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Radiation safety

The use of human factors methods to identify and mitigate safety issues in radiation therapy

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ABSTRACT

Background and purpose: New radiation therapy technologies can enhance the quality of treatment and reduce error. However, the treatment process has become more complex, and radiation dose is not always delivered as intended. Using human factors methods, a radiotherapy treatment delivery process was evaluated, and a redesign was undertaken to determine the effect on system safety.

Material and methods: An ethnographic field study and workflow analysis was conducted to identify human factors issues of the treatment delivery process. To address specific issues, components of the user interface were redesigned through a user-centered approach. Sixteen radiation therapy students were then used to experimentally evaluate the redesigned system through a usability test to determine the effectiveness in mitigating use errors.

Results: According to findings from the usability test, the redesigned system successfully reduced the error rates of two common errors ($p < .04$ and $p < .01$). It also improved the mean task completion time by 5.5% ($p < .02$) and achieved a higher level of user satisfaction.

Conclusions: These findings demonstrated the importance and benefits of applying human factors methods in the design of radiation therapy systems. Many other opportunities still exist to improve patient safety in this area using human factors methods.

In recent years, new and advanced technologies have revolutionized the planning and delivery of radiation therapy. However, the treatment process has become more complex, and radiation dose is not always delivered as intended [1]. A recent article in the New York Times described the devastating effects that resulted when human error had gone unnoticed during the treatment process [2]. Given the concerns raised in the media, radiation therapy is now under increased scrutiny and its safety is being questioned [3,4].

To improve patient safety and the quality of radiation therapy, industry has focused largely on creating new delivery apparatus and software systems [5]. While these new technologies can enhance the quality of radiation therapy and reduce error [1,6], it has also been reported that they can create new sources of error for treatment incidents to occur [1,7–9]. For instance, Record and Verify (R&V) systems that have been recently developed to ensure accurate delivery of treatment plans are often associated with usability issues that can lead to incidents [1,8]. This indicates a need to improve the interaction between users and these technologies.

Human factors engineering involves the study of human behavior, abilities and limitations, and the application of this knowledge to design systems for safe and effective human use [10–16]. Aside from evaluating and designing the technology itself, human factors engineering also takes into account the workflow and work environment that can affect human–machine interaction. As such, a system designed with human factors principles can often improve safety, minimize use errors, reduce training time and increase efficiency [17]. A number of human factors studies have been conducted in order to improve technologies and work environments of various healthcare providers, such as nurses [18–20], physicians [21–23] and radiologists [24–27]. However, there has been limited focus on radiation therapists despite the demanding nature of their work [28–31].

This multi-phase study is intended to investigate and address human factors issues in this area. The phased-approach included an evaluation of a treatment delivery process to identify human factors issues, the redesign of the existing system to address the

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issues found, and finally an experimental evaluation to assess the redesign.

Material and methods

This study was conducted at Princess Margaret Hospital (PMH) in Ontario, Canada. PMH is staffed with approximately 150 radiation therapists and is equipped with 16 linear accelerators. This study focused on the Synergy® linear accelerator system manufactured by Elekta (Elekta Medical Systems, Crawley, UK). This system was controlled with the Desktop Pro™ 7 control system, in conjunction with MOSAIQ™ (IMPAC Medical Systems, Sunnyvale, CA), a R&V system.

To investigate potential issues with the treatment process, field observations were conducted to observe how users interact with the delivery system. The primary author conducted observations for a total of 30 h over a 3-month period at the treatment facilities. A workflow analysis was conducted, and areas that were associated with a high likelihood of incidents were identified. The existing system was then redesigned using a user-centered approach to address the identified issues. In addition to applying existing usability guidelines, the redesigned system was demonstrated to experienced radiation therapists through two informal focus groups. Feedback that could improve usability of the system and/or patient safety of the process was used to refine the design.

To determine if the redesigned system improved user performance and reduce the risk of use errors, a usability test was conducted to compare the current and redesigned systems. Usability testing is a common technique for evaluating tools and technologies, where a sample of end users are asked to interact with the system of interest while being observed by an investigator [32]. Sixteen radiation therapy students enrolled in the Radiation Science Program at PMH were recruited to participate in the usability test. The testing sessions were conducted in a PMH treatment unit. A mock-up of the redesigned system was created for the usability test. A repeated-measures experiment was conducted where each participant was asked to take part in four scenarios using each system (i.e. eight scenarios in total) and perform regular treatment delivery tasks. Three out of the four scenarios for each system were designed with a high potential for certain use errors to occur. The fourth scenario acted as a control, with no errors planted. The error rates of committing the three planted errors, as well as the overall time taken to complete each scenario, were measured. At the end of the testing session, participants were asked to fill out a questionnaire to compare various attributes of the two systems.

