Radiotherapy Newsletter of the HPA

# Safer Radiotherapy

December 2010 Issue 2

Welcome to the second issue of *Safer Radiotherapy*. The aim of the newsletter is to provide a regular update on the analysis by the Health Protection Agency of radiotherapy error (RTE) reports. These reports are submitted to the National Reporting and Learning System (NRLS) of the National Patient Safety Agency (NPSA), to promote learning and improve patient safety.

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

Regular features include:

- RTE Data Analysis – undertaken by the HPA, highlighting key messages and trends identified from a three-month period of RTE reports
- 'Error of the Month' – will provide 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
- HPA Patient Safety in Radiotherapy Steering Group – updates on the work of this group.

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

Thanks to all contributors to this issue. The next issue of *Safer Radiotherapy* will be published in March 2011 and will be available at www.hpa.org.uk/radiotherapy

***Kim Baldwin***
***Editor***

## HPA Patient Safety in Radiotherapy Steering Group

To further improve and optimise RTE analysis in the UK the Steering Group has identified the following key workstreams:

- Establish a central repository for all UK RTEs (to include near misses) with regular data analysis and dissemination of findings to the RT community to facilitate learning
- Contribute to the identification of the underlying causes of RTEs by developing causative factor taxonomy and reviewing error detection methods
- Refine the *Towards Safer Radiotherapy* process coding to identify redundant sub-codes, to establish if additional codes are needed to reflect new technologies and techniques, and to clarify any ambiguous terminology.

While the Steering Group will lead on this work, engagement with the RT community will continue to be essential in the development of the RTE analysis.

### INSIDE THIS ISSUE



***The HPA Radiotherapy Team is based at CRCE Chilton***

### EDITORIAL HEADLINE

## Are We Meeting the Challenges?

The ESTRO 29 Pre-Meeting Teaching Course on Patient Safety in Radiation Oncology posed many challenges to the radiotherapy community. The aims of the programme were to promote working with awareness and learning from past experiences. Several prospective and retrospective risk identification techniques were presented. A key message from Jean-Marc Cosset (ICRP) was that accidents in radiotherapy, whatever their severity, must be identified, analysed and reported, in order to learn from experience. Ola Holmberg (IAEA) suggested that the implementation of recommendations needs to be effective, targeted and relevant.

In response to these challenges the UK is well positioned. It has an established RTE reporting mechanism for England and Wales, with regular data analysis by the HPA. Learning is shared through this newsletter and during HPA clinical site visits. Feedback from the radiotherapy community indicates that these visits provide effective, targeted and achievable recommendations. However, there is more work to be done as indicated in the HPA PSRT Steering Group update above.

# RTE Data Analysis: May–July 2010

The HPA Patient Safety in Radiotherapy Steering Group is working on a review of methods of detection and developing a causative factor taxonomy to be used in conjunction with the TSRT process coding system.

### *How can you help?*

Include in RTE reports a brief description of the circumstances surrounding the incident, detailing any significant contributory factors leading to the RTE and how the error was detected, as outlined in *Implementing Towards Safer Radiotherapy*[*]. Further guidance is available in *Good Practice in RTE Reporting*[†].

### Uptake rate

Datasets analysed between December 2009 and July 2010 indicate 24 radiotherapy departments are submitting RTE reports with the TSRT9 trigger code[*]. Previous NRLS searches indicate a total of 53 departments submit RTE reports to the NPSA. To ensure inclusion of your RTE reports in the HPA analysis and to contribute to national learning, use the TSRT9 trigger code.

***The TSRT9 trigger code will remain unchanged until further notice***

Those departments that have adopted the trigger code have also positively adopted the local classification and coding of RTEs, with just 35 of 654 RTE needing to be classified and coded by the HPA.

### Understanding TSRT terminology

Some ambiguity exists with regard to what constitutes an RTE and RTE classification. All RTEs can be considered to be a type of non-conformance. This is an unintended divergence between a radiotherapy treatment delivered or a radiotherapy process followed and that defined as correct by local protocol, as defined by TSRT. Definitions of each classification of RTE are given in TSRT and examples of each may be seen in the panel.

