Public Health England

Safer Radiotherapy

Radiotherapy Newsletter of Public Health England
April 2014 Issue 12

Welcome to the twelfth issue of *Safer Radiotherapy*. The aim of the newsletter is to provide a regular update on the analysis by PHE of radiotherapy error (RTE) reports. These anonymised reports are submitted voluntarily to the National Reporting and Learning System (NRLS) of NHS England (formerly the NHS Commissioning Board) or directly to PHE, to promote learning and minimise recurrence of these events.

Safer RT is designed to disseminate learning from RTEs to professionals in the radiotherapy community to positively influence local practice and improve patient safety.

Regular features include:

RTE Data Analysis – undertaken by PHE, highlighting key messages and trends identified from a three-month period of RTE reports

Error of the Month – provides advice on preventing recurring errors in the patient pathway

Guest Editorials – are invited from those wishing to contribute to issues surrounding patient safety issues in radiotherapy

Patient Safety in Radiotherapy Steering Group – updates on the work of this multidisciplinary group

Any comments and suggestions for inclusion in the newsletter would be gratefully received. They should be sent to **radiotherapy@phe.gov.uk**.

Thanks to all contributors to this issue. The next issue of *Safer RT* will be published in July 2014.

Helen Best
Editor

Patient Safety in Radiotherapy Steering Group (PSRT)

Once again we can report an increase in the number of radiotherapy departments contributing to the national voluntary reporting system.

A total of 98% of current NHS radiotherapy providers in the UK are now sharing their RTEs for inclusion in the analysis by PHE. The remaining provider is working with PHE staff to participate in this initiative. This reflects a mature reporting culture and the ongoing commitment of local staff to improving patient safety in radiotherapy.

Building on previous surveys of reporting RTEs, a third survey will be undertaken by PHE to identify current challenges to reporting, and how lessons are learned from local and national analysis. Please look out for the survey, which will be emailed to heads of radiotherapy services soon.

This is your opportunity to tell us how we can help you.

INSIDE THIS ISSUE

The Radiotherapy Team is based at CRCE Chilton

EDITORIAL HEADLINE

Basic Safety Standards – Update

On 17 January 2014, the much anticipated revised Basic Safety Standards Directive was published in the Official Journal of the European Union as Council Directive 2013/59/Euratom. It is intended to replace a range of existing directives but, for radiotherapy, the key impact will be to replace the existing Basic Safety Standards and Medical Exposure Directives. These were implemented in Great Britain by the Ionising Radiations Regulations 1999 and the Ionising Radiation (Medical Exposure) Regulations 2000 and by parallel regulations in Northern Ireland.

New regulations will be required by 6 February 2018 to transpose the new Directive. At this stage, the format and specific content of the new regulations is under discussion, but radical changes are not expected to the overall regulatory frameworks in the UK. The format of the new regulations may be different, but many of the specific requirements of the new Directive are already embedded in UK regulations or practice. Nevertheless, the radiotherapy community will be consulted as the new regulations are developed.

RTE Data Analysis: December 2013 – February 2014

Quarterly Analysis

Submissions from 50 RT departments across England, Scotland and Wales contributed to this issue's full data analysis, for 1 December 2013 to 28 February 2014, which is available at **www.hpa.org.uk/radiotherapy**.

The analysis includes data on primary process coding and severity classification of the RTEs. A breakdown of primary process codes by classification levels is also included.

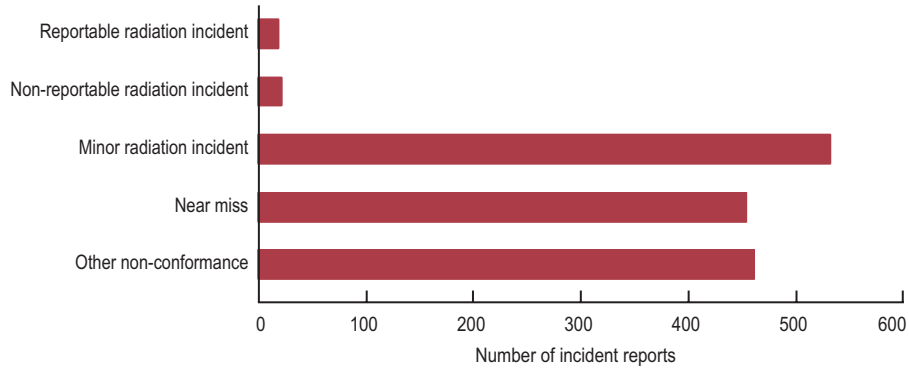
Classification of RTEs

Of those RTEs reported for the period December 2013 – February 2014, 1445 out of 1483 reports (97.4%) were classified as minor radiation incidents, near misses or other non-conformances (see Figure 1). This is consistent with previous analyses. These are lower level incidents which would have no significant effect on the planning or delivery of individual patient treatments. However, over the past four issues there has been a steady increase in the number of minor radiation incidents reported, from 25.3% in Issue 9 to 35.8% in this issue. This may be due to the increase in imaging associated reports.

