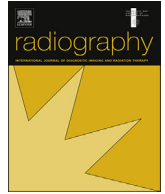




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Improving patient safety in radiotherapy through error reporting and analysis

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ABSTRACT

Aim: To improve patient safety in radiotherapy (RT) through the analysis and publication of radiotherapy errors and near misses (RTE).

Materials and methods: RTE are submitted on a voluntary basis by NHS RT departments throughout the UK to the National Reporting and Learning System (NRLS) or directly to Public Health England (PHE). RTE are analysed by PHE staff using frequency trend analysis based on the classification and pathway coding from Towards Safer Radiotherapy (TSRT). PHE in conjunction with the Patient Safety in Radiotherapy Steering Group publish learning from these events, on a triannual and summarised on a biennial basis, so their occurrence might be mitigated.

Results: Since the introduction of this initiative in 2010, over 30,000 (RTE) reports have been submitted. The number of RTE reported in each biennial cycle has grown, ranging from 680 (2010) to 12,691 (2016) RTE. The vast majority of the RTE reported are lower level events, thus not affecting the outcome of patient care. Of the level 1 and 2 incidents reported, it is known the majority of them affected only one fraction of a course of treatment. This means that corrective action could be taken over the remaining treatment fractions so the incident did not have a significant impact on the patient or the outcome of their treatment. Analysis of the RTE reports demonstrates that generation of error is not confined to one professional group or to any particular point in the pathway. It also indicates that the pattern of errors is replicated across service providers in the UK.

Conclusion: Use of the terminology, classification and coding of TSRT, together with implementation of the national voluntary reporting system described within this report, allows clinical departments to compare their local analysis to the national picture. Further opportunities to improve learning from this dataset must be exploited through development of the analysis and development of proactive risk management strategies.

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Introduction

Patient safety has been defined as avoiding harm from the care that is intended to help.¹ To maintain or improve patient safety, error has to be prevented, or minimised. When the opportunity for error is weighed against the incidence of error, radiotherapy (RT) may be seen as a safe form of treatment for cancer.² Although error within RT might be described as rare in the UK, when it does occur the consequence can be significant, with this in mind it is essential

for the RT community not to become complacent about the associated risks.

The remit of the Medical Exposures Group (MEG) within Public Health England (PHE) includes the provision of independent advice on medical and dental radiological practice and radiation safety of practices involving medical exposures of radiation across the UK. MEG also support the development of the national reporting system for radiotherapy errors and near misses (RTE), undertake the analysis of the data collated through this system and regularly publish reports intended to promulgate information in order that the probability of similar events can be reduced.

In 2006, a report³ by the Chief Medical Officer (CMO) for England launched a range of initiatives relating to patient safety in RT.

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The CMO provided funding for the Health Protection Agency (now PHE) to establish a dedicated resource to support the RT community in improving safety in RT. A further initiative by the CMO resulted in the joint publication 'Towards Safer RT' (TSRT) by the professional bodies in 2008,⁴ which set out key recommendations to improve patient safety. These recommendations included the establishment of a dedicated RTE reporting system that all providers should participate in for the improved learning from these events. The Patient Safety in RT Steering Group (PSRT) was tasked with taking this forward through a collaborative programme of work with the RT community. This multidisciplinary group's membership includes representatives from PHE, Society and College of Radiographers (SCoR), Royal College of Radiologists (RCR), Institute of Physics and Engineering in Medicine (IPEM), and a patient representative.

The fundamental role of reporting and learning systems is to enhance patient safety by learning from failures of the healthcare system.⁵ It is known that most problems are not just a series of random, unconnected one-off events; they are provoked by poor systems and often have common root causes which can be generalised and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may go unnoticed if incidents are not reported and analysed.⁶

Experience has shown that as an organisation's reporting culture matures, staff becomes more likely to report incidents. There is an emerging evidence base that organisations with a higher rate of reporting have a stronger safety culture. High reporters aim to learn from incident reporting to make patient care safer.⁷ With this in mind an increase in incident reporting should not necessarily be taken as an indication of worsening patient safety, it may indicate an increasing level of awareness of safety issues among healthcare professionals and a more open and transparent culture across the organisation.