[*] Available at www.nrls.npsa.nhs.uk/resources/clinical-specialty/radiology-and-radiotherapy/ and click on Implementing 'Towards Safer Radiotherapy'

[†] Good Practice in RTE Reporting. An ongoing series to demonstrate how to report RTEs occurring throughout the patient pathway. Available at www.hpa.org.uk/radiotherapy

### When is an RTE not an RTE?

*Example*

Planner generates a radical treatment plan with the origin incorrectly defined and therefore incorrect isocentre shifts. Checker detects the error prior to the authorisation process and returns treatment plan for rectification to the planner. Treatment plan is generated with the correct origin defined and checks undertaken as required by local procedure. Treatment plan is authorised, transferred to R&V system and treatment delivered as prescribed.

This would not require reporting to the NPSA as outlined in TSRT. The error was detected and corrected as part of the checking procedure, as documented locally. However, this information may be of value in informing local working practices.

### When is an RTE a 'near miss'?

*Example*

Planner generates a radical treatment plan with the origin incorrectly defined. Checker undertakes plan checks but the error in defining the origin is not detected. Treatment plan is authorised and is passed to the data entry room. Treatment plan is reviewed and the error is detected by the radiographer. Treatment plan is returned to the planner for rectification and plan generated with the correct origin defined and checks undertaken as required by local procedure. Treatment plan is authorised, transferred to R&V system and treatment delivered as prescribed.

This would require reporting as a 'near miss' as defined by TSRT. The error was not detected and corrected by the checker as part of the checking procedure. If the error had gone undetected, the isocentre could have been incorrectly positioned and treatment could have been delivered incorrectly, depending on local procedures. There was the potential for an incorrect exposure of the patient.

### When does a 'near miss' become a 'minor radiation incident'?

*Example*

Planner imports CT dataset 1 and outlines organs at risk as per local procedure. Oncologist reviews CT dataset 1 prior to target volume delineation and notes patient position is not as requested on the referral form. CT dataset 1 is deemed to be unfit for purpose. Patient is recalled and CT dataset 2 acquired with the patient positioned as requested. Treatment is delivered as prescribed.

This would require reporting as a 'minor radiation incident' as defined by TSRT. The error was detected during the oncologist's review of the CT dataset and treatment was delivered as prescribed. However, the initial exposure of the patient to ionising radiation resulted in CT dataset 1 being unfit for purpose.

### What is an 'other non-conformance' RTE?

*Example*

Plan checker undertakes treatment plan checks and records results. Treatment plan sent to the data entry room where the radiographer notes missing signature of the checker on the treatment plan as required by local procedure. Treatment plan returned to the checker to sign.

This would require reporting as an 'other non-conformance' as defined by TSRT. The error would not affect correct treatment delivery but omission of the signature is a deviation from local procedure.

# Quarterly Analysis

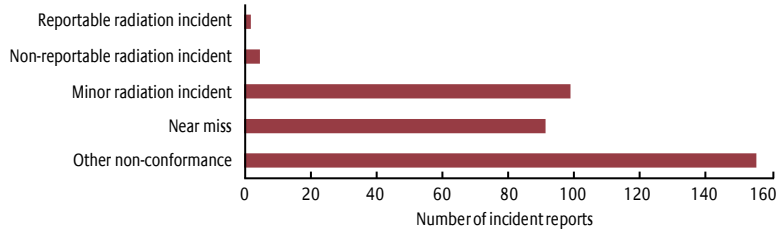
The full data analysis of the submitted RTE reports for 1 May to 31 July 2010 is available at **www.hpa.org.uk/radiotherapy**

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

## Classification of RTEs

Of those RTEs reported to the NPSA for the period May–July 2010, 98% were classified as minor radiation incidents, near misses or other non-conformances (see Figure 1). These are all lower level incidents which would have no significant effect on the planning or delivery of individual patient treatments.

