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The journey towards safer radiotherapy: are we on a road to nowhere?

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Original Article

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Abstract

Background: Harnessing available knowledge and learning from our errors are prerequisites of delivering on the challenge of improving patient safety. Towards Safer Radiotherapy, published in 2008, was a response from the UK's (UK) radiotherapy community to concerns arising from high profile errors. The report was a driver for the development of a national reporting and learning system for radiotherapy.

Materials and methods: A literature review was conducted covering the years from 2009 to 2020. Search terms used were radiotherapy errors, patient safety, incident learning, human factors and trend analysis. A total of 10 papers reported recommendations or implementation of changes to service delivery models following systematic error analysis. None of these were from UK service providers.

Conclusions: Twelve years on from the publication of Towards Safer Radiotherapy, there is little evidence of impact on safety culture within the UK radiotherapy community. Although the UK has a large radiotherapy error dataset, there remain unanswered questions about the impact on the safety culture in radiotherapy.

Introduction

In the foreword to Towards Safer Radiotherapy, Sir Liam Donaldson noted that 'we still have not yet mastered the art of harnessing all available knowledge, both national and international, to reduce adverse events in healthcare' (pg. 4).[1] This insight was a nod to the vast pool of learning available within and beyond healthcare that can inform patient safety initiatives. The report itself contained 37 recommendations intended to help service providers improve safety within radiotherapy departments. Of these, two relate specifically to sharing learning recommending the creation of a radiotherapy specific reporting and learning system (pg. 51) as well as research into the optimal way of sharing learning (pg. 52).[1]

The national voluntary reporting and learning system that evolved from this report has gained traction across the UK radiotherapy community. A revision published in 2016, updated the standardised terminology, classification and coding to include a causative factor taxonomy. This enables departments to compare local analysis of errors against the national picture.[2] Analysis of data collated by Public Health England indicates that errors occur across the spectrum of radiotherapy presenting opportunities for inter- and intra-departmental learning.[3] While the UK reporting and learning system is undoubtedly generating a large dataset from which to tease out learning about causes of error, there remains a paucity of evidence from within that community about its impact upon safety culture.

Materials and Methods

A literature review was conducted covering the years from 2009 to 2020. The search was conducted using Google Scholar. Search terms used were radiotherapy errors, patient safety, incident learning, human factors and trend analysis. A total of 18 publications were identified. Of these, eight were excluded as being theoretical papers. Ten papers reported recommendations or implementation of changes in clinical services following systematic error analysis.

A subsequent supporting internet-based literature search was conducted. Search terms used were incident learning systems, human factors engineering and trend analysis. Additional literature on specific high profile radiotherapy incidents, as well as national and international disasters was sourced to supplement texts in the field of error theory and disaster management.

Learning from Errors

A number of authors have published work reporting analysis of risk and errors. Shafiq et al. (2009) reported a review of 7,741 internationally reported incidents and near misses. This informed the radiotherapy risk profile published by the World Health Organisation which cited

communication, training and adherence to protocols as being the main areas requiring focus to improve patient safety.[4] These findings largely echo the broad thrust of Towards Safer Radiotherapy which produced recommendations on communication, training and competence in addition to quality assurance, audit and change management.[1] Both reports provide a broad perspective of whole service delivery reflecting acknowledged areas of risk within radiotherapy service delivery.

Reports from individual service providers are generally more focussed on specific problems and tend to fall into broad categories of human factors analysis or trend analysis. Portaluri et al. report a human factors analysis with a focus on operator error. This paper cites skill-based errors arising from attention failure, mental fatigue, distractions and overconfidence as key causes of error.[5] While this paper reports causes of error identified through reactive analysis that are widely recognised within radiotherapy, it fails to address the contribution of latent issues within the sociotechnical system. It also fails to provide the context within which incidents occurred which is essential to the wider sharing of learning from errors.[6]

Other authors have reported proactive interventions using human factor methodology to assess risks within the radiotherapy process with a view to designing out error. It has been argued that simplifying systems to reduce reliance on human vigilance and reduce the complexity of information presented is an important patient safety design principle.[7] This was reflected in research conducted across two UK radiotherapy departments investigating the final checks prior to initiating a treatment exposure. Using human factor methodology, the researcher identified risk of error associated with the method used to perform the final check and the presentation of data to the radiographers. Recommendations were made for the implementation of a new checking protocol and the problems with the user interface were presented to manufacturers. The changes standardised the checking protocol and proposals were made to simplify the user interface.[8] Although this work is the only primary research of its type in radiotherapy, and has been disseminated through multiple forums, to date there has been no publication reporting implementation and effectiveness of the proposed changes.

