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Risk factors in radiotherapy

Risk factors for near-miss events and safety incidents in pediatric radiation therapy

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ABSTRACT

Background and purpose: Factors contributing to safety- or quality-related incidents (e.g. variances) in children are unknown. We identified clinical and RT treatment variables associated with risk for variances in a pediatric cohort.

Materials and methods: Using our institution's incident learning system, 81 patients age ≤21 years old who experienced variances were compared to 191 pediatric patients without variances. Clinical and RT treatment variables were evaluated as potential predictors for variances using univariate and multivariate analyses.

Results: Variances were primarily documentation errors (n = 46, 57%) and were most commonly detected during treatment planning (n = 14, 21%). Treatment planning errors constituted the majority (n = 16 out of 29, 55%) of near-misses and safety incidents (NMSI), which excludes workflow incidents. Therapists reported the majority of variances (n = 50, 62%). Physician cross-coverage (OR = 2.1, 95% CI = 1.04–4.38) and 3D conformal RT (OR = 2.3, 95% CI = 1.11–4.69) increased variance risk. Conversely, age >14 years (OR = 0.5, 95% CI = 0.28–0.88) and diagnosis of abdominal tumor (OR = 0.2, 95% CI = 0.04–0.59) decreased variance risk.

Conclusions: Variances in children occurred in early treatment phases, but were detected at later workflow stages. Quality measures should be implemented during early treatment phases with a focus on younger children and those cared for by cross-covering physicians.

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Patient safety in radiation therapy (RT) has recently come under greater scrutiny with reports issued by the Institute of Medicine (IOM), the American Association of Physicists in Medicine (AAPM), and the International Atomic Energy Agency (IAEA), and recommendations set forth by professional societies to help detect and prevent medical errors [1–3]. Given the risk for error and potential severity of harm to patients undergoing RT, there is a pressing need for in-depth analysis of the frequency and types of safety incidents that occur. Common root causes for near-misses and safety incidents (NMSI) are errors in technology, communication, human behavior, and treatment planning (e.g. errors during simulation, contouring, and entering treatment parameters) [4,5]. Previous studies exploring patient- and treatment-specific variables associated with near-misses demonstrate that children and adolescents experience more NMSI than adults [1,6]. To date, however, there has been no literature describing the nature of and risk factors for near-misses in pediatric patients.

Here, we analyze reports of variances from our institution's incident-learning system (ILS) that involve children treated with RT over a six-year period. The number of true NMSI is relatively small; thus, we have also included an analysis of incidents related to workflow issues, an approach supported by existing literature demonstrating relationships among workflow issues, patient safety, and quality of care [7,8,9,10,15]. We characterize the nature of these variances (which include both NMSI and workflow issues) and identify specific variables associated with risk for variances in children. With a better understanding of the types of incidents that have occurred at our institution, we hope to highlight aspects of RT and workflow that may be targeted to mitigate future events and improve patient safety.

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Methods and materials

Data collection

From our institution's ILS and medical records, we extracted all reports for patients ≤21 years old who experienced variances between 3/1/2011 and 2/22/2017, and identified a control cohort consisting of all patients ≤21 years old treated during the same period without variances. Data for each variance regarding root cause, treatment phase at which the event was detected, and the reporting provider were obtained through ILS review. Root causes were categorized as errors in documentation, communication, treatment planning, or treatment delivery. Examples are provided in Supplementary Table 1. NMSI were defined as variances that could potentially harm a patient if they reached the patient. Workflow issues were defined as variances that may not directly affect patient safety, but have potential to impact quality of care by decreasing efficiency and causing disadvantageous downstream effects. Examples include process errors, such as late submission of contours and failure to approve simulation notes in a timely manner.

Patient-specific variables assessed for association with variance included age, tumor diagnosis, Karnofsky Performance Score (KPS) (between 0 and 100), pain score (between 0 = no pain and 4 = severe pain), metastatic disease, cross-covering physician involvement, and enrollment in clinical trials. Tumor diagnoses were categorized as sarcomas, lymphomas, non-lymphoma hematologic disorders, abdominal tumors (including colorectal, liver, kidney, adrenal gland tumors), brain/nervous system tumors, head/neck tumors, or other cancers grouped together due to low prevalence in our cohorts (e.g. skin, gynecologic, prostate, lung cancers). RT-specific variables included treatment modality, urgent treatment initiation (within 3 days of simulation), anesthesia use, dose per fraction, number of fractions, and total dose. Treatment modalities were categorized as conventional treatment; 3D conformal technique; intensity-modulated radiation therapy (IMRT), image-guided IMRT (IG-IMRT), or volumetric modulated arc therapy (VMAT); stereotactic body radiation therapy (SBRT) and Cyberknife; or electron therapy.