**FIGURE 1** ***Classification breakdown of RTE reports extracted from the NRLS using the TSRT9 trigger code, May–July 2010 (352 reports)***




Of the 352 RTEs reported, 155 were in the other non-conformance category. Of note, 35 concerned pre-treatment planning processes, of which 23 were related to 'management of process flow'. The timeliness of target volume delineation and completion of prescription were indicated as causes. For 38 reports the RTE occurred at the 'treatment unit process' mainly attributed to 'on-set imaging: approval process'. The timeliness of verification image evaluation and image approval were indicated as the main deviations from local procedure.

> IR(ME)R Regulation 7(8) requires that a clinical evaluation of the outcome of all exposures must be recorded. Evaluation of on-treatment verification exposures provides the basis for adjustment or continuation of treatment and must therefore be carried out in a timely manner.

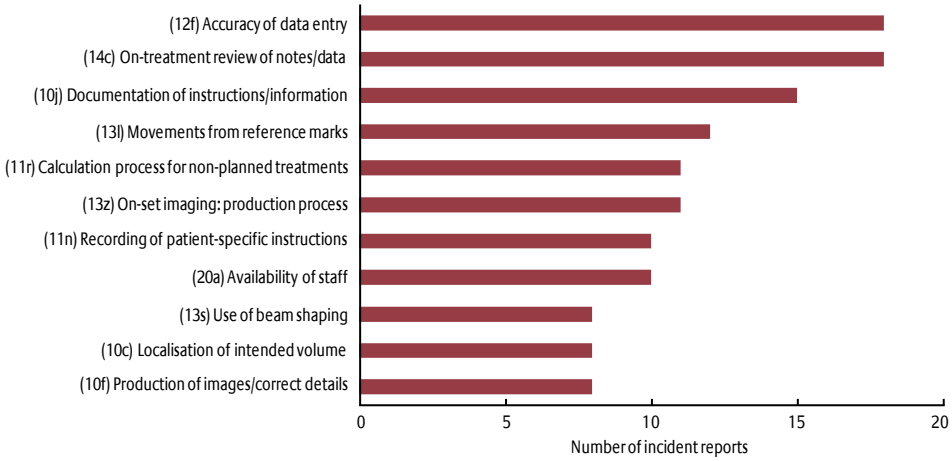
## Primary Process Code

The main themes (points in the patient pathway where the majority of reported RTEs occurred) of dataset are shown in Figure 2. Accuracy of data entry is a common point in the pathway where errors are made. See 'Error of the Month'.

## Secondary Process Code

Additional coding was supplied with 34% (120 out of 352) of RTE reports submitted during the period May–July 2010. Of these, 38% indicated 'end of process checks'. Nearly half of these were recorded at the 'pre-treatment activities/imaging' process. Consideration should be given to the minimum criteria to produce the required standard from pre-treatment activities.

**FIGURE 2** ***RTE Main Theme (129 out of 352 reports), for May–July 2010 (with process code indicated)***




For further information or enquiries please contact the HPA Radiotherapy Team, Úna O'Doherty and Kim Baldwin, **radiotherapy@hpa.org.uk**

## ERROR OF THE MONTH

# Accuracy of Data Entry

**TSRT Process Code:**
**Treatment data entry process (12)**
**Accuracy of data entry (f)**

Accuracy of data entry has been highlighted as a point in the patient pathway where RTEs commonly occur. In the dataset analysed here (May–July 2010) nearly 90% of the 'accuracy of data entry' RTEs occurred due to manual population of the R&V system with incorrect information regarding:

- machine parameters, e.g. gantry and collimator angles
- monitor units
- energy
- movement from reference marks
- date of birth
- patient-specific information, e.g. bladder status.

