

Radiotherapy Newsletter of Public Health England January 2019 Issue 27

Protecting and improving the nation's health

PHE publications gateway number: GW-140



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#### Welcome to Safer Radiotherapy (RT).

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 on a voluntary basis through the National Reporting and Learning System (NRLS) of NHS Improvement or directly to PHE, to promote learning and minimise recurrence of these events. Safer RT is designed to disseminate learning from RTE to professionals in the RT community to

positively influence local practice and improve patient safety. Published three times a year, Safer RT contains key messages and trends from the analysis of RTE reports. Any comments and suggestions for inclusion in the newsletter can be sent to radiotherapy@phe.gov.uk and would be gratefully received. Thanks to all contributors to this issue. The next issue of Safer Radiotherapy will be published in May 2019 and will be available at:

www.gov.uk/government/collections/medical-radiation-uses-dose-measurementsand-safety-advice

#### Helen Best, Editor

# Editorial headline – Fifth Biennial radiotherapy error and near miss data report

The fifth biennial report on data submitted for analysis under the national voluntary reporting and learning scheme will soon be published by PHE. A total of 15,830 RTE reports from UK NHS RT providers are presented. The report includes data from December 2015 to November 2017. The analysis contains comparisons to the previous biennial report (December 2013 to November 2015) and aggregate data (December 2007 to November 2015). The UK inspectorates for IR(ME)R also shared anonymised synopsis of closed reportable radiation incidents from the same time period for inclusion in the analysis.

As with previous reports the vast majority of the reports were lower level incidents having little or no significant effect on the planning or delivery of individual patient treatments. Of note, there was a decrease in the number of reportable events from 1.8% to 1.0%. Consistent with the previous report, the most frequently reporting events continue to be associated with treatment unit processes (41.2%) and with on-set imaging processes in particular (11.5%). Early data on safety barrier and causative factors, which were introduced part-way through this reporting period, are also included. This report enables benchmarking exercises and facilitates comparison of local analysis with the national picture.

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# National dose reference levels for radiotherapy planning CT scans

Following completion of a survey of UK RT providers by IPEM, national dose reference levels for radiotherapy planning CT scans have been set and are published on the PHE website. The use of dose reference levels is a useful method of demonstrating dose optimisation has taken place as required under the lonising Radiation (Medical Exposure) Regulations. The following table provides dose index values, which can be taken to be equivalent to formal NDRLs.

Examination	CTDI <sub>vol</sub> per	DLP per complete	Scan length
	sequence (mGy)	examination (mGy cm)	(mm)
Breast	10	390	360
Gynaecological	16	610	400
Lung 3D	14	550	390
Lung 4D	63	1750	340
Prostate	16	570	340
Brain	50	1500	290
Head and Neck	49	2150	420

Radiotherapy planning CT scans are not considered diagnostic scans, and therefore the use of the term Diagnostic Reference Levels is not appropriate. Further information can be found at the following website:

www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/ndrl

#### CQC IR(ME)R annual report published

The CQC has published the 2017/18 IR(ME)R annual report. The report includes a summary of enforcement activities and a breakdown of notifications of significant accidental or unintended exposures and exposures much greater than intended as reported directly to the CQC. The full report can be found at –

#### www.cqc.org.uk/sites/default/files/20181115-IRMER-annual-report-2017-18-FINAL.pdf

#### Links to international patient safety resources

ASTRO and AAPM RO-ILS Quarterly report Q4 2017

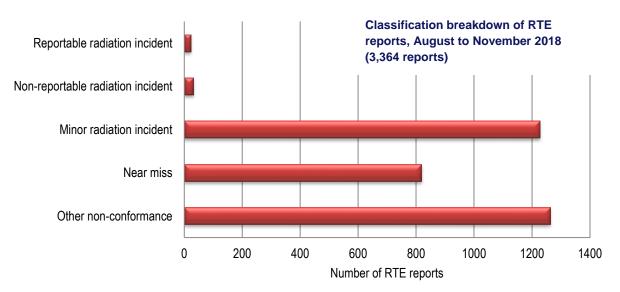
Autorité De Sûreté Nucléaire (French Nuclear Safety Authority) Publications for Professionals

IAEA, SAFRON Updates on Patient Safety in Radiotherapy

### **RTE Data analysis: August to November 2018**

Submissions from 55 NHS UK providers out of 61 contributed to this issue's full data analysis, covering August to November 2018. Six providers have not reported or not used the TSRT9 trigger code to report RTE through the NRLS for this reporting period.

The full data analysis is available at www.gov.uk/government/collections/medicalradiation-uses-dose-measurements-and-safety-advice and includes data on primary process coding, safety barriers, causative factors, methods of detection and the severity classification of the RTE.