It is essential that the local reporting and learning system is readily accessible and offers an efficient solution to enable reporting. The third in a series of surveys of UK RT providers in 2014⁸ on reporting culture demonstrated that those departments with fully electronic single reporting and learning solutions, which were accessible in all areas of the clinical department, were most likely to submit RTE reports.

The focus on learning from errors is likely to continue as clinical departments are encouraged and even mandated to participate in error and near miss reporting. Recommendations of the Francis Report⁶ into failings at the Mid-Staffordshire NHS Foundation Trust included a requirement for openness, transparency and candour throughout the NHS to support a culture of protecting patients and removing poor practice. A revised basic safety standards directive (BSSD 2013/59/Euratom) was published in the Official Journal of the European Union⁹ in December 2013, this called for RT providers to implement an 'appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice'. New regulations will be required by February 2018 to transpose the new directive into UK legislation.

Materials and Methods

The National Reporting and Learning System (NRLS) operates an anonymised voluntary reporting system to collect and learn from patient safety incidents for England and Wales. As of April 2016 the NRLS transferred from NHS England to NHS Improvement. Under a data sharing agreement with the NRLS, PHE continues to extract RTE data from the NRLS, and share learning from these events with the aim of improving clinical practice. PHE developed a mechanism for NHS RT providers in Northern Ireland and Scotland in 2012, to

share reports directly with PHE so they too might participate in this voluntary scheme.

As with any voluntary reporting system, the data will only reflect those incidents that are reported and may not necessarily be representative of the actual level of occurrence. As such, this data needs interpreting with care.

TSRT⁴ provides definitions for the terminology to be used in discussing RTE and proposed two taxonomies for use in describing RTE. The 'classification of radiotherapy errors grid' (Appendix 1) describes the severity of the incident and is made up of five levels, one being the most severe as a 'reportable radiation incident' and five being a 'non-conformance'. The 'RT pathway coding' (Appendix 2) describes where on the patient pathway the error has occurred. This has 21 constituent codes and 193 subcodes extending across the patient pathway.

The PSRT ask RT department staff to apply a trigger code, 'TSRT9', to each report. The trigger code is entered into the first open text field of the local reporting and learning system report proforma. This trigger code makes RTE specifically searchable on the NRLS database, ensuring all are easily identified and sent to the PHE for analysis.

In addition local reporters are asked to classify and code all errors according to the taxonomies presented in TSRT within their local reporting and learning system for subsequent submission for analysis by PHE staff as part of a voluntary reporting scheme.

Inclusion of free text to describe the events surrounding the RTE with reports enables consistency checking of the RTE report. In practice the trigger code and TSRT taxonomies are typically added to the first open text box in the following manner:

TSRT9/level 3/13/13hh

On receipt of the reports, PHE staff with clinical radiotherapy expertise perform consistency checking of the local application of the classification and coding from TSRT. Consistency checking of the appropriate application of the coding and classification taxonomies is high, with agreement routinely achieved in >80% of reports. It is thought the high level of agreement in the application of the taxonomies is in part due to the publication of a guidance document¹⁰ on the use of the trigger code and application of the coding and classification, development of a supplementary series on good practice in RTE reporting¹¹ and familiarisation with the taxonomies.

The proposed trigger code, terminology and taxonomies have now been adopted for use in RT departments across the UK thus enabling national sharing and analysis of these events. The TSRT taxonomies form the basis of the frequency trend analysis employed by PHE. An established Access database acts as a repository for the data. It also supports the analysis of the data through the use of scripted reports on frequency and trends analysis. The database has access restricted to named individuals directly involved with the quality assurance and analysis of the data. All data is uploaded to the database by import of Microsoft Excel spreadsheets. For the purposes of the analysis each RTE report submitted is included as a single report.

The analysis is reported to the PSRT for peer review and comment before being disseminated to the RT community to provide learning opportunities. In July 2010² the first in a series of biennial data reports was published on patient safety incidents reported to the NRLS between August 2007 and November 2009. This analysis aimed to provide learning from incidents already reported, to trial the application of the taxonomies from TSRT and to test the mechanism for reporting. This publication was closely followed in September 2010 by the introduction of a series of newsletters entitled 'Safer RT'¹² providing regular updates on the

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