% were related to treatment field/volume (≥0.5 cm deviation from planned field), 37.6% were due to omission or incorrect placement of accessories, and 18.1% were deviations from prescribed daily or total dose. Of all these errors, 87 (15.6%) were directly attributed to incorrect programming of the R&V system, and 39 (7.0%) were related to inadequate documentation of technical changes (e.g., physician change in prescribed dose) that were not detected despite the R&V system being in place.

Association between tumor site and error risk

Tumor types with error rates per patient significantly greater than average were sarcoma (5.5%; 95% CI, 4.2–7.3%) and head and neck (4.6%; 95% CI, 3.9–5.4%; Table 2). Sites with significantly lower than average error rates per patient were breast (1.1%; 95% CI, 0.8–1.4%), genitourinary (1.3%; 95% CI, 0.9–1.7%), and lung (1.4%; 95% CI, 1.0–1.8%).

When the number of treatment volumes was used as the denominator of the error rate, the head-and-neck rate was no longer significantly greater than the average (1.4%; 95% CI, 1.2–1.7%) owing to the relatively greater number of volumes treated for these patients. The error rate for sarcoma and lymphoma sites remained significantly greater than the average: 4.0% (95% CI, 3.0–5.3%) and 2.1% (95% CI, 1.6–2.7%), respectively.

Association between technical factors and risk of error

In the logistic regression model of technical factors, the use of external shields was associated with the greatest risk of error (RR = 4.39; 95% CI, 3.06–6.29%) (Table 3). The risk of error was also elevated when MLC shielding was used during treatment (RR = 1.92; 95% CI, 1.29–2.87%). In a direct comparison between MLC shielding and external shielding, the latter was associated with a nonsignificantly increased risk of error (RR = 2.29; 95% CI, 0.69–3.61%).

Compared with the use of no wedges, the risk of error was significantly greater if internal wedges were used (RR = 2.55; 95% CI, 1.44–4.52%) but not if external wedges

Table 3. Association between technical factors and RT error

	Relative risk (95% CI)	*p*
Multileaf collimator	1.92 (1.29–2.87)	0.001
External shield	4.39 (3.06–6.29)	<0.001
External wedge	1.25 (0.84–1.86)	0.28
Internal wedge	2.55 (1.44–4.52)	0.001

Abbreviation: CI = confidence interval.
Comparisons are between use of the specified accessory vs. nonuse. See text for comparisons of different accessories.

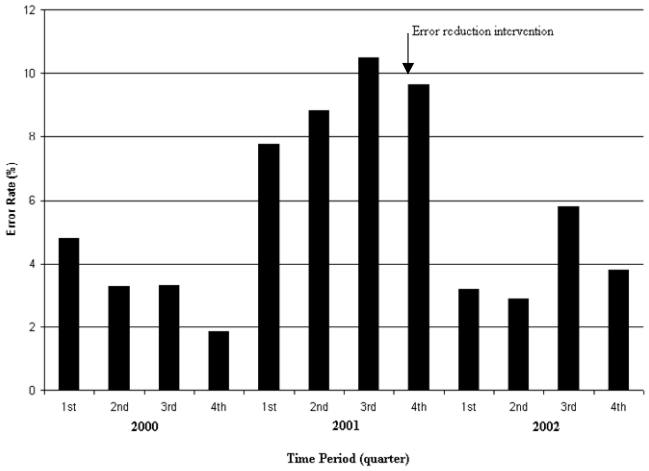

Fig. 2. Error rate per patient among head-and-neck patients before and after implementation of an error reduction strategy.

were used (RR = 1.25; 95% CI, 0.84–1.86%). If the two methods are directly compared, the relative risk of error associated with internal wedges was significantly greater than that of an error with an external wedge (RR = 2.04; 95% CI, 1.11–3.77%).

Clinical consequences of errors

The clinical severity scores for the 555 errors, as graded by the radiation oncologist, were as follows: none, 44.1%; minor, 50.3%; moderate, 5.2%; and severe, 0.4%. Overall, 94.4% of the errors were judged to be of little or no clinical significance.

Assessment of error reduction intervention

The error rate per patient in the head-and-neck site group peaked at 10.5% in the third quarter of 2001. After the introduction of processes intended to reduce errors, the rate subsequently dropped to 3.8% in the last 3-month period analyzed (Fig. 2). The site group now addresses technical issues in its weekly rounds on an ongoing basis.

DISCUSSION

The capacity to identify, systematically report, and analyze medical errors within health-care settings is a necessary component of any institutional effort to reduce errors (4).

We found that the rate of RT errors was low and that the large majority of errors were thought to be of little or no clinical consequence. These findings are similar to those reported in prior studies, although it is notable that the denominator used to calculate error rates varies widely among different reports. Studies in which the number of patients or RT courses is used as the denominator typically report error rates of 1.2–3.5% (1, 2, 5, 6). However, when treatment fractions or segments are used as the denominator, error rates are generally $<1\%$ (1, 2).