Reportable radiation incidents (Level 1) made up 18 (1.2%) of all reports. 'Movement from reference marks' comprised 3 (16.6%) and 'ID of reference marks' 2 (11.1%) of all Level 1 RTEs reported for this time period. Non-reportable radiation incident reports (Level 2) made up 20 of all reports (1.4%).

Of the 531 minor radiation incidents (Level 3) reported, 123 (23.2%) of this subset were related to the 'on-set imaging production process', making it the most frequently occurring code in this classification. The second most frequently occurring incident at 69 (13.0%) was 'use of on-set imaging'. On-treatment imaging is discussed further in this issue of *Safer RT*.

Figure 1 ***Classification breakdown of RTE reports using the TSRT9 trigger code, December 2013 – February 2014 (1483 reports)***



The most commonly occurring RTE process code in the near-miss (Level 4) classification was 'on-set imaging: approval process', with 30 reports (6.6%).

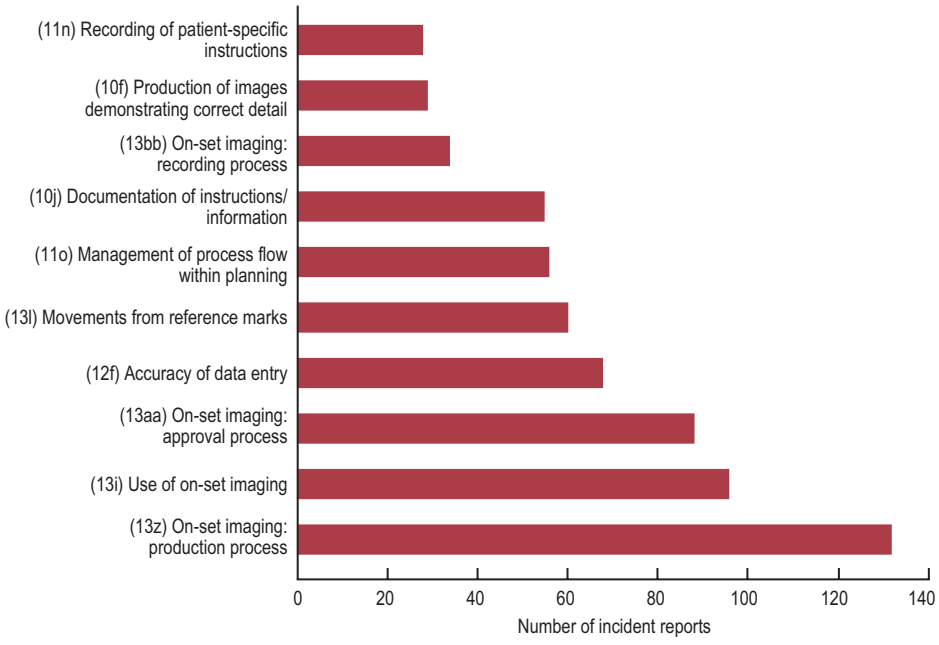
Within the non-conformance (Level 5) classification 'management of process flow within planning' had 53 reports (11.5%), making this the most frequently occurring RTE in this classification.

Primary Process Code

The main themes (points in the patient pathway where the majority of reported RTEs occurred) for this dataset are shown in Figure 2.

Imaging process codes contributed to 350 of the reports in the main themes (54.1%). Of these 350 reports, only one report was reportable to the appropriate authorities. Imaging associated RTEs are discussed in the panel. Of note, 'production of images demonstrating correct detail' contributed to 29 of the reports in the main themes (1.9%) – this is discussed further in the *Error of the Month*.

