Public Health England

Radiotherapy Newsletter of Public Health England

Safer Radiotherapy

August 2013 Issue 9

Welcome to the ninth issue of *Safer Radiotherapy* – the first from Public Health England (PHE). The newsletter was previously published by the Health Protection Agency (HPA). Its aim is to provide a regular update on the analysis by PHE of radiotherapy error (RTE) reports. These reports are submitted voluntarily to the National Reporting and Learning System (NRLS) of the NHS Commissioning Board to promote learning and improve patient safety.

Safer RT is designed to disseminate learning from RTEs to professionals in the radiotherapy (RT) community to 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 in radiotherapy
- **Patient Safety in Radiotherapy Steering Group** – updates on the work of this multidisciplinary group (IPEM, RCR, SCoR, PHE and service users)

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 October 2013 and will be available at **www.hpa.org.uk/radiotherapy.**

Helen Best
Editor

Patient Safety in Radiotherapy Steering Group (PSRT)

From 1 April 2013 the Health Protection Agency was abolished and its functions transferred to Public Health England, whose primary purpose is to protect and improve the public's health and wellbeing. This will not influence the principles adopted by the PSRT, specifically its multidisciplinary approach.

Work is progressing in Northern Ireland with seeking formal agreement to sharing data to include in the analysis.

In Scotland work on a pilot for data collection and transfer continues. A second dataset from a Scottish radiotherapy department has been received by PHE for analysis. In the second phase of the pilot the intention is to extend this to other centres in Scotland.

This comprehensive reporting will facilitate UK-wide learning from RTEs, which is a highly effective tool for improving patient safety.

Please continue to report RTEs to inform ongoing safe and effective radiotherapy practice.

INSIDE THIS ISSUE

Please note: PHE radiotherapy publications will continue to appear on the HPA website until further notice – look out for updates in future newsletters.

The Radiotherapy Team is based at CRCE Chilton

EDITORIAL HEADLINE

Update to Basic Safety Standards

Negotiations on the Euratom Basic Safety Standards (BSS) Directive at the Atomic Questions Group (AQG) concluded on 29 May 2013, with all member states signalling agreement with the final text proposed by the Irish presidency.

The European Parliament, EU Legal Services and the Jurist Linguists will feed into the process before the BSS proposal may be adopted by the Council of Ministers. The UK expects that the adoption process will go smoothly, but there remains the possibility that the BSS will return briefly to the AQG in September or October 2013 under the Lithuanian presidency, should the remaining processes raise significant issues.

The revised BSS will have implications for legislation in the UK – more to follow in future newsletters.

RTE Data Analysis: January–April 2013

Quarterly Analysis

Submissions from 41 RT departments contributed to this issue's full data analysis, for 1 January 2013 to 31 April 2013, 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 given.

Classification of RTE

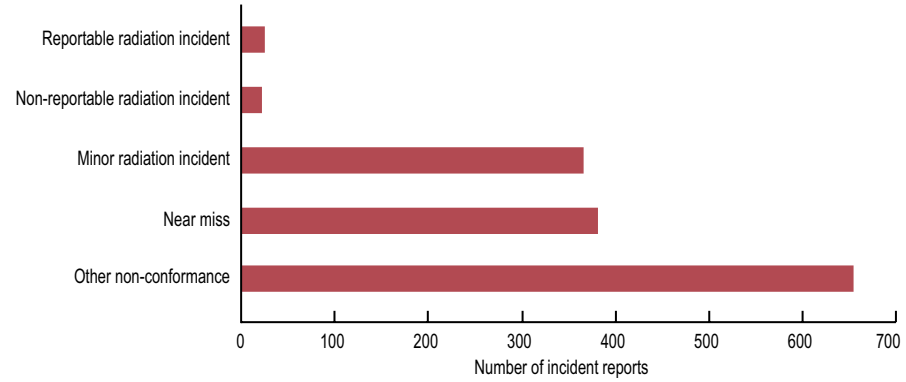
Of those RTEs reported to the NRLS for the period January–April 2013, 1400 out of 1445 reports (96.9%) were classified as minor radiation incidents, near misses or other non-conformances (see Figure 1). This is consistent with previous analyses. These incidents would have no significant effect on the planning or delivery of individual patient treatments.

Reportable radiation incidents (Level 1) made up 24 of all reports (or 1.6%). 'Movements from reference marks', 'Patient ID process' and 'On-set imaging: approval process' each comprised 2 (8.3%) Level 1 RTEs reported to the NRLS for this time period.

Non-reportable radiation incident reports (Level 2) made up 21 of all reports (1.5%). The majority of Level 1 and 2 RTE reports related to treatment unit processes, equating to 12 (50.0%) and 8 (38.1%), respectively. This marks a reduction from 65.4% and 69.2%, respectively.

Of the 365 minor radiation incidents (Level 3) reported, 40 (10.9%) 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 39 reports (10.7%), was 'On-set imaging: approval process'. On-treatment imaging is discussed further in Issue 7 of *Safer RT*.