Statistical analysis

Data were analyzed using Stata 13. Normally distributed variables were compared between control and variance cohorts by *t*-tests. Non-normally distributed variables were compared using Wilcoxon-rank-sum tests. Normality was determined by assessing histogram distributions and outcomes from Shapiro–Wilk tests. Chi-squared tests were used to compare categorical variables. Fisher's test was performed in circumstances where the sample subset contained fewer than 5 reports. Univariate logistic regression and forward-stepwise variable selection algorithm were used to select predictors for the final multivariate logistic regression model predicting variance.

Results

Variance report characteristics

A total of 81 variances among children were identified and compared against 191 patients who did not experience variances. A process map for RT, adapted from Ford et al., is shown in Fig. 1 [2]. Variances most frequently occurred during patient assessment (39.5%, $n = 32$) and treatment planning (38.3%, $n = 31$). The most common root cause was documentation error (56.8%, $n = 46$), followed by errors in treatment planning (25.9%, $n = 21$), communication (13.6%, $n = 11$), and treatment delivery (3.7%, $n = 3$). The most common root cause for variances that occurred during patient assessment was documentation error (87.5%, $n = 71$). Variances during treatment planning phases were most commonly documentation (45.2%, n = 37) or treatment planning errors (38.7%, $n = 31$).

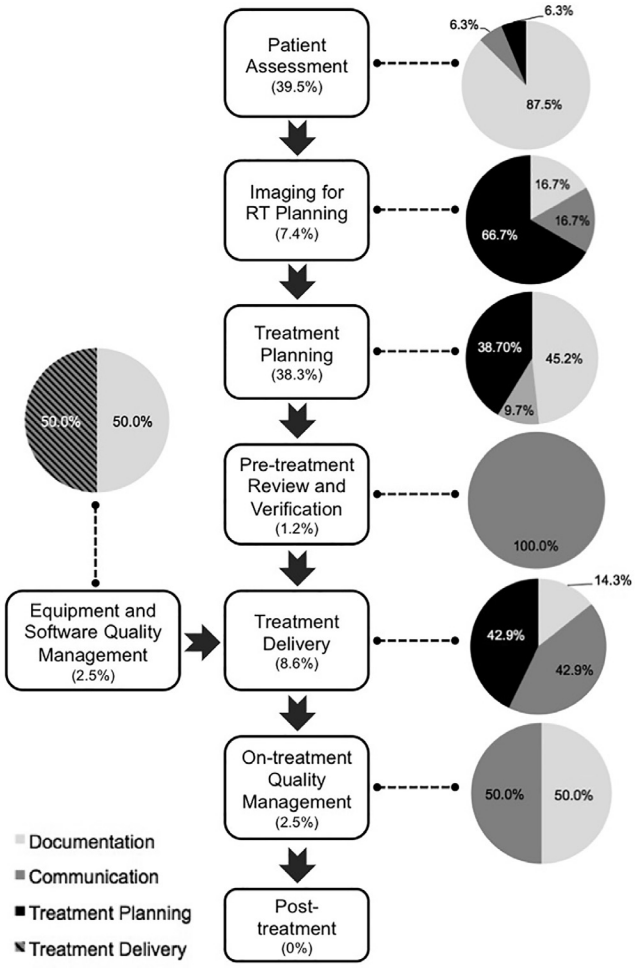

Fig. 1. Process map for RT workflow. This map illustrates the treatment phases in RT workflow, as well as the breakdown by root cause for NMSI occurring in each treatment phase.

Some variances were identified as workflow issues (64%). When excluded, 55% of the remaining incidents, or NMSI, were attributed to treatment planning errors, followed by errors in documentation (24%), communication (10%), and treatment delivery (10%). A complete stratification of workflow phases during which variances occurred and associated root causes is shown in Fig. 1.

Variances were most commonly detected during treatment planning (21%), followed by patient assessment (18%), imaging for RT planning (18%), pre-treatment review and verification (16%), treatment delivery (15%), and on-treatment quality management (12%). Quality assurance tasks that were highest yield for variance detection included therapists' chart checks, physicists' chart checks, and time-out processes; however, this data was not available for a substantial number of variance reports. Radiation therapists were the most common reporters (62%), followed by dosimetrists (23%) and physicists (16%). Although variances were frequently discovered during physician treatment planning and physician treatment review, no reports were made by physicians.

Patient- and disease-specific factors associated with variances

We evaluated several patient- and disease-specific factors that we hypothesized could affect risk for variances. Descriptive

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