### **Classification of RTE**

Of those 3,364 RTE reported for the period August to November 2018, 3,309 reports (98.3%) were classified as minor radiation incidents, near misses or other non-conformances. These are lower-level incidents which would have no significant effect on the planning or delivery of individual patient treatments.

Reportable radiation incidents (level 1) made up 23 (0.7%) of all reports. There were 23 singular events across 23 different subcodes for all level 1 RTE. Non-reportable radiation incident reports (level 2) made up 32 (1.0%) of all reports. 'On-set imaging: approval process' comprised 6 (18.8%) of all level 2 RTE. Level 1 and 2 reports made up 55 (1.7%) for this reporting period which is consistent with the previous analysis (1.8%, n = 51).

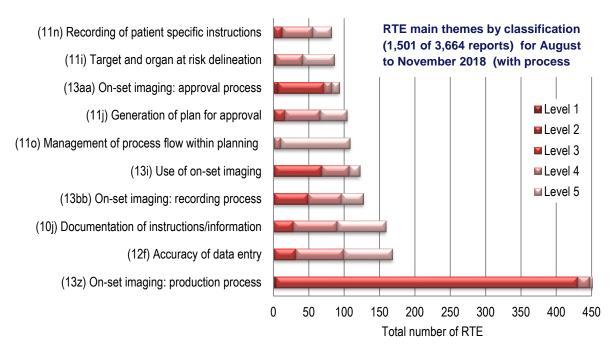
Of the 1,227 minor radiation incidents (level 3) reported, 427 (34.8%) of this subset were related to the 'on set imaging: production process', making it the most frequently reported code in this classification, consistent with previous analyses.

The most frequently reported RTE process code in the near miss (level 4) classification was 'accuracy of data entry' with 68 reports (8.3%). Within the non-conformance (level 5) classification 'management of process flow within planning' comprised 98 reports (7.8%) making this the most frequently reported RTE in this classification.

#### Primary process code

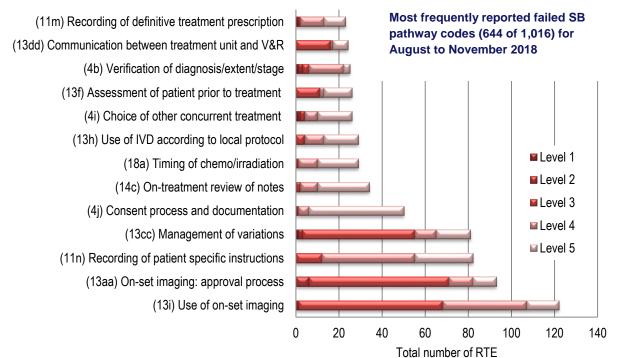
The main themes (points in the patient pathway where the majority of reported RTE occurred) for this dataset are shown below. Consistent with the previous 12 analyses 'on-set imaging: production process' is the most frequently occurring process code

(12.3%, n = 452), examples of this include selecting the incorrect pre-set for an exposure. Guidance on this error can be found in issues 7 and 18 of Safer RT.



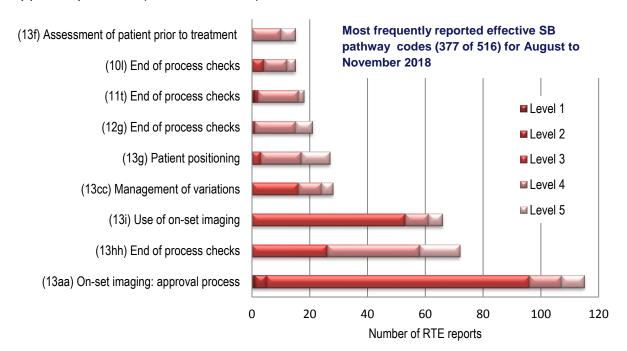
#### Safety Barriers (SB)

A number of individual pathway codes can be allocated to each RTE report to identify all points in the pathway where the error was not picked up. All subcodes were analysed across the 3,364 RTE reports, a total of 1,016 subcodes were identified as failed safety barriers (SB). Only 25 (2.5%) of these RTE were Level 1 or 2 errors where the SB had failed. The most frequent failed SB reported is represented below and are broken down by classification. Treatment unit process 'use of on-set imaging' is the most frequently reported failed SB (12.0%, n=122).