A weakness in the use of human factors interventions to improve safety within a healthcare setting is healthcare professionals' limited knowledge of human factors and ergonomics which combined with institutional resistance presents a major obstacle to change.[9,10] Overcoming the inbuilt resistance within healthcare systems is a key challenge for those seeking to inform safety improvements through the application of safety science. This can best be achieved through human factors professionals working closely with clinicians to improve healthcare systems.[10]

A number of authors report studies using human factors based methodology to assess risk of error and make evidence-based practice changes that are judged to reduce the risk of error.[11–14] Use of ecological interface design enabled evaluation of system design with focus group research demonstrating improved situational awareness and increased error detection.[11] An ethnographic field study and workflow analysis enabled a system redesign that successfully reduced common errors and achieved higher user satisfaction.[12] A heuristic evaluation of the treatment delivery system identified 75 usability issues of which 18 had the potential for major impact upon patient safety. Recommendations were developed to ameliorate against the risk.[13] In a paper reporting the use of human factors methodology to assess risk within the quality assurance system, the authors detail a range of interventions drawn from process engineering and human factors engineering to improve engagement with quality assurance across their service.[14] In each of these papers, rather than focussing on individual errors, the authors have taken a systems-based approach to identify risk of error and strategies to ameliorate those risks. Critically, each paper is informed by human factors professionals strengthening the validity. Sadly none of these papers originates from the UK and there is no literature to suggest that learning from these studies has been absorbed by UK service providers.

Incident Learning Systems

Trend analysis through the interrogation of data acquired using incident learning systems (ILS) is another approach taken in radiotherapy. The UK national reporting and learning system is one such mechanism used to elicit learning about patient safety in radiotherapy. Others exist and have reported their findings to enhance learning and patient safety.

Discussing the challenges of identifying learning from errors, Rafter et al. lament the absence of a systematic approach to measuring adverse events in healthcare.[15] They cite recurring themes around vincristine administration errors[16] and the underlying failures identified within the Francis Report[17] as examples of failure to take a systematic approach to learning from errors. Their argument is weakened by a failure to discuss the UK national reporting and learning system for radiotherapy which established clear definitions and mechanisms to support learning from errors. Their broad argument is however supported by Martinez et al. who in a review of processes to deal with adverse events within a single hospital reported a wide variation of how they are identified and reviewed. They concluded there was a need for a more coordinated approach to incident learning.[18]

Several international authors have reported local experience of ILS in radiotherapy. An article detailing retrospective trend analysis from 1,063 incident and near miss reports presented a mixed picture where a reduction in events in one part of the pathway was offset by increases elsewhere. The authors reported that major modifications to process maintained a stable rate of near misses per course with some statistically significant reduction in actual incidents.[19] A weakness of the study was its use of a limited taxonomy for error classification in comparison to the UK system.

A similar study reported an overall drop in errors over a 3-year period resulting from managing errors through an incident learning system. The authors report that implementing an ILS has improved openness and engagement with reporting systems over the period of the study contributing to safety improvements.[20] This study is however weakened by a failure to account for the effect of technological changes planned prior to commencement of the study. The change from manual to electronic data transfer may well have had a significant effect on error rates. This is however not explored in the paper.

The literature shows a complex picture of error causes in radiotherapy with human behaviour, communication, technical issues and poor human factors engineering all being identified as significant factors.[21–24] The wide range of approaches taken to investigation and data analysis only serves to complicate the subject. That there is a steady increase in reported incident learning using ILS is to be welcomed. There is however a challenge to overcome. Although the use of ILS is growing concurrently with improved awareness of safety culture, there are gaps in knowledge and experience that are yet to be addressed within radiotherapy. There is also as yet no evidence of a clear link between learning, improved

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safety and clinical outcomes.[25] This is a gap the radiotherapy community must endeavour to close.