### How can we minimise the risk of this RTE occurring?

***Points to consider***

1. Create an appropriate environment with minimal distractions for staff (TSRT pages 5,10 and 35)
2. Use primary source data, e.g. treatment plan for isocentre shifts to minimise/avoid replication of data
3. Review working practice for redundant processes and unnecessary transcription
4. Review the purpose and relevance of data entry checks (TSRT rec 5)
5. Model treatment unit couches within the treatment planning system, avoiding manual entry of transmission factors (TSRT rec 12)
6. Use treatment planning system for planning and monitor unit calculation of palliative cases
7. Network simulator to R&V system to transfer machine parameters (TSRT rec 13)
8. Network hospital information system to oncology management system for population of patient demographics.

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GUEST EDITORIAL

# Can *Towards Safer Radiotherapy* Make a Real Difference?

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This article reviews a fatal IMRT error which occurred in New York City in 2005 and was published in the *New York Times* (NYT) in 2010. My purpose here is to assess whether or not following the recommendations of *Towards Safer Radiotherapy* (TSRT) could prevent such an incident occurring in the UK.

The NYT reported that the patient was to receive radical radiotherapy for carcinoma of the oropharynx*. A multi-field IMRT plan was produced, verified with EPID portal dosimetry and successfully delivered for the first four fractions. The clinician then requested replanning before the next fraction in order to "reduce the dose to the teeth". Problems occurred when attempting to save the new plan and the system generated error messages. The plan was saved without any MLC data. There was no second physicist check and no verification plan was generated or checked. A total dose of 39 Gy in three fractions was delivered without the MLC. The NYT reported that the patient complained of feeling hot after the overdoses but was reassured by staff. A second verification plan was then created and the absence of the MLC noted. Treatment was discontinued. The patient died two years later.

* A number of recent incidents that have occurred worldwide have been summarised in a PowerPoint presentation – Module 2.10 Accident update – some newer events (UK, USA, France) – on the IAEA website: http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Training/1_TrainingMaterial/AccidentPreventionRadiotherapy.htm

The manufacturer of the equipment issued an alert after the event in 2005 regarding the importance of monitoring computer software for any disruption, especially during the process of saving or transferring data: any warning or error message that appears should be investigated. It also highlighted the standard quality assurance procedures recommended in the product user manuals (2004):

- Verify all plans before use
- Perform QA tests on a phantom to make sure the plan is correctly transferred to the treatment machine
- Visually verify the shape of the dynamic MLC before treating.

All the staff involved in this incident were fully trained and accredited. There were detailed IMRT treatment plan QA procedures in place which were violated. The following recommendations from TSRT are relevant:

- Concerns raised by patients must be taken seriously and investigated promptly (TSRT rec 21)
- Questioning irrespective of position within the organisation should be actively encouraged (TSRT rec 1) – the necessity for the urgent replan might have been questioned
- Each radiotherapy centre should have protocols within its quality system which define what data are to be checked by planners and prescribers along radiotherapy pathway and how the results of these checks are to be recorded (TSRT rec 6)
- Checks and verification should be performed independently by entitled operators working to clear protocols, which make explicit the individual's responsibilities and accountability (TSRT rec 7) – a clear understanding of the pathway is the responsibility of all staff
- TSRT recommends that information about an error should be shared as early as possible during or after the investigation and that, to prevent recurrence, the lessons learnt from root cause analysis should be disseminated locally and through a national and anonymised learning system (TSRT recs 23 and 35) – this incident was not shared with the wider professional community for five years.

The root cause of this error was the failure to follow standard operating procedures which were fully established. One of the most important of the TSRT recommendations is:

> *all procedures should be documented and subject to review every two years or whenever there are significant changes (TSRT rec 30)*

TSRT is relevant and its implementation should have prevented occurrence of the described incident. TSRT can make a difference.

## DATES FOR THE DIARY

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| 28–30 January 2011 | Society and College of Radiographers Annual Conference, Birmingham |
| 23 February 2011 | BIR Meeting: Expanding the UK IMRT Service |
| December | *Summary of Findings and Recommendations from 31 CQC Proactive IR(ME)R Radiotherapy Inspections:* for a copy please contact irmer@cqc.org.uk |
| March | *Safer Radiotherapy*, Issue 3 |