Figure 2 ***RTE main themes (646 out of 1483 reports), for December 2013 – February 2014 (with process code indicated)***

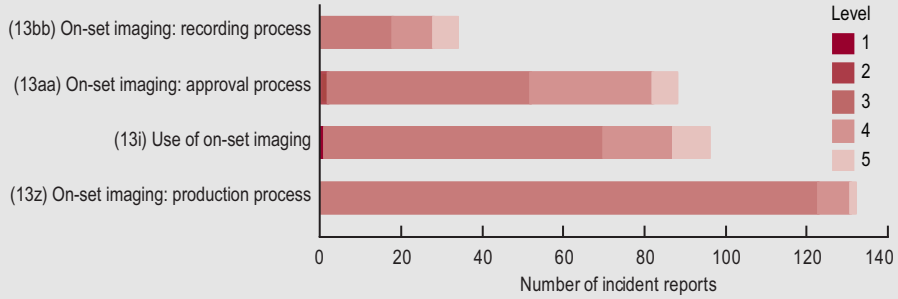


The data analysed is submitted by the RT community. If you have any suggestions on how the process coding can be refined, please email the Radiotherapy Team at **radiotherapy@phe.gov.uk**.

Imaging Associated RTE Reports

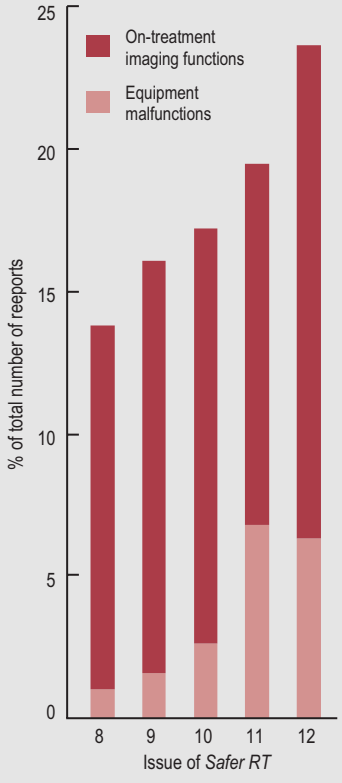
Since Issue 8 (August–December 2012) the proportion of imaging associated RTE reports has gradually increased, from 13.8% to 23.6% in this issue. These types of errors cross a range of imaging functions, as seen in Figure 1. It should be noted that the majority of these errors are lower level incidents. Figure 1 highlights this, showing that only 3 out of 350 reports from this reporting period are Level 1 or 2 events.

Figure 1 ***Imaging associated errors by classification level, December 2013 – February 2014***



Further review of imaging associated error reports (Figure 2) shows that the subset of equipment malfunction associated reports as a proportion of these reports has increased from 1% to 6.8%, across a number of RT departments. These types of errors should be reported both locally and externally to the MHRA and the relevant manufacturer, and appropriate action should be taken to ensure that patients are not receiving unnecessary exposures.

Figure 2 ***Imaging associated reports including equipment malfunctions, by issue of Safer RT***



The increase in these types of error reports may reflect the rapid uptake and increase in the use of image guided radiotherapy. Despite pressures to introduce new techniques and technologies, the greatest care should be taken to ensure all new systems are introduced safely. Appropriate time should be given to training, equipment testing, QA and development of supporting documentation, and workflow. In addition, changes to practice should be audited and learning points used to inform practice.

A further factor in the growth in the number of these reports may be the increase in the number of departments reporting, from 42 to 50 during the period being considered. These types of reports will continue to be monitored in future issues of *Safer RT.* Guidance on the use of imaging can be found elsewhere*,†.

Application of on-treatment imaging codes

As the number of imaging associated errors increases, learning opportunities from these events should be maximised. Consistency in applying coding is central to this. Consistency checking by PHE shows that some variation remains in coding on-treatment imaging RTEs. Further guidance on consistency coding and how to minimise these types of RTE can be found in Issue 7 of *Safer RT*.

* National Radiotherapy Implementation Group (2012). Image Guided Radiotherapy (IGRT): Guidance for implementation and use. Available at www.sor.org/sites/default/files/document-versions/National%20Radiotherapy%20Implementation%20Group%20Report%20IGRT%20Final.pdf.

† RCR, SCoR and IPEM (2008). On Target: Ensuring Geometric Accuracy in Radiotherapy. London, RCR. Available at www.rcr.ac.uk/docs/oncology/pdf/BFCO(08)5_On_target.pdf.