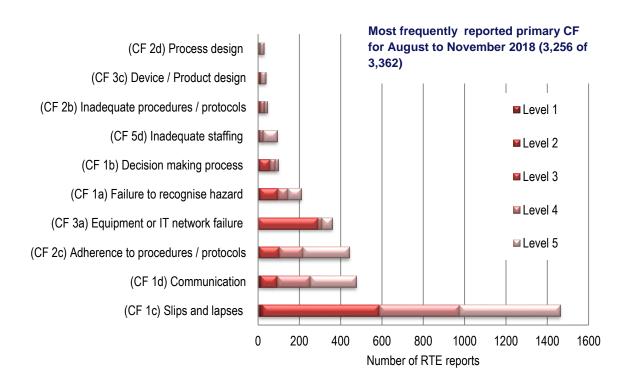
Effective safety barriers or methods of detection (MD) can now be identified utilising the safety barrier taxonomy. For the reporting period August to November 2018. 29 different providers indicated MD across 516 (15.3%) incidents. The most frequently

reported effective safety barrier for this reporting period was 'on-set imaging: approval process' (22.3%, n = 115).



#### **Causative Factors (CF)**

CF have been applied to 3,362 RTE during the reporting period August to November 2018. The most frequently reported primary CF are shown below; the most frequent was individual 'slips and lapses' (43.5%, n = 1,463). Multiple CF can be associated with each RTE; the primary CF is the root cause and the subsequent CF are the contributory factors associated with an incident. Contributory factors were indicated across 893 reports, 177 of these contained multiple CF leading to 1,210 contributory factors. The most frequently reported contributory factor was 'adherence to procedures/protocols' (33.1%, n = 400).



# Case note of an unintended overexposure of a patient during palliative radiotherapy treatment in December 2017

Between 27 December 2017 and 4 January 2018 a patient undergoing a course of radiotherapy received a dose of ionising radiation much greater than that intended. A full report can be found at

#### www.gov.scot/publications/unintended-overexposure-patient-during-palliativeradiotherapy-treatment-edinburgh-cancer-centre-december-2017/pages/1/

A patient had a metastatic left anterior hilar lymph node tumour invading the mediastinum. The patient was referred for radiotherapy treatment of the mediastinum with no further elaboration of the particular area of the mediastinum on which the treatment should be focussed.(5a, CF1d) The treatment was planned on Friday 22 December 2017 and the patient completed 20Gy in 5# treatment on 4 January 2018. On 5 March 2018 a follow up clinic noted that the mass in the left anterior hilar lymph node had increased in volume.(MD 17a)

On 6/7 March 2018 a review of the radiotherapy fields found that the tumour in the left anterior hilar lymph node had not been covered by the radiotherapy. The most likely scenario was that during planning there was a need to expand an initial field, which had been placed centrally on the mediastinum, by extending it to the lower right, this field was unintentionally shifted (rather than extended) (11i, CF1c) during the planning process and the error remained unnoticed. (11t, CF2c) The report stated that staffing and workload pressures were a contributory factor in

this incident.(CF5d)

The incident might be coded as follows:

#### TSRT9/ Level 1/ 11i/ 11t/ 5a/ MD17a/ CF1c/ CF1d/ CF5d/CF2c

Recommendations following the incident included in the report were

- Regular peer reviews of radical plans should continue and consideration be given to regular retrospective audit of volumes for palliative treatment
- Documentation relating to training of staff prior to entitlement should be reviewed
- Training plans should include details of training which must be completed, this should include the person undergoing the training, the person confirming satisfactory completion of that training and the date completed
- A review of the palliative work flow should be completed
- Consideration should be given for more descriptive information on the proposed treatment fields on the radiotherapy booking form

Dates for the diary				
26 February	SRP, Regulation of medical radiological equipment, London			
13 March	IPEM, MPE update, Manchester			
13 March	RTQ SIG, 3 <sup>rd</sup> Annual meeting, London			
29 March	BIR, MR in radiotherapy, London			
26-30 April	ESTRO 38, Milan			
May 2019	Safer Radiotherapy Issue 28			

# **Reporting survey**

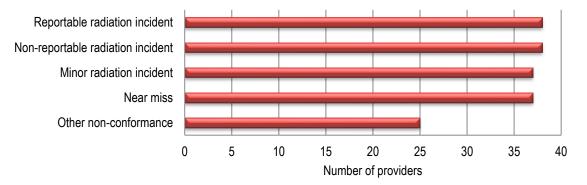
A survey to identify current trends in reporting to the voluntary national reporting and learning system was sent to all radiotherapy providers across the UK. This included 61 NHS providers and 7 independent providers. A total of 46 surveys were returned, achieving a 67.6% response rate. However, not all respondents completed all questions. The survey included 6 questions, the results of which are outlined below.

Q1. When asked if the provider submitted RTE reports for inclusion in the national analysis 95.6% (n = 44) stated yes. Those who answered 'no', stated this was because they worked in the independent sector.

Q2/3. Providers were asked if they used the trigger code, classification and coding from the development of learning locally and nationally, 100% stated yes to local reporting (n = 46) and 96% to national reporting (n = 44). Two independent providers did not report nationally.