Patients with multiphase plans (e.g., head-and-neck) or those tumor types with diverse anatomic locations (e.g., sarcoma and lymphoma) were found to be associated with a greater risk of error. After accounting for the greater number of separate treatment volumes in the head-and-neck plans, the error rate for these plans was not greater than average, suggesting that the more complicated treatment increased the opportunity for error to occur in these patients. The higher error rate in the lymphoma and sarcoma site groups was thought to be due to the varied anatomic distribution of these tumors, so that beam accessories and field arrangements do not easily become part of a standard treatment routine that is recognized by the radiation therapists.

The development of internal protocols to systematically implement new technology has been identified as a priority in the departmental quality assurance process. It was noted during the study interval that as new technology was introduced, it was used in different ways both within site groups and among different site groups. Within the head-and-neck site group, for example, patients with similar tumors were being treated with different techniques, with different beam-modifying devices being used to deliver similar treatments. This was thought to be producing unnecessary variability in the work performed by the radiation therapists. For all site groups, the transition from paper charting of RT technical notes to electronic charting was gradual, at times creating uncertainty as to where changes in RT plans were documented. The error reduction efforts undertaken by the head-and-neck site group were largely directed at these potential sources of error. These efforts were followed by a substantial reduction in error rate for this site group. It is possible that this reduction only represents "regression toward the mean" after a coincidental temporary rise in 2001. However, the radiation therapists, physicists, and oncologists involved in that site group were able to identify processes of care thought to contribute to errors, and when these processes were improved, the error rate declined. A continuous quality improvement program has been developed, one goal of which is to develop protocols that standardize as much as possible the technical aspects of RT planning and delivery for all site groups.

As expected, the use of beam-modifying devices was associated with an increased risk of error, because they can be incorrectly placed in the RT field. Prior studies have also found that approximately 35–50% of RT errors are related to the use of beam-modifying devices (2, 5, 7). We had no strong *a priori* hypotheses regarding which of the technical factors would be associated with errors. External wedges and shields required manual placement by the radiation therapists and so were subject to a daily risk of human error. In contrast, internal shields and wedges are programmed electronically before treatment and should, if programmed correctly, be more reliable. Direct comparisons of devices used for the same purpose (e.g., internal and external wedges) revealed that compared with external wedges, internal wedges were associated with a significant increase in the risk of error, after adjusting for tumor site. Anecdotally, radiotherapy and physics staff thought that this was related

to the requirement for manual programming of internal wedges by the radiation therapists at the treatment units and to the inability to perform a visual check to ensure that internal wedges were placed correctly. In the summer of 2002, a computerized interface between the R&V system and the units with internal wedges was implemented so that the planners programmed internal beam modifiers without the need for manual reprogramming at the treatment unit. This has dramatically reduced this source of error. Increasingly, our department is using segmented beams in place of wedges to account for variations in tissue thickness. Future work will be required to determine whether this will lead to a reduction in errors.

Although R&V software has been shown in some studies to reduce RT errors (6), it is also recognized that it can introduce a new source of error in the process of treatment planning and delivery (1, 2, 7, 8). We found that a small number of errors were directly attributable to erroneous programming of software intended to reduce errors. Incorrect manual transcription of RT treatment parameters from the planning system to the R&V system was responsible for the majority of these cases. The development of electronic data transfer between these systems should reduce this source of error. It was also noted that for some software/hardware interfaces, the RT could be delivered without the internal wedge being inserted into the beam as programmed. Our results are similar to those reported in 1998 by Macklis *et al.* (2), in an analysis of 59 errors that occurred over 1 year. In that study, 15% of errors were related to the use of the R&V system. Patton *et al.* (1) reported that nine of 38 errors (23%) were related to the use of an R&V system. Goldwein *et al.* (9) point out that R&V systems do not obviate the need for good judgment and appropriate safety systems. Overreliance on R&V technology, not the technology per se, is the major source of error (2, 9).

This study has limitations that must be considered. The increasing error rate over time might not reflect a true increase in errors but rather more complete reporting of errors and the radiation therapists' greater recognition of the importance of error documentation for continuous quality improvement. Additionally, the statistical test for trend in the error rate over time is relatively insensitive to the decrease in error rate seen over the last year of the study. Conversely, because our error rate is based on incident reports, undetected errors are not included, and this could lead to an underestimate of the true error rate. Calandrino *et al.* (5) found that when *in vivo* dosimetry was used to identify unplanned treatment deviations, the undetected error rate per patient was 0.45%.

In summary, we found that errors in the delivery of RT were rare and generally thought to be of no or minor clinical significance. As expected, the use of beam-modifying devices increased the risk of error. We noted that the introduction of new technology can create new and unanticipated ways for errors to occur, particularly if these technologies are not introduced in a uniform manner. As radiation oncology departments adopt these technologies, efforts to develop explicit and uniform protocols for implementation and timely assessment of error rates can help ensure that they are introduced in a safe and effective way.

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