Figure 1 ***Classification breakdown of RTE reports extracted from the NRLS using the TSRT9 trigger code, January–April 2013 (1445 reports)***



The most commonly occurring RTE process code in the near-miss (Level 4) classification was 'Use of on-set imaging', with 31 reports (8.1%). On-set imaging contributed to the top three most frequently occurring process codes in this level, consistent with Level 3 findings.

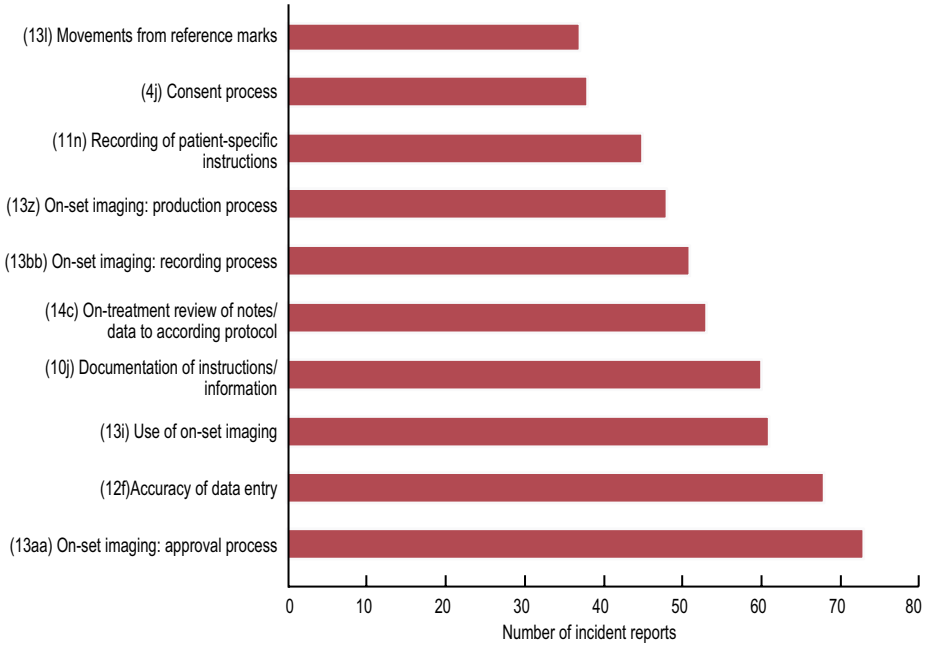
Within the non-conformance (Level 5) classification, 'Management of process flow within planning' had 32 reports (4.9%) and 'Timeliness of plan production' had 15 reports (2.3%). These were the most frequently occurring RTEs in this classification.

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. Of note, 'On-treatment review of notes/data to according protocol' contributed to 53 of the reports in the main themes (9.9%). This is discussed further in the *Error of the Month*.

If your department has examples of good practice relating to RTE prevention please email the Radiotherapy Team at **radiotherapy@phe.gov.uk**.

Figure 2 ***RTE Main Themes (534 out of 1445 reports), for January–April 2013 (with process code indicated)***



The data analysed is submitted by the RT community, therefore your comments and suggestions regarding the RTE analysis are welcomed. For further information or enquiries please contact the Radiotherapy Team at **radiotherapy@phe.gov.uk**.

National Reporting of RTEs

PHE continues to support radiotherapy departments in contributing to the national initiative for voluntary reporting of RTEs. The number of departments reporting has now reached 47. We would like to thank all the departments that have been in touch with the Radiotherapy Team for support.

That does mean there remain six departments that are currently not using the TRST trigger coding to report RTEs to the NRLS.

Reporting RTEs is a requirement of the English NHS Commissioning Board and a peer-review measure. If any departments require support please contact the Radiotherapy Team at radiotherapy@phe.gov.uk.

ACCIRAD Project Update

The ACCIRAD project was discussed in the editorial headline of the last issue of *Safer RT*. Under this EU-funded project, a workshop was held by the Greater Poland Cancer Centre. Its primary aim was to develop guidelines to encourage all countries to promote implementation of the requirements of Article 11 of the Medical Exposure Directive (MED).

Workshop topics included:

- National experience in implementing MED requirements (national, regional and local levels).
- National legal provisions in implementing MED requirements
- Classification, reporting (to legal entities, patients and professionals) and registration of radiotherapy incidents
- EU member state policies for risk management in radiotherapy (national recommendations)
- Innovations in risk management (software, research, new methodology, pilot projects, etc)
- Preventive measures (quality assurance and control, clinical audits, etc)
- Lessons learnt from radiotherapy incidents/accidents
- Education and training in risk management in radiotherapy

The workshop was attended by professionals from many EU member states. Representatives from the UK included Professor Andrew Nisbet (NHS), member of the scientific committee and panel of experts; Dr Stephen Evans, scientific committee of the European Federation of Organisations for Medical Physics (EFOMP); and Helen Best from PHE.