It is important to urge a note of caution to those who see ILS as the panacea to safety in radiotherapy. In a systematic review of the effectiveness of ILS on improving patient safety, Stavropoulou et al. found limited evidence showing a link between ILS and safety improvements. Studies showed corrections of procedural errors and techniques but little evidence of sustained safety improvement or cultural change.[26] The authors concluded that ILS are most effective when used and owned by local teams in specific departments rather than at a wider level.[26] This conclusion raises questions about the direction of travel in UK radiotherapy incident learning.

Isomorphic Learning

The terms of reference for Towards Safer Radiotherapy included to 'find ways of reporting errors and near misses to the whole radiotherapy community, thereby facilitating knowledge and learning which might prevent repetition' (pg. 7).[1] This draws upon the principle of similarities between different systems discussed by von Bertalanffy in his book on the development and applications of General System Theory.[27] Core to this is the phenomenon of the commonality of principles across widely differing biological, sociological and mechanical systems giving rise to the theory of isomorphic laws that apply across different scientific fields. That these structural uniformities exist give rise to the possibility of learning from other disciplines.[27]

This theory was developed by Toft and Reynolds[28] who introduced the concept of organisational isomorphism (pg. 27) to explain the commonality between disparate disasters, supporting an empirical approach to learning and reducing risk. At the core of their work was the role of isomorphic learning in facilitating improved risk management. Their work presents a strong case for the use of isomorphic learning across industries and disciplines. It carries with it an important caveat that learning is dependent upon rigorous enquiry, knowledge of context and organisational culture (pg. 65–86).[28]

Drawing upon the work of von Bertalanffy[27] and Toft and Reynolds,[28] we are led to ask questions about the effectiveness of the national reporting and learning system for radiotherapy. While it incorporates the principles of isomorphic learning into the system design, there would appear to be significant gaps that might inhibit effective learning. Can we say with any certainty that there is rigorous investigation? Do we really know the context of the learning being shared with us? What evidence exists of learning being applied across and within the UK radiotherapy community? Can we evidence impact on organisational culture? With limited published evidence it is difficult to begin answering such questions. This in turn leads us to ask whether the information being provided by the radiotherapy reporting and learning system is presented in a format that facilitates isomorphic learning.

Wider Learning and Radiotherapy Safety

Using grounded theory, Toft and Reynolds were able to demonstrate common links running through diverse events such as the Coldharbour Hospital Fire, the Dudgeons Wharf Explosion, the Fairfield Care Home Fire, the Summerland Leisure Centre Fire and the Taunton Rail Fire. Issues identified include poor communication, infrastructure and process design failures, interpretation of regulations, decision making in conditions of ignorance and effects of organisational change.[28]

Within the Public Health England radiotherapy error analysis, there is a large volume of potential learning arising out of the 58,913 voluntary reports submitted between January 2010 and December 2019. Data has been submitted from all NHS providers indicating an evolving safety culture within radiotherapy.[29] Design of the system however means that data analysis is quantitative rather than qualitative. Broad themes are extracted from the data and presented to the reader enabling local analysis and interpretation to inform patient safety initiatives.[29] The data shows that similar events are happening with a relatively high frequency year on year. There does not appear from the data published in this report to be any clear indication of a downward trend in the frequency of such events.

The limited evidence of local changes in response to this data may be viewed as evidence of what Toft and Reynolds[28] call passive learning. They broadly defined this as knowing about something (pg. 66). If passive learning is knowing about something, then they argued it follows that active learning is knowing about something and taking steps to ameliorate the risk (pg. 66). Although there is merit in presentation and local analysis of the national radiotherapy error data, the learning is inherently passive as limited knowledge of context inhibits opportunity for isomorphic learning. Knowledge of context is an important component in the understanding of interplay within a sociotechnical system[30] and therein facilitation of isomorphic learning.[28,31]

Arguably within UK radiotherapy, the most valuable learning has come from the reviews of serious harm events. Two such events were precursors to the publication of Towards Safer Radiotherapy. An incident in a radiotherapy centre that led to the discovery of involuntary automaticity[32] and a further incident at the Beatson Oncology Centre[33] were comprehensively investigated and the learning widely disseminated across the radiotherapy community. Shared learning was facilitated by reports providing context thereby enabling improved local risk assessment in response to investigation findings. A further event occurred in Edinburgh.[34] Although not as widely reported, the findings provided valuable insight into regulatory compliance with learning applicable across the radiotherapy community. The sharing of these incidents, setting detailed analysis of events within the wider context of organisational structure and culture enabled isomorphic learning across the radiotherapy community. It provided a learning opportunity that the national reporting and learning system is not designed to facilitate. The author is aware of similar events that have not been widely shared with the radiotherapy community. These can be regarded as missed learning opportunities and perhaps reflect a safety culture that is not as mature as we would believe.