ERROR OF THE MONTH

Pre-treatment activities

TSRT Process Code: Production of images demonstrating correct detail (10f)

This code accounted for 29 (1.9%) RTEs reported from December 2013 to February 2014. This was one of the top ten most commonly occurring RTEs. Of note, 16 (55%) of these errors were minor radiation incidents.

This RTE involves the production of images in the pre-treatment area, including CT, simulation and clinical mark-up. The main themes highlighted within these reports included insufficient imaging of anatomy, inappropriate scanning levels, incorrect laterality and standard gantry angles for simulator images not used.

How can we minimise the risk of this RTE occurring?

Points to consider

1. Ensure appropriate site-specific scanning levels and protocols are in place for all routine imaging
2. Ensure all relevant documentation is available and complete before initiating exposure
3. Defer to expert users for unusual cases prior to initiating exposure. Where possible, discuss and agree appropriate scanning levels and protocols for unusual cases in advance with the multidisciplinary team
4. Ensure laterality checks are completed using primary source documentation before exposures are initiated
5. For CT scans, review and ensure the topogram/scanogram indicates correct scanning levels before commencing CT
6. Check all required anatomy has been captured on the image before the patient leaves and that the image is fit for purpose
7. Ensure staff are adequately trained, competent and appropriately entitled in the use of the technology
8. Audit staff compliance with written procedure and protocols and monitor locally reported RTEs to identify further preventive action

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GUEST EDITORIAL

Image Guided Radiotherapy (IGRT) Risk vs Benefit

Carl Rowbottom
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It is now more than 10 years since the introduction of on-treatment 3D verification from the integration of cone-beam CT on the linac. Cone-beam CT has seen a step change in on-treatment imaging compared to 2D kV and MV imaging methods, and it is likely that cone-beam CT image quality will continue to improve to produce near-diagnostic quality images in the future.

Given the potential applications for daily on-treatment imaging and adaptive radiotherapy, the risk-benefit analysis of concomitant dose in radiotherapy needs to be reviewed. It is clear that concomitant dose leads to an increased risk of second malignancy. The primary question is therefore:

'Is the increased risk justified'?

When considering this question the radiation dose given to the patient from radiotherapy needs to be taken into account. In general, 1–3% of patients receiving radiotherapy will develop second malignancies and the benefit of radiotherapy is routinely justified against this background risk.

It is common practice to estimate the radiation risk from concomitant imaging using the linear no-threshold model of risk. There are two issues with this approach. Firstly, the risk estimate from this model is reasonable for fractionated doses of less than 4 Gy. For doses above this level the risk is overestimated by this model. The risk model is more likely linear plateau or linear exponential, resulting in lower estimates of risk for radiotherapy dose region[1]. Secondly, the risk can be calculated, with significant uncertainty, whereas the benefit to the patient is more difficult to estimate and often omitted from the justification, providing a biased analysis against the use of daily imaging.

A tumour that is expected to experience significant inter-fraction motion is highly likely to benefit from more frequent imaging to reduce the risk of geometric miss. An example is gynaecological cancer where the cervix position varies significantly from day to day[2]. Qiu et al[3] calculated that daily cone-beam CT imaging for gynaecological treatments increases the dose by 0.1–0.6 Sv, depending on the risk model used. This is only 0.1–2.5% of the dose received by the organ from the radiotherapy. The majority of the risk comes from radiotherapy and not from daily cone-beam CT imaging.

A more balanced risk-benefit analysis of daily cone-beam CT imaging is required to ensure patients are able to experience the highest standards of radiotherapy.

References

1 Murray L, Henry A, Hoskin P, et al. Second primary cancers after radiation for prostate cancer: a systematic review of the clinical data and impact of treatment technique. *Radiother Oncol* 2014; **110**(2): 213–28.

2 Haripotepornkul NH, Nath SK, Scanderbeg D, et al. Evaluation of intra- and inter-fraction movement of the cervix during intensity modulated radiation therapy. *Radiother Oncol* 2011; **98**(3): 347–51.

3 Qiu Y, Moiseenko V, Aquino-Parsons C, et al. Equivalent doses for gynecological patients undergoing IMRT or RapidArc with kilovoltage cone beam CT. *Radiother Oncol* 2012; **104**(2): 257–62.

DATES FOR THE DIARY

28 April	IPEM, Workflow, It's Not Just DICOM, London
19 May	BIR, Radiotherapy – Meeting The Current and Future Workforce Challenges for Patient Care in a Changing Context, London
8 July	IPEM, MPE Update, Newcastle upon Tyne