The PHE presentation was on voluntary reporting and learning systems in the UK. We would like to thank the RT departments that completed detailed questionnaires on their current practice on risk assessment, RTEs and near-miss reporting. These formed the basis for much of the discussion at the workshop. The UK proposals for amendments to the guidelines were supported by a number of member states, and were consistent with the current national reporting and learning systems in place in the UK.

ERROR OF THE MONTH

On-treatment review of notes and data

TSRT Process Code:
On-treatment review of notes/data to according protocol (14c)

This code accounted for 53 RTEs (or 3.6%) reported from January to April 2013. This is one of the top ten most commonly occurring RTEs. Of note, this RTE has been in the top ten in five previous issues of *Safer RT*.

This RTE concerns patient-specific checks on treatment notes and data being carried out following the RT department's protocol. The main themes highlighted within these reports include weekly checks being incomplete or missed. For example, verifying that FSD checks have been completed may be one of the weekly checks.

How can we minimise the risk of this RTE occurring?

Points to consider

1. Use oncology management systems (OMS) wherever possible to schedule tasks appropriately for reviewing notes and data
2. Allocate the task, with a clear timeframe for completion
3. Ensure it is clear who is responsible for the task and how its completion is annotated
4. Ensure the environment for completing the review is fit for purpose
5. Ensure safety-critical items are included in this review of notes and data. This information should also be documented in clinical procedures and protocols
6. Optimise the use of the OMS for collating patient notes and data
7. Investigate the use of the OMS for 'paper-lite' working, eg QCL and Taskpad
8. Audit staff compliance with written procedure and protocol

Of note, national recommendations state that the precise details of checking procedures are vital to their value.*

* *Towards Safer Radiotherapy* (recommendation 5).

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GUEST EDITORIAL

Epinal Radiotherapy Incident

Aurelie Isambert and Marc Valero

Autorité de sûreté nucléaire

In January this year two radiation oncologists and a medical physicist were sentenced to 18 months in prison for their role in radiation overdoses that killed 12 people in France. Between 2001 and 2006, nearly 450 patients receiving radiotherapy for prostate cancer were given too high a dose of radiation at Jean-Monnet hospital in Epinal, France. It is the most serious incident involving ionising radiation that has occurred in France.

The French Nuclear Safety Authority (ASN) and the General Inspectorate of Social Affairs (IGAS) were asked by the Minister of Health to investigate an overexposure incident at the hospital that came to light in 2005.

A new treatment technique for external beam therapy using dynamic wedges instead of static mechanical wedges was implemented in the radiotherapy department in May 2004. At that time, only one medical physicist was working in the department and the radiographers were trained to implement this new type of procedure on the treatment planning system (TPS). Unfortunately, the ambiguous terminology of the TPS was misunderstood. In addition, independent monitor unit (MU) calculations and *in vivo* dosimetry were no longer carried out. The investigation also revealed a lack of medical follow-up of the patients. For over a year, poor planning led to overdoses ranging from 20% to 35% for 24 patients, leading in turn to ten deaths.

During the course of the investigation, it was also found that, from 2001 to 2006, daily use of megavoltage portal imaging for patient set-up and the related additional dose, ranging from 0.15 to 0.2 Gy each day, were not taken into account in the total delivered dose. As a consequence, 424 patients received radiation overexposures of up to 10%, leading to two deaths.

Following legal proceeding instigated by the Patients' Association, a trial took place during September and October 2012. The verdict was given in January 2013, but the defendants and the public prosecutors have appealed.

The medical physicist and the radiation oncologists were found guilty of manslaughter and involuntary wounding leading to disability, by negligence or breach of an obligation of prudence imposed by statute or regulations.

In addition, the medical physicist was convicted for removal of evidence and obstruction of justice. He was sentenced to three years' imprisonment (of which 18 months were suspended) and banned from practising for five years. A fine was also imposed.

The radiation oncologists were also convicted for failure to help people in distress. They were sentenced to four years' imprisonment (of which 30 months were suspended) and banned from practising for life. Again, fines were imposed.

This incident resulted in the French Ministry of Health implementing an action plan in 2007 for the safety of patients undergoing radiotherapy. The plan contained 33 national measures, including distribution of a handbook for professionals on notification of significant radiation protection events. The French National Cancer Institute (INCa) managed the plan, which also involved the radiation oncologists and medical physicists' societies and the ASN.

PHE Comments

It is important to note that the convictions against the radiation oncologists and medical physicist did not relate to the errors made before and during the treatments administered.

As now in France, within the open reporting culture that has been developed in the UK, radiotherapy departments will not be penalised for reporting genuine errors. It is far more likely that areas that require attention will be identified and support provided as necessary. Although departments that choose to deviate from national practice and guidance may have to justify their actions.

DATES FOR THE DIARY

21–23 October	UKRO, Nottingham
October	*Safer Radiotherapy,* Issue 10