Q4. Only 36 out of the 44 providers submitting RTE for inclusion completed Q4 which asked how frequently reports were submitted. Of the providers who responded to this question 50% (n = 18) stated they reported once per month, 41.7% (n = 15) reported on completion of each RTE report, 5.6% (n = 2) reported every 6 months and 2.8% (n = 1) reported once per week.

Q5. 38 out of the 44 providers conveyed information outlining which levels of classification of RTE were shared for national analysis as seen in the graph below -



Q6. It is clear from the above graph that 13 providers who completed this survey do not report all levels of RTE. When asked to explain the rationale for not reporting all levels of RTE 53.8% (n = 7) of respondents explained this was due to the burden of reporting. One provider stated 'other non–conformances' were not included within their reporting system, and another explained that these were "dealt with locally in line with Trust policy". Another response stated "the department has a dual reporting mechanism. All level 1-4 incidents are reported externally. All level 5 are reported internally".

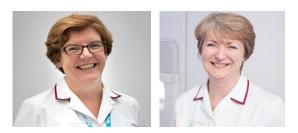
Q7 Given the opportunity for further comment respondents stated -

"I feel all departments should be encouraged to report all severity of errors nationally for learning" and "Inconsistency of reporting from departments and the reporting of different levels skews data analysis and therefore national reporting and learning"

Reporting culture has developed since the previous 2014 survey with an overall increase in the number of providers reporting and classification levels reported. This is consistent with findings in the triannual analysis. PHE will continue to support providers with the adoption of the new taxonomies.

# **Guest Editorial**

Safety considerations for the Magnetic Resonance Linac (MR Linac) Helen McNair, Lead research radiographer Erica Scurr, Lead MRI radiographer The Royal Marsden NHS Foundation Trust



The recent availability of MR Linac<sup>1,2</sup> is a significant development in the planning and delivery of radiotherapy treatments. However, it also has had a major impact on safety considerations in the radiotherapy department. To ensure good practice, the introduction of MR in the radiotherapy department must be considered alongside the existing MR policies of the hospital and the Medicines and Healthcare products Regulatory Agency<sup>3</sup>. This requires collaboration between departments and teams, providing an opportunity for diagnostic and therapeutic radiographers and the radiotherapy and MR physicists to work together. Furthermore, the increase in demand of MR simulation and the purchase of MR scanners by radiotherapy departments will also mean that radiotherapy staff will need additional specialist training and must become familiar with the MR environment. The MR local rules need to be incorporated into the existing radiation local rules, designated controlled areas need to be defined and access limited to those staff designated as MR personnel, and the role of a Responsible Radiotherapy MR person created. All staff in radiotherapy departments should be trained according to their level of access and authorisation. The implications of an untrained workforce may be catastrophic if the hazards of the MRI environment are not fully understood and mitigated (Table 1). This is best achieved via collaboration with experienced MR diagnostic colleagues, which is professionally valuable and rewarding. The MR Linac is the first technology to simultaneously generate magnetic resonance images and deliver X-rays, allowing radiotherapy to be adjusted in real time and delivered more accurately and effectively than ever before.

Hazard/ Risk	Safety issues
Static field magnets – projectile effect, function of monitoring equipment	<u>Attractive force</u> - Potential hazard of the projectile effect of ferromagnetic material in a strong magnetic field can result in serious injury and has resulted in fatalities. Static field can affect monitoring equipment- must only use MR compatible monitoring and support equipment <u>Torque</u> - Can affect certain implantable mechanical devices eg pacemakers, stents, clips, prostheses which can result in tissue damage and/or damage to the implanted device
Time varying field gradients – biological effects	Peripheral nerve and muscle stimulation - Can lead to discomfort and may result in limb movement or ventricular fibrillation Acoustic noise - Hearing damage, tinnitus
Radiofrequency magnetic fields- thermal heating	Thermal heating - Leading to heat stress, induced current and contact burns
Cryogens	<u>Cryogen</u> - Asphyxiation, cold burns, frostbite, hypothermia and explosion <u>Quench</u> - Uncontrolled escape of cryogen

Table 1. Hazards of MR and associated risks

References

2. Kerkmeijer LG, et al MR-Linac Consortium Clinical Steering Committee. The MRI-Linear Accelerator Consortium: Evidence-Based Clinical Introduction of an Innovation in Radiation Oncology. Front Oncol. 2016 Oct 13;6:215

<sup>1.</sup> Mutic S, Dempsey JF. The ViewRay system: MR-guided and controlled radiotherapy. Semin Rad Onc. 2014 Jul;24(3):196-9

<sup>3.</sup> Medicines and Healthcare Products Regulatory Agency. Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. March 2015.