The national reporting and learning system for radiotherapy is a tool designed to improve safety culture across the profession. It happened in response to concerns following the incidents cited above. There is however evidence from beyond radiotherapy of cultural failings in organisations that have had catastrophic consequences. Lord Justice Sheen[35] identified a catalogue of management, supervisory, organisational and system design failures that contributed to the Herald of Free Enterprise Disaster. This was the consequence of a poor safety culture within that organisation which allowed human errors to occur. This finding of poor safety culture was a theme in other high profile disaster reports including the Piper Alpha Disaster,[36] the King's Cross Underground Fire[37] and the Marchioness sinking on the River Thames.[38] In these and other disasters, it was found that poor safety culture created

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the circumstances for human error to occur. Themes identified within these disasters are also evident in radiotherapy incidents where latent effects from management decisions created circumstances that predispose to human error.[32–34] Whether learning from such events is directly transferrable to radiotherapy is a matter for debate. That there are broad themes running through them from which learning can be gleaned is however undeniable.[28] It is reasonable therefore as a profession to ask how open we are to learning from other disciplines.

Institutional resistance to learning from errors has been identified in the oil industry[39] and the military.[40] Flournoy[39] noted that resistance to learning from the Deepwater Horizon Disaster was an issue with a fundamental rethink of safety culture required. Whitehead et al. [40] in a review of attitudes and perception of Royal Air Force personnel following the loss of a Nimrod found that can-do military culture and a hierarchical structure contributed to filtering out of key information compromising safety culture. Interestingly, they noted that the organisation settled into a new equilibrium following disaster providing an illusion of safety through increased safety bureaucracy.[40]

Within healthcare, there are some examples of successful integration of learning from industry, particularly around patient handover and communication between surgery and intensive care units. Although there have been some successes, the autonomous silos within which many services work contribute to resistance to external learning.[41] Again, there is little evidence about the radiotherapy experience.

Conclusion

The writing of Towards Safer Radiotherapy and subsequent establishment of the national reporting and learning system for radiotherapy was an important step in addressing concerns about the safety culture within UK radiotherapy. The system has harvested vast quantities of data classifying causes of radiotherapy incidents. This achievement is to be applauded by all who care about patient safety. Questions however remain about the efficacy of the system.

The system has enabled quantitative analysis of error data and sharing of learning with the radiotherapy community. That learning is however generalised. It does not provide context and therefore inhibits the ability of service providers to implement meaningful change to their own services. The lack of qualitative data means that scope for meaningful isomorphic learning is limited. To some extent, the system design compromises our ability to maximise learning opportunities.

Although 12 years have passed since the publication of Towards Safer Radiotherapy, there is limited evidence of improvements in UK safety culture. There is scope for learning and improving safety drawing upon the experience of other healthcare disciplines, industries and the expanding human factors profession. As yet, there is little evidence that the UK radiotherapy community is embracing these opportunities. The fact that no UK radiotherapy department has reported their experience of implementing the checking protocol recommended by Gilbert[8] is an indication of resistance to change that exists across the profession. Combined with a lack of published error focussed research, it may be inferred that the profession is talking the talk but not necessarily walking the walk.

When Towards Safer Radiotherapy was written, the aim was to set a course towards a safer more risk aware culture in radiotherapy. Although opportunities for learning from errors abound, questions remain about openness within UK radiotherapy. Twelve years on from Sir Liam Donaldson's comments, the workforce appear still not to be harnessing all available knowledge to reduce risk of errors. With Towards Safer Radiotherapy, the service embarked on a journey but it remains to be seen whether we are on a road to nowhere.

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