A two-sided McNemar test was conducted to analyze the error rates associated with the two systems. A two-way ANOVA was conducted with the system and scenario as the main factors and the overall completion time as the dependent variable. Responses from the multiple-choice questions were analyzed by the Cochrane test to determine any significant difference across the three possible answer choices (i.e. *current system*, *redesigned system*, or *no preference*). For questions that showed a significant difference, a pair-wise comparison (i.e. *current system* versus *redesigned system*) was conducted using a two-sided McNemar test. Comments from participants were analyzed qualitatively for any recurring themes. To ensure inter-rater reliability, a second rater reviewed recordings for two of the participants and collected data for task completion times and error rates. Agreement between the investigator and the second rater was measured using the Intraclass Correlation Coefficient (ICC) at a confidence level of 95%. SPSS Statistics 17.0 (IBM, Chicago, IL), was used to conduct the above statistical analyses.

This study was approved by the Institutional Research Ethics Committee (Ref. No: 08-0300-AE and 08-1097-AE).

Results

Based on findings from the field observations and workflow analysis, the area that was found to be of particular concern was the checking process performed by radiation therapists prior to treatment delivery. At PMH, radiation therapists are required by policy to perform many checks to minimize the potential for use errors. These include checking the approval status of the treatment plan and the planning images, verifying the setup iso-center with the planning images, and verifying the linear accelerator parameters for each beam. However, other than being stated in the policy, these checks are not reinforced in any way, and are highly dependent on individual compliance. This was particularly an issue during the patient setup procedure where therapists are required to perform many manual tasks. In addition, the main user interface (MOSAIQ™) that is associated with the checking process is not fully integrated into the workflow of therapists. The necessary information required to complete checks is displayed on multiple screens. As a result, therapists find the checking process inefficient and inconvenient.

Based on the above findings, the main user interface (MOSAIQ™) was redesigned to address issues with the checking process, particularly its heavy reliance on policy and inefficient workflow. Fig. 1 compares the current and redesigned interface and highlights some of the changes that were made. Important features of the redesign include an automated checklist that ensures proper checks are completed prior to treatment, a more efficient structure with fewer steps, and a more prominent display of important information. With the automated checklist, the system would perform various checks automatically, including new messages, change in approval dates, and image approval status. If any of these items require attention, therapists must acknowledge them before they could proceed to deliver treatment. New and important messages were highlighted, and important information, such as the patient's profile picture and planning images, were displayed on the main screen for easier access. With these changes, the minimum number of mouse clicks required for therapists to perform the necessary checks was decreased by 71% (i.e. from 14 clicks to 4 clicks).

A usability test was conducted to compare the current and redesigned interfaces. Three errors were planted within scenarios including (1) overlooking an important note, (2) shifting the treatment couch incorrectly, and (3) overlooking a change of approval dates. These use errors can contribute to various adverse events, and were chosen due to their common occurrence. The overall time taken to complete each scenario was also measured.

The error rates for the three planted errors were analyzed. Data for one participant was removed due to technical difficulties that may have affected their ability to detect the error. As shown in Fig. 2, the error rate for overlooking an important note decreased significantly from 73% to 33% when the redesigned interface was used ($p < .04$), while the error rate for overlooking changes in approval dates decreased from 56% to 0% when the redesigned interface was used ($p < .01$). However, the rate for shifting the treatment couch incorrectly did not differ across the two interfaces and remained at 44%.

The mean overall task completion time for the redesigned interface was 6.0 ± 0.2 min (363 ± 13 s), which was 5.5% faster than the time of 6.4 ± 0.2 min (384 ± 13 s) for the current interface. Results from the ANOVA showed the interface effect was significant ($F(1, 15) = 7.91$, $p < .02$), and there were no interaction effects between the interfaces and scenarios.

Results from the questionnaire showed that significantly more participants thought the redesigned interface was better at showing the information that they needed ($p < .01$), at drawing their attention to important items ($p < .01$), at helping them detect various errors ($p < .01$), and at enabling them